Select Health Medical Policies

Orthopedics Policies

Table of Contents

Table of Contents Continued on Page 2...

Table of Contents, continued

Select Health

MEDICAL POLICY

ANNULAR TISSUE REPAIR SYSTEMS (XCLOSE)

Policy # 462

Implementation Date:9/28/10

Review Dates: 9/15/11, 7/18/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 9/15/18, 8/8/19, 8/20/20, 7/29/21, 7/5/22, 8/22/23, 9/18/24

Revision Dates:

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The spine is made up of vertebrae cushioned by small discs consisting of a tough outer layer (annulus) and a soft inner layer (nucleus). When a herniated disc occurs, a small portion of the nucleus pushes out through a tear in the annulus into the spinal canal. This can irritate a nerve and result in pain, numbness or weakness in the back, as well as in a leg or arm. Though many patients respond to conservative treatment, some patients require surgery to relieve their pain or reduce signs and symptoms related to nerve impingement. The usual procedure performed is a simple discectomy. This involves removing the herniated disc material and re-approximating the overlying muscles, ligaments, and skin. The opening in the annulus is usually left to heal/close on its own.

The Xclose Tissue Repair System has been developed to address this issue of potential re-herniation due to lack of surgical closure of the rent in the annulus. It consists of two non-absorbable polyethylene terephthalate (PET) braided surgical sutures and T-anchor assemblies, connected with a loop of a smaller suture. The suture loop is used to facilitate tightening, drawing the larger suture assemblies together, thereby re-approximating the tissue. The construct is provided sterile and preloaded on a disposable delivery instrument. This device then closes the opening in the annulus in the hopes of reducing re-herniation.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover annular tissue repair systems, including the Xclose device, as there is lack of any published evidence to support improved health outcomes for patients undergoing simple discectomy procedures when compared to the standard of care. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A thorough search of the medical literature and a review of the manufacturer's website identified no systematic reviews or published peer-reviewed studies concerning the Xclose system, or any similar system.

Documents provided by the manufacturer identify multiple poster presentations and peripheral studies implicating issues with the lack of annular closure after discectomy procedures. No published studies, however, demonstrate superior health outcomes compared to the current standard of care.

An unpublished study which has been embargoed due to recent submission for publication in a peer-reviewed journal was made available by Anulex for review. This study was a single blind, multicenter, prospective, and comparative study demonstrating outcomes out to 1 year. It fails to demonstrate any difference in pain related outcomes or statistically significant differences in re-surgery rate compared to patients undergoing discectomy without annular closure. Though a post hoc analysis suggested a difference in second surgery rate for a subset of physicians who did 5 or more procedures, this difference barely met statistical significance with a p-value of 0.049. This second outcome was not a planned primary or secondary outcome, and thus, whether the conclusions can be generalized or suffers from biases related to patient selection is unknown. Of additional concern is the unexplained high dropout rate, with half of the patients narrowly meeting the demands for statistical significance at a 95% confidence interval. Given the limitations in this study, it remains difficult to conclude that annular tissue repair systems have a proven benefit for patients.

A Hayes review completed in June of 2013 continues to support the current coverage position. It noted that there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the Xclose Plus Tissue Repair System for repair of the annulus fibrosis.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

22899	Unlisted procedure, spine

HCPCS CODES

L8699	Prosthetic implant, not otherwise specified

Key References

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4. Food and Drug Administration (FDA). (2006) 510(k) Summary Xclose Tissue Repair System. August 8, 2010. U.S. Department of Health & Human Services. Available: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062307.pdf. Date Accessed: August 10, 2010.
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Annular Tissue Repair Systems (Xclose™), continued

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MEDICAL POLICY

ANTEROLATERAL LIGAMENT RECONSTRUCTION AS PART OF KNEE RECONSTRUCTION SURGERY

Policy # 571

Implementation Date:7/28/15

Review Dates: 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/17/24

Revision Dates:

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Description

The anterolateral ligament (ALL) has been identified as a distinct structure originating at the lateral femoral epicondyle, just anterior to the lateral collateral ligament (LCL) and inserting on the anterolateral aspect of the proximal tibia, midway between Gerdy's tubercle and the fibular head. Some hypothesize that the ALL may play a role in controlling internal tibial rotation, and thus, affect the pivot shift phenomenon that can occur after knee reconstruction surgery. However, studies assessing the functional importance of the ALL are not available.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover anterolateral ligament reconstruction as part of knee reconstruction surgery as it is unproven.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Limited published studies are available evaluating the effectiveness and safety of anterolateral ligament (ALL) repair in isolation or as part of an anterior cruciate ligament (ACL) reconstruction. Only one systematic review and two primary literature articles were identified for review as part of a July 2015 review of this topic. Very little information regarding the clinical utility of ALL repair is found in any of the published literature to date. The published information is primarily illustrations of the biomechanics of the

Select Health

ligament. The 2015 study by Sonnery-Cottet et al. examined outcomes from 92 patients who underwent both ACL and ALL repair. Because the patients were not randomized into; 1) ACL only, and, 2) ACL + ALL groups, it is impossible to know from this case series how repair of the ALL improved or worsened outcomes.

In conclusion, no meaningful evidence has been published illustrating the clinical need of repairing the anterolateral ligament, in isolation, or as part of an anterior cruciate ligament reconstruction.

Billing/Coding Information

CPT CODES

29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29999	Unlisted procedure, arthroscopy

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

ARTIFICIAL SPINAL DISC REPLACEMENT

Policy # 243
Implementation Date:3/1/04
Review Dates: 1/13/05, 2/28/06, 8/21/08, 6/11/09, 11/29/12, 10/24/13, 10/20/16, 9/15/18, 8/8/19, 8/20/20, 8/19/21, 7/27/22, 8/22/23, 9/18/24
Revision Dates: 2/1/05, 12/12/06, 12/20/07, 2/12/08, 7/14/08, 8/13/09, 4/13/10, 6/30/11, 9/30/11, 3/11/14, 12/16/14, 3/26/15, 5/28/15, 10/7/15, 10/20/16, 8/9/17, 3/13/18, 9/24/18, 11/6/19, 2/5/20, 6/5/20, 6/8/21, 1/13/22, 2/16/22, 4/12/22, 8/10/22, 12/1/22, 7/14/25

Related Medical Policies:
#622 Cervical and Lumbar Spinal Fusion and Combined Decompression/Fusion

Disclaimer:
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Description

Currently, the standard treatment for chronic low back pain which has been non-responsive to conservative therapy is either a single level or multi-level spinal fusion. This surgery results in reduced mobility and is complicated frequently by failure of the fusion. In recent years, efforts to create an artificial intervertebral prosthesis similar in function to an artificial hip or knee joint have been undertaken. These devices are proposed to allow for maintenance of some spinal mobility and improved outcomes over spinal fusion.

Proposed advantages to use of these devices include shorter surgical time, the lack of need for harvesting of bone graft materials and possibly shorter hospital lengths of stay. However, questions remain regarding the effectiveness of this therapy compared to spinal fusion, long-term durability of this procedure, and consequences of failure of this treatment.

Current FDA-approved devices for the lumbar spine include the SB Charité III lumbar disc, and the Prodisc-L Total Disc Replacement System. The Charité III, however, was voluntarily withdrawn from the market by its manufacturer in August 2011. The FDA has approved the Prestige ST Cervical Disc System and the ProDisc-C Total Disc Replacement System for the cervical spine. The Mobi-C Cervical Disc Prosthesis received initial FDA pre-market application (PMA) approval on August 7, 2013, for a single level disc replacement. On August 23, 2013, the FDA provided a second PMA approval for use of the Mobi-C implant at 2 levels.

The **ProDisc-L Total Lumbar Disc** (Synthes Spine Inc., West Chester, PA) is a weight-bearing modular implant consisting of 2 cobalt-chromium alloy endplates and a snap-fit ultra-high molecular weight polyethylene (UHMWPE) insert. The endplates have a large serrated "keel" and 2 small spikes that anchor the endplate to each vertebra, and, according to the manufacturer, provide postoperative implant stability. Long-term fixation to the vertebral bodies is intended to be achieved through bony ingrowth. After implantation, the ProDisc-L allows spinal motion of 13° flexion, 7° extension, 10° lateral bending, and 3° axial rotation as measured through in vitro testing. The ProDisc-L is modular, with "mix and match" components so that the implant can be customized to an individual patient's anatomy. Two endplate sizes, 3 polyethylene insert heights, and 2 lordosis angles are available. The insertion procedure for the ProDisc-L is potentially less invasive than that for the Charité, and requires less distraction of the disc space, because the ProDisc-L endplates are inserted while collapsed.

The **Prestige ST Cervical Disc System** (Medtronic, Minneapolis, MN) is a metal-on-metal cervical prosthesis consisting of 2 stainless steel components, which articulate via a ball and trough system. The superior component of the implant contains the ball portion of the mechanism, and the inferior component

Select Health

incorporates the trough portion. Once implanted, the device permits a minimum of 10° of flexion/extension, a maximum of 10° degrees of lateral bending, and 2 mm of anterior/posterior translation. The flat portion of each component, which contacts the vertebral endplate, is aluminum oxide grit blasted for bone ingrowth. Each component is affixed to the vertebral body by 2 bone screws through an anterior flange. The bone screws are held in place by a lock screw mechanism. The Prestige ST is available in 4 different heights (6, 7, 8, and 9 mm) and 2 different depths (12 and 14 mm).

The **ProDisc-C Total Disc Replacement** (Synthes Spine Inc., West Chester, PA) is a device made from metal and plastic that is placed between two adjacent vertebral bodies (neck bones) to replace a diseased cervical disc. The ProDisc-C Total Disc Replacement consists of three parts:

- Two metal (cobalt-chrome alloy) endplates that are anchored to the top and bottom surfaces of the adjacent vertebral bodies
- A plastic (ultra-high molecular weight polyethylene or UHMWPE) inlay that fits between the two endplates

The plastic inlay and endplates are intended to restore the natural distance between the two vertebrae (disc height). The top (superior) endplate can slide over the domed part of the plastic inlay, which can allow movement at the level where it is implanted. The ProDisc-C Total Disc Replacement is intended to be used in skeletally mature patients (people who have stopped growing) for reconstruction of the disc from C3−C7 following removal of the disc at one level for intractable symptomatic cervical disc disease (SCDD), a condition that results from a diseased or bulging disc. The device is intended to stabilize the operated spinal level. Unlike a fusion procedure, the ProDisc-C Total Disc Replacement is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function.

The **Mobi-C Cervical Disc Prosthesis** (LDR Medical, Austin, TX), (FDA approval, February 2019) consists of two metal (cobalt-chrome alloy) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent cervical vertebrae to replace a diseased cervical disc that is causing arm pain and/or weakness or numbness. The Mobi-C Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least six weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C Cervical Disc Prosthesis.

The implanted device is designed to restore the distance between the two vertebrae (disc height) and allow motion at the operated spinal level as the plastic core moves against the metal endplates multiple levels of disc disease reflects the unproven nature of this indication.

The **Orthofix M6-C Artificial Cervical Disc** (Orthofix, Lewisville, TX) received FDA approval in February 2019. It is an intervertebral disc prosthesis designed to permit motion of a functional spinal unit in the cervical spine when replacing a degenerated native disc. The M6-C Artificial Cervical Disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc. This design enables the M6-C Artificial Cervical Disc to move in all six directions of freedom, with independent angular rotations (flexion-extension, lateral bending and axial rotation) along with independent translational motions (anterior-posterior and lateral translations as well as axial compression). The sheath is designed to minimize any tissue ingrowth as well as the migration of wear debris. The serrated fins provide acute fixation to the superior and inferior vertebral bodies. The TPS coating increases the bone contact surface area.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers artificial spinal disc replacements for FDA approved indications. All other conditions for use of these are considered experimental/investigational.

Conditions necessary for coverage of any location are:

1. Must meet all criteria for spinal fusion outlined in SH policy 622

2. Lack of severe facet arthritis at the level of the disc replacement

AND

Must meet the following indications for either Lumbar or Cervical as outlined below:

Lumbar Criteria:

1. Symptomatic degenerative disc disease (DDD) specific to one of the following:

   Select Health covers one- or two-level lumbar disc replacement utilizing an FDA-approved disc* appropriate to the healthcare system where the member receives care

2. No evidence of isolated radicular compression syndromes, except at the level of disc replacement

   a. The patient has no contraindications as listed below

*Examples include:

- One-level, or two-level, lumbar disc replacement utilizing ProDisc-L; or

- One-level lumbar disc replacement utilizing activL at L4−L5 or L5−S1

Lumbar Contraindications:

A. Active systemic infection or infection localized to the site of implantation
B. Severe lumbar spinal stenosis
C. Allergy or sensitivity to implant materials (e.g., cobalt, chromium, molybdenum, polyethylene, polyurethane, ethylene oxide residuals, titanium, stainless steel, aluminum, vanadium)
D. Pars defect
E. Clinically compromised vertebral bodies at the affected level due to current or past trauma
F. Degenerative spondylolisthesis of grade > 1
G. Severe spondylosis
H. Ankylosing spondylitis
I. Radiographic evidence of spinal instability
J. Osteoporosis defined as DEXA bone mineral density T-score ≤ -2.5 (this contraindication is in ProDisc-C and Mobi-C as well)

Cervical Criteria:

1. Symptomatic degenerative disc disease (DDD) specific to all the following:

   - Select Health covers FDA-approved discs** for one level or two-level (contiguous or non-contiguous) cervical disc replacement appropriate to the healthcare system where the member receives care

2. Radiculopathy with motor or sensory deficit or symptomatic myelopathy
3. Concurrent or planned, sequential one to two level artificial cervical disc replacement, without cervical spinal fusion, or with prior or planned cervical spinal fusion at adjacent levels, is considered medically necessary for the management of cervical spinal pathology
4. The patient has no contraindications as listed below.

**Examples include:

1 level:

- Bryan Cervical Disc

- M6-C Artificial Cervical Disc
- MOBI-C
- Prestige Cervical Disc
- Prestige LP Cervical Disc
- PCM (Porous Coated Motion)
- ProDisc-C Total Disc Replacement
- Secure-C Artificial Cervical Disc
- Simplify Cervical Artificial Disc

2 levels:

- MOBI-C
- Prestige LP Cervical Disc
- Simplify Cervical Artificial Disc

Cervical Contraindications:

A. Active systemic infection or infection localized to the site of implantation
B. Allergy or sensitivity to implant materials (e.g., cobalt, chromium, molybdenum, polyethylene, polyurethane, ethylene oxide residuals, titanium, stainless steel, aluminum, vanadium)
C. Pars defect
D. Clinically compromised vertebral bodies at the affected level due to current or past trauma
E. Degenerative spondylolisthesis of grade > 1
F. Severe spondylosis
G. Rheumatoid arthritis
H. Radiographic evidence of spinal instability
I. Osteoporosis defined as DEXA bone mineral density T-score ≤ -2.5 (this contraindication is in ProDisc-C and Mobi-C as well)

Select Health does NOT cover artificial intervertebral cervical or lumbar disc for all other non-FDA approved indications, as these are considered experimental, investigational, and unproven, whether done simultaneously or at different times, due to a paucity of published evidence supporting long-term safety and effectiveness.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Charité III: The Charité III artificial spinal disc was approved in October 2004 for single level disc replacement surgery lumbar spine surgery involving levels L4−S1. This approval was contingent on further post-approval studies being performed to clarify safety, efficacy, and durability questions related to the use of these devices. No other devices are currently FDA approved for artificial spinal disc replacement of the cervical, thoracic, or lumbar spine.

The FDA approval was a result of a randomized, controlled study involving 205 patients. This study involved implanting 205 investigational subjects with the Charité artificial disc and comparing the safety and efficacy to 99 control subjects who received a commercially available spinal fusion cage filled with iliac crest autograft. Each investigational site was also required to enroll their first 5 Charité artificial disc subjects as training cases with a total of 71 training subjects enrolled. The treatment and control groups were implanted with the devices via an anterior surgical approach. Adverse events considered by the investigators to be device-related, including back and lower extremities pain, implant displacement, and subsidence, were greater in the investigational group (1 6/205, 7.8%) compared to the control group (4/99, 4.0%). Additionally, it was noted that 6.3% of patients receiving the device developed superficial wound infections at the site vs. 2% for the control group. Device failures were those that required reoperation, revision, removal, or supplemental fixation. Device failures occurred in November 2005 (5.4%) Charité artificial disc and 8/99 (8.1%) control subjects. The majority of these events were supplemental fixation: 9/205 (4.4%) Charité artificial disc subjects and 6/99 (6.1%) of control subjects. Two (1.0%) Charité artificial disc subjects required removal of their implant. There were 2 adverse events which occurred in the control group that were not present in the Charité artificial disc subjects. 18/205 subjects (18.2%) experienced pain at the donor graft site, and 9/99 (9.1%) experienced pseudoarthrosis.

The primary effectiveness endpoint of this study was the difference in proportion of overall success between the 2 treatment groups. The success status of subjects was summarized by treatment group using counts and percentages. The table below compares the success rates for the individual primary outcome parameters for all randomized subjects as well as the overall success rates, using both the sponsor's and FDA's ODI success criteria. Primary endpoint data were collected and analyzed 24 months after surgery.

The analysis population which was used to assess these endpoints consisted of all randomized subjects who completed all evaluations at the 24-month time point, regardless of when the 24-month measurements occurred.

Table 12 Comparison of Success Rates for Efficacy at 24 Months

Characteristic	25% Improvement		15-point Improvement	
	Charité	Control	Charité	Control
Number of subjects (completers)	184	81	184	81
Oswestry score from baseline				
Success	130 (71%)	50 (62%)	117(64%)	47(58%)
Device failures[1]				
Success	175 (95%)	74(91%)	175(95%)	74(91%)
Major complications[2]				
Success	182(99%)	80(99%)	182(99%)	80(99%)
Neurological deterioration[3]				
Success	167(91%)	77(95%)	167(91%)	77(95%)
Overall Success Rate	117 (64%)	46(57%)	107(58%)	44(54%)

[1] Device failures requiring revision, reoperation, or removal.
[2] Major complications defined as major vessel injury, neurological damage, nerve root injury, or death.
[3] Slight deterioration, significant deterioration, or mixed response at 24 months.

The 2-sided 90% confidence interval indicates that the overall success rate for the Charité artificial disc is not worse than the control rate by more than 10%, regardless of which set of study success criteria is used. Secondary endpoints comprised measurements of components of the primary endpoints (ODI and

neurological scores) pain, using a visual analog scale (VAS), quality of life, using the Short Form-36 Questionnaire (SF-36), disc height, using a standard lateral radiograph, migration of the device, radiolucency for Charité artificial disc subjects.

All the results from the secondary endpoints at 24 months indicate the non-inferiority of the Charité artificial disc group to the control group.

In 2011, Johnson & Johnson voluntarily removed the Charité device from the market.

ProDisc-L: Select Health's policy covering the Charité disc is based on 24-month outcome data demonstrating general equivalency in outcomes between artificial disc and control groups. Long-term European data are also available for the ProDisc-L implant as well. A 2005 study by Tropiano et al. followed 64 patients with single or multiple level implantations with the first generation ProDisc implant for a mean follow-up of 7 years. Clinical results were evaluated by assessing pre-operative and post-operative lumbar pain, radiculopathy, disability, and modified Stauffer-Coventry scores (range 0−20). Overall, patients experienced significant postoperative improvements in low-back pain, lower-limb pain, and impairment (Modified Stauffer-Coventry score: 7.04 ± 3.34 preoperatively to 16.1 ± 2.76 postoperatively, $p < 0.0001$). Radiographic studies did not detect periprosthetic radiolucency's, migration, mechanical failures, or substantial decrease in bearing height at follow-up. 31% had intraoperative penetration of the implant through the posterior part of the superior and/or inferior endplates and into the vertebral body; end-plate penetration had no significant effect on clinical outcome. Siepe et al. reported similar results in 108 patients tracked over a mean follow-up period of 34 months. In that study, patients who underwent multi-segmental replacement experienced some deterioration in results 12−24 months after surgery, though pain remained significantly lower than preoperative levels. The authors also reported a 19.6% complication rate with 10.9% of patients requiring revision surgery.

Bertagnoli et al. published several prospective studies examining longitudinal outcomes in various subgroups implanted with the ProDisc device. In 18 patients with disabling adjacent-level discogenic low-back pain, with or without L1−S1 radicular pain, Oswestry Disability Index (ODI) scores decreased, on average, from 65.40 ± 1.51 to 29.00 ± 1.57 at 24 months. The FDA considers a minimum 15-point change in the Oswestry score as clinically significant change in patients who undergo spinal fusion. Visual analog scale (VAS) pain ratings improved from 7.73 ± 0.33 at baseline to 3.50 ± 0.42 at 24 months. Moreover, between the 3- and 24-month follow-ups, ODI and VAS scores continued improving, or were maintained, in 16 of 18 patients (89%). Improvement was statistically significant for ODI scores ($p = 0.002$) but not for VAS ratings. The percentage of patients who reported never using medications to control pain at 24 months increased over preoperative levels (NSAIDs 31.2% to 64.2%; narcotics 68.7% to 92.8%; Tramadol 37.5% to 42.8%) (statistical significance not reported). Preoperatively, 23% of patients worked part-time and 13% worked full-time. At 24 months, these rates had improved to 38% and 27%, respectively (statistical significance not reported). No device-related complications were reported.

A similar study in 2005 of 25 patients treated with multilevel ProDisc arthroplasty (15 double segmental, 10 triple segmental) revealed similar findings. Bertagnoli et al. reported that the baseline ODI and VAS scores improved and were maintained at 24 months (65.0 to 21.6 and 8.3 to 2.1, respectively). At 24 months, 96% of patients were either completely satisfied (no pain, unimpaired ADLs, and employment) or satisfied (slight pain occurring ≤ once daily requiring no medication and minimal impairment in employment or ADLs). The percentage of patients who reported never using medications to control pain at 24 months increased from preoperative levels (NSAIDs 28.0% to 68.0%; narcotics 56.0% to 96.0%; Tramadol 40.0% to 92.0%) (statistical significance not reported). The percentage of patients working full-time increased from approximately 7% at baseline to 40% at 24 months postoperatively (statistical significance not reported). One case of partial implant subsidence was reported.

In 104 single level ProDisc recipients, preoperative ODI had decreased significantly at 24 months (55 to 28 vs. 52 to 32, respectively). VAS ratings had similarly decreased in both groups (7.5 to 4.5 and 7.5 to 3.8, respectively). Outcomes did not differ between smokers and nonsmokers. At 24 months, 96% of patients were either completely satisfied (no pain and unimpaired ADLs and employment) or satisfied (slight pain occurring ≤ once daily requiring no medication and minimal impairment in employment or ADLs). The percentage of patients who reported never using medications to control pain at 24 months increased from preoperative levels (NSAIDs 5.8.0% to 59.0%; narcotics 83.0% to 90.0%; Tramadol 74.0% to 79.0%) (statistical significance not reported). Patients reported a 3-fold increase in full-time and

a 4-fold increase in part-time employment (statistical significance not reported). No cases of device-failure were reported.

In a similar clinical population of 22 patients 60 years of age or older who received the ProDisc-L implant, Bertagnoli et al. reported that the improvements in ODI and VAS scores at 3 months (27.29 ± 1.47 to 14.50 ± 1.81 and 8.02 ± 0.28 to 3.96 ± 0.42) were generally maintained at 24 months. Only one patient did not report improvement in VAS and ODI scores postoperatively. Two cases of implant subsidence and 2 cases of foot drop occurred subsequent to implantation.

Limited long-term data are available from randomized controlled trials. The Investigational Device Exemption Study, done as part of the PMA application for the ProDisc-L, included 292 subjects at 17 U.S. study sites. Patients were randomized to ProDisc-L (162 patients) or circumferential fusion (50 patients). Implantation was considered successful if subjects met the following criteria:

- Improvement in the ODI ≥ 15% at 24 months compared to the score at baseline
- No re-operation required to remove or modify the ProDisc-L implant (investigational group) or to modify the fusion site or correct a complication with an implant (control group)
- Improvement in Short Form-36 (SF-36) (i.e., 24-month score - pre-operative score > 0)
- Neurological status improved or maintained (motor, sensory, reflex, straight leg-raise)
- Radiographic success

Radiographic success in the investigational group was defined by the applicant as:

- No radiographic evidence of device migration or subsidence > 3 mm
- No extensive radiolucency along the implant/bone interface (< 25% of the interface's length for each endplate defined as a success)
- Range of motion (ROM) at the implanted level will be maintained or improved from the pre-operative baseline
- No loss of disc height > 3 mm
- No evidence of bony fusion

Radiographic success in the control group was defined by the applicant as:

- No radiographic evidence of device migration or subsidence > 3 mm
- No implant loosening (no halos or radiolucency's around the implant)
- No motion on flexion/extension films (success defined as < 3 mm translation and < 5° angulation)
- No loss of disc height > 3 mm
- Strong evidence of fusion, including > 50% trabecular bridging bone or bone mass maturation and increased or maintained bone density at the site
- No visible gaps in the fusion mass

Success in terms of "ROM at the implanted level maintained or improved" if the flexion/extension ROM at 24 months was "normal," where "normal" ROM was defined as follows:

- L3/L4 normal if ROM ≥ 6° (with ± 3° measurement error applied) and < 20° (device design limit)
- L4/L5 normal if ≥ 6° (with ± 3° measurement error applied) and < 20° (device design limit)
- L5/S1 normal if ≥ 5° (with ± 3° measurement error applied) and < 20° (device design limit)

According to these criteria, overall success at 24 months was higher among ProDisc patients relative to fusion controls (63.5% vs. 45.1%, p = 0.0053). Operative time, estimated blood loss, and hospital days averaged 218.6 minutes, 451.0 cc, and 4.4 days for fusion controls vs. 120.8 minutes, 203 cc, and 3.5 days for ProDisc patients. The number of device-related adverse events was lower in the ProDisc group than in the control group (17% vs. 20%), though this difference was not significant. The following device-related failures were reported for fusion and ProDisc, respectively:

- Migration > 3 mm: 1 patient (1.4%) vs. 3 patients (2.0%),

- Subsidence > 3 mm: 0 patients vs. 1 patient (0.7%)
- Radiolucency: 1 patient (1.4%) vs. 0 patients
- Loss of disc height > 3 mm: 1 patient (7.2%) vs. 0 patients.

In June 2008, the Charité and ProDisc-L were reviewed again and found that most of the data was subanalyses of earlier published data that compared outcomes across various patient populations or devices. The most recent of these, Guyer et al. (2008) examined the relationship between age and treatment outcomes in patients who were implanted with the Charité artificial spinal disc. This study was a reanalysis of the original IDE data from 276 patients and found that clinical outcomes, satisfaction, and the rate of adverse events in older patients (46−60 years) did not differ significantly from those of younger patients 18−45 years.

Two economic analyses, both manufacturer-sponsored, reported comparative costs between spinal fusion and artificial disc replacement. Levin et al. compared charges between the 2 procedures in 53 patients with degenerative disc disease, 36 who underwent artificial spinal disc replacement with the ProDisc-L, and 17 who underwent circumferential fusion. For patients with 1-level disease, the following charges were reported:

Outcome	Fusion	Disc Replacement	P-Value
Mean total charge	$46,280	$35,592	(P = 0.0018)
OR charges	$18,950	$12,000	(P < 0.05)
Implant charges	$13,990	$13,800	(P = 0.9)
Estimated blood loss	794 mL	412 mL	(P = 0.0058)
Mean OR minutes	344 minutes	185 minutes	(P < 0.05)
Mean length of stay	4.78 days	4.32 days	(P = 0.394)
Surgeon fees and anesthesiologist charges	$4917 and $473	$1413 and $253	(P < 0.0001, for both)

The following costs were reported for patients with 2-level disease:

Outcome	Fusion	Disc Replacement	P-Value
Mean total charge	$56,823	$55,524	(P = 0.55)
OR charges	$20,560	$15,340	(P = 0.0003)
Implant charges	$18,460	$27,600	(P < 0.05)
Estimated blood loss	No difference	No difference	No difference
Mean OR minutes	387 minutes	242 minutes	(P < 0.05)
Mean length of stay	No difference	No difference	NS
Surgeon fees and anesthesiologist charges	$5857 and $525	$2826 and $331	(P < 0.05 for each)

It is notable in this analysis, the surgeon's fees for disc replacement, mean OR minutes, and OR charges were calculated to be less for disc replacement vs. fusion procedures. However, that has not been the Select Health experience in the limited number of cases performed to date. Surgeons are typically charging significantly more for this procedure and the Select Health fee schedule is set 10%−20% higher than the corresponding fusion code due to the increased complexity of performing this procedure vs. a similar level fusion.

In a study funded by DePuy, the manufacturer of the Charité artificial disc, Guyer et al. developed an economic model comparing the Charité disc to three different spinal fusion procedures: anterior lumbar interbody fusion (ALIF) with iliac crest bone graft (ICBG); ALIF with INFUSE Bone Graft and LT-Cages; and instrumented posterior lumbar interbody fusion (IPLIF) with ICBG. The model assessed direct costs (not charges) from hospital and payer perspectives. Direct costs were analyzed based on two systems: diagnostic related groups (DRG) and per-diem. In both arms of the study, DRGs were used to estimate

total charges based on claims data. In the DRG arm, cost/charge ratios were applied based on geographic location to derive costs for each comparator. The per diem arm accounts for some payers' negotiated contracts for spine procedures and calculated payer costs according to a pre-established, fixed payment for a day of patient care in addition to reimbursing 100% of the cost of the implant. Cost data were obtained from 71 U.S. hospitals.

Hospital costs are the same using either method. Compared with Charité, hospital costs were 12% more costly for ALIF with ICBG, 36.5% more costly with ALIF with INFUSE, and 36.5% more costly with IPLIF. From a payer perspective, the per-diem arm compared with TDR, ALIF with ICBG has 4.4% lower cost, whereas ALIF with INFUSE and IPLIF have costs of 16.1% and 27.1% higher, respectively. In the DRG arm compared with TDR, payer cost is 87.1% higher for ALIF with ICBG, 82.8% higher for ALIF with INFUSE, and 99.0% higher for IPLIF.

Shim et al. conducted the only study comparing outcomes for the Charité and ProDisc implants. This retrospective study compared outcomes for 33 patients who were implanted with Charité and 24 who were implanted with ProDisc. At 3 years, groups reported statistically identical levels of pain and disability. Rate of degradation of the facets was also statistically identical between groups (Charité = 36.4%; ProDisc = 32%). Segmental ROM of the replaced segments was well-preserved, but ROM of L5-S1 of the ProDisc was significantly less than that of the Charité.

The 3 published technology reviews offered similar conclusions about Charité and ProDisc. Short-term data offer promising results about the safety and efficacy of artificial lumbar disc replacement. However, some uncontrolled studies raise concerns about potential degradation of adjacent discs and facets. The artificial disc itself may also wear out and revision surgery may be needed. Long-term data from controlled trials are lacking. Moreover, no studies have compared artificial disc outcomes to those achieved with intensive physical and behavioral therapy, which recent studies suggest offer similar outcomes to spinal fusion. None of these reviews recommended artificial spinal disc implantation.

Prestige ST Cervical Disc: Fewer studies are available on the Prestige cervical disc prosthesis. The IDE study submitted as part of the PMA application involved 36 sites, 276 patients randomized to the Prestige disc, and 265 to a surgical fusion control group. Individual subject success (i.e., overall success) was defined in the study protocol as success in certain clinical outcome parameters:

- An improvement of at least 15 points from the baseline Neck Disability Index score;
- Maintenance or improvement in neurological status;
- No serious adverse event classified as implant-associated or implant/surgical procedure-associated; and
- No additional surgical procedure classified as "Failure."

In addition, an alternate overall success determination was made based on the above criteria with the addition of functional spinal unit (FSU) height maintenance. FSU height was considered maintained if it did not decrease more than 2 mm after 6 weeks following surgery.

Bayesian statistical methods were used to predict 24-month values from the existing 12-month data for patients lacking complete 24-month data for all effectiveness variables. These Bayesian analyses yielded probability estimates for the Prestige disc of approximately 100% for equivalency and 95.9% for superiority at 24 months. Adding FSU height into the success criteria, the probability that the 24-month overall success rate for the Prestige group was equivalent to the 24-month success rate for the control group was 100%. The probability of superiority was 99.7%. Overall, the probability of success at 24 months in a patient who receives the Prestige cervical disc is 78.8%. (95% CI: 72.1% - 85.0%). In contrast, the chance of success in cervical fusion patients at 24 months is 70.0% (CI: 62.7% - 77.4%).

The number of subjects requiring any second surgery intervention (revision, removal, reoperation, or supplemental fixation) was 3.3% (9/276) in the Prestige group and 9.1% (24/265) in the fusion control group, a statistically significant difference. The Prestige group had a statistically lower rate of secondary surgical procedures related to implant revisions and supplemental fixations. Prestige patients also experienced a lower rate of implant removals, but it was not statistically different. These findings resulted in a lower second surgery failure rate for Prestige patients.

Porchet et al. published preliminary data from a multicenter, prospective, randomized controlled trial involving 55 patients with cervical degenerative disc disease enrolled in four centers in the UK. The

Prestige II disc (an earlier version of the Prestige ST) was implanted in 27 patients, while 28 underwent cervical fusion. Data were available for 37 patients at 12 months and 9 patients at 24 months. There was no significant difference in the distribution of adverse events between the two groups (19 vs. 17). Both patient groups experienced improvements in neck disability, neck pain frequency and intensity, and arm pain frequency and intensity from baseline. However, the improvement did not differ significantly between groups. A prospective study by Robertson et al. of the Prestige I (another early version of the Prestige ST) reported on 11 patients at 36 months and 12 patients at 48 months, the majority of whom continued to experience improved pain, functioning, and quality of life, relative to preoperative levels. One patient required removal of the prosthesis at 12 months. Another required fusion secondary to advanced DDD below the implant.

On July 18, 2016, the FDA expanded the approval of the Prestige LP artificial disc for use at two levels. Originally the device was approved in 2014 for a single disc level between C3 and C7. The basis of the expanded FDA approval was the study by Lanman et al., which provided Level 1 evidence of effectiveness and durability of this device in a prospective randomized, multicenter trial comparing efficacy, safety and durability to anterior cervical disc fusion (ACDF). This study actually demonstrated statistically significant SUPERIORITY to ACDF on several measures: overall success (observed rate 78.6% vs 62.7%; posterior probability of superiority [PPS] = 99.8%), Neck Disability Index success (87.0% vs 75.6%; PPS = 99.3%), and neurological success (91.6% vs 82.1%; PPS = 99.0%) and noninferiority in all other measures. It did not demonstrate significant heterotopic ossification or loss of range of motion during the 7-year study period. This evidence is as strong, if not stronger, than that for the Mobi C device also approved for 2 cervical levels.

Another study published in 2017 (Gornet et al.), shows the proportion of patients experiencing any AE was 93.3% (195/209) in the investigational group and 92.0% (173/188) in the control group, which were not statistically different. The rate of patients who reported any serious AE (Grade 3 or 4) was significantly higher in the control group (90 [47.9%] of 188) than in the investigational group (72 [34.4%] of 209) with a posterior probability of superiority of 0.996. Radiographic success was achieved in 51.0% (100/196) of the investigational patients (maintenance of motion without evidence of bridging bone) and 82.1% (119/145) of the control patients (fusion). At 24 months, heterotopic ossification was identified in 27.8% (55/198) of the superior levels and 36.4% (72/198) of the inferior levels of investigational patients. Arthroplasty with the Prestige LP cervical disc is as effective and safe as ACDF for the treatment of cervical DDD at 2 contiguous levels and is an alternative treatment for intractable radiculopathy or myelopathy at 2 adjacent levels.

ProDisc-C Cervical Disc: Nabhan et al. performed a study which compared the ProDisc-C to fusion. This prospective randomized and controlled radiographic and clinical study included 25 patients. The patients with cervical disc herniation were enrolled and assigned to either study group (receiving a disc prosthesis) or control group (receiving anterior cervical discectomy and fusion [ACDF], using a cage with bone graft and an anterior plate). Radiostereometric analysis was used to quantify intervertebral motion immediately as well as 3, 6, 12, and 24 weeks postoperatively. Further, clinical results were judged using visual analogue scale and neuro-examination. Cervical spine segmental motion decreased over time in the presence of disc prosthesis or ACDF. However, the loss of segmental motion is significantly higher in the ACDF group, when looked at 3, 6, 12, and 24 weeks after surgery. We observed significant pain reduction in neck and arm postoperatively, without significant difference between both groups ($P > 0.05$). Cervical spine disc prosthesis preserves cervical spine segmental motion within the first 6 months after surgery. The clinical results are the same when compared to the early results following ACDF.

A June 20, 2011 Hayes Technology Review compared total disc replacement with anterior cervical discectomy and disc fusion. Most of the literature reviews consisted of patients who primarily had single-level disease. No assessment of success rates beyond 3 years existed, even for trials that have reported clinical outcomes at 4 and 5 years. Hayes identified several moderate-size randomized controlled trials (RCTs) comparing different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF) have been published. Evidence to date demonstrates that TDR is at least as effective as ACDF in improving signs and symptoms associated with degenerative disease and improving quality of life (QoL) for up to 2 years. The evidence also shows that total disc replacement (TDR) reduces the need for reoperation and reduces the incidence of dysphagia. Low-quality evidence suggests that ACDF reduces the risk of new adjacent segment disease but may have higher rates of intraoperative and perioperative complications. Reliable follow-up data for more than 3 years are lacking for both benefits and harms.

Positive but sparse evidence suggests that bi-level TDR is less safe than single-level TDR, although a few studies with several limitations suggest it is comparable to bi-level ACDF in safety and efficacy.

Mobi-C Cervical Disc Prosthesis: A technology assessment performed in January 2014 identified one systematic review and thirteen primary literature articles for review. These studies included 1,213 patients who received the Mobi-C device. The average follow-up time for the 9 studies that reported was 27.6 months with only one study duration less than 24 months.

The systematic review published by BCBS TEC from 2013 looked at cervical arthroplasty broadly concluded there were no studies illustrating long-term outcomes for the Mobi-C device. The, Park et al. study also published in 2013, however, was not included in the BCBS TEC review and followed patients out to 40 months with favorable outcomes (decrease in mean numeric rating scores for the neck and arm, neck disability index scores, Odom success rates). BCBS TEC further concluded artificial intervertebral disc arthroplasty for the treatment of cervical degenerative disc disease did not meet TEC criteria. This statement was made after reviewing literature on 6 artificial disc products, and only including 6 papers from RCTs.

Related to the efficacy and safety of the Mobi-C implant compared to fusion surgery this was addressed by 3 of the 13 (23%) papers. The inclusion criteria between these three papers, as well as the published outcomes of the trials, are sufficiently disparate in that no meaningful conclusions can be drawn. For example, at two years, Singh et al. and Davis et al., published the following conflicting results regarding revision rates at 24 months:

The Mobi-C implant also compared favorably to other artificial disc implants. Park et al. and Yi et al. (2 papers from Yi et al.) studied how Mobi-C compares to other commercially available cervical discs on the market (i.e., Bryan, Prestige LP, PCM). Both authors examined different primary endpoints. Park et al. showed that in terms of incidence of adjacent segment degeneration the Mobi-C was 1.76% above the mean and Yi et al. showed that heterotopic ossification was 4.2% above the mean with Mobi-C than with Bryan or ProDisc-C at 3 years.

The remaining question concerning Mobi-C implant is related to any different effect it may have on heterotopic ossification. Seven of the thirteen (53.8%) papers that studied Mobi-C reported incidence of HO. These studies identify heterotopic ossification to occur at similar rates to what occurs with other cervical spine implants. Specific characteristics of noted in the literature is that HO increases over time, older males are more prone to development of HO and HO restricts cervical ROM over time.

Authors vary on their definition of “clinical significance” as it pertains to degree of HO present at follow-up. There appears to be inconsistent reporting of HO in the clinical setting as Bao et al. report no HO at 16.5 months where Park et al. showed 94.1% HO at 24 months. The R-squared for this data is 0.149 which illustrates poor fit between HO at follow-up (FU) and follow-up times. Beaurain et al., Guerin et al. and Lee et al. all established that significant HO was present at follow-up, but that ossification did not affect clinical outcomes.

As the Mobi-C implant is the only cervical disc implant FDA approved for 2 adjacent level implants, particular focus was given to the evidence related to efficacy and safety of the device in this setting. The evidence of comparative efficacy and safety related to this two-level implantation to ACDF is quite limited. Of the 13 primary literature articles, 5 (38%) addressed 2-level replacement or 2-level fusion. Only 1 of the 5 (20%) (Singh et al.) performed what could be considered a head-to-head analysis of this issue. Singh et al. retrospectively analyzed 1, 2 and 3 level reoperation rates and found that at 3.5 years, 1 and 2 level reoperation rates were identical with a rate of 4.2% but 3 level rates were 18.8%. However, this data is an aggregate of 5 different devices, so no conclusions can be reached to determine the efficacy of Mobi-C in this regard. Though the other 4 studies examined 2-level treatments, no conclusions regarding the efficacy of Mobi-C’s 2-level arthroplasty vis-à-vis 2-level fusion can be derived from the current body of evidence. No studies provided evidence for outcomes beyond 3.5 years nor discussed the potential implications regarding heterotopic ossification.

A recent prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results was published in the J Neurosurgery Spine November 7, 2014. The study evaluated the safety and effectiveness of 2-level total disc replacement (TDR) using Mobi-C cervical artificial disc at 48 months’ follow-up. Three hundred thirty patients with degenerative disc disease were randomized and treated with

cervical total disc replacement (225 patients) or the control treatment, anterior cervical discectomy and fusion (ACDF) (105) patients). Patients were followed up at regular intervals for 4 years after surgery. At 48 months, both groups demonstrated improvement in clinical outcome measures and a comparable safety profile. Data was available for 202 TDR patients and 89 ACDF patients in calculation of the primary endpoint. TDR patients had statistically significantly greater improvement than ACDF patients for the following outcome measures compared with baseline. Neck Disability index scores, 12-item Short Form Health Survey Physical Component Summary scores, patient satisfaction, and overall success. ACDF patients experienced higher subsequent surgery rates and displayed a higher rate of adjacent-segment degeneration as seen on radiographs. Overall, TDR patients maintained segmental range of motion through 48 months with no device failure. Four-year results from this study continue to support TDR as a safe, effective, and statistically superior alternative to ACDF for the treatment of degenerative disc disease at 2 contiguous cervical levels.

Orthofix M6-C: The data demonstrates that patients treated with the M6-C artificial cervical disc had significant improvements in neck and arm pain, function and quality of life scores. Additionally, these patients had a significant difference in the reduction of pain and opioid medications use when compared to anterior cervical discectomy and fusion (ACDF) patients. At 24 months, patients in the ACDF group who were still using pain medications had a seven times higher rate of opioid use than those in the M6-C disc group. A prospective, non-randomized, concurrently controlled clinical trial, the M6-C IDE study was conducted at 23 sites in the United States with an average patient age of 44 years. The study evaluated the safety and effectiveness of the M6-C artificial cervical disc compared to ACDF for the treatment of single level symptomatic cervical radiculopathy with or without cord compression. The overall success rate for the protocol-specified primary endpoint for the M6-C disc patients was 86.8 percent at 24 months and 79.3 percent in the control group. This data statistically demonstrates that cervical disc replacement with the M6-C disc is not inferior to treatment with ACDF.

Secondary outcomes at 24 months include:

- Patients who received the M6-C disc demonstrated statistically significant improvement in the Neck Disability Index as measured at week six and months three, six, 12 and 24.
- Meaningful clinical improvement was seen in the following pain scores:
    - 91.2 percent of patients who received the M6-C disc reported an improvement in neck pain compared to 77.9 percent in patients who underwent the ACDF procedure.
    - 90.5 percent of the M6-C patients reported improvement in arm pain scores compared to 79.9 percent in ACDF patients.
- Prior to surgery, 80.6 percent of the M6-C disc patients and 85.7 percent of the ACDF patients were taking some type of pain medication for the treatment of their cervical spine condition. At 24 months, the rate of M6-C patients who were still taking some type of pain medication dropped to 14.0 percent compared to 38.2 percent of the ACDF patients.
    - Of these, there was a seven times higher rate of opioid use with the ACDF patients than with patients who received the M6-C disc.
- There was a statistically significant difference in the average mean surgery time – 74.5 minutes for patients receiving the M6-C disc versus 120.2 minutes for those patients having the ACDF procedure.
- In addition, there was a statistically significant difference in the mean length of hospital stay – 0.61 days for the M6-C patients versus 1.10 days for ACDF patients.
- Subsequent surgery at the treated level was needed in 4.8 percent of the ACDF patients compared to 1.9 percent of the M6-C disc patients.
- There were no device migrations reported in the study.
- Overall patients receiving the M6-C disc reported a 92-percent satisfaction rate with the surgery, and 93 percent said they would have the surgery again.
- There were 3.8 percent serious adverse events related to the device or procedure in the M6-C disc group versus 6.1 percent in the ACDF group.
- Reference 105

A Hayes Knowledge Review from June 12, 2019, found the literature search retrieved a very limited body of peer-reviewed published evidence evaluating the M6-C Artificial Cervical Disc for the

treatment of symptomatic cervical radiculopathy. Overall, positive benefits in patient-centered outcomes of pain, disability, and satisfaction were shown with an acceptable safety profile. However, the sample sizes were small with only limited follow-up periods of up to 24 months.

Results of the pivotal Investigational Device Exemption Study that led to Food and Drug Administration (FDA) approval of this device suggested noninferiority to the operative standard of care, ACDF; peer-reviewed publication of this study is pending. In addition, an ongoing clinical trial comparing the M6-C device with ACDF will address some evidence gaps.

A health technology assessment from the Ontario Health Technology Assessment Series included the M6-C Artificial Cervical Disc in their economic analysis and found the device to be a good value for total disc replacement versus ACDF.

Overall, the literature search retrieved a very limited body of evidence evaluating the M6-C Artificial Cervical Disc for the treatment of symptomatic cervical radiculopathy. Study sample sizes were small (n=30 to 36 patients), relative to the prevalence of symptomatic cervical radiculopathy. The range of follow-up was 3 to 24 months. In general, positive benefits with respect to patient-centered outcomes of pain, disability, and satisfaction were shown without negative outcomes. Reportedly, the safety profile was acceptable. No published studies comparing total disc replacement with the standard of care for operative management, ACDF, were located.

A 2017 Hayes Medical Technology Directory report cited the North American Spine Society (NASS) evidence–based guidelines on "Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders." The guidelines concluded that surgical intervention is suggested for rapid relief of symptoms, and asserts the following conclusions regarding surgical choices:

1. Anterior cervical discectomy alone produces similar outcomes equivalent to anterior cervical discectomy and fusion (ACDF), but addition of an interbody graft for fusion improves sagittal alignment.

2. ACDF with and without plating results in similar clinical outcomes, but plating improves sagittal alignment.

3. Anterior and posterior surgery produce comparable clinical outcomes (but the working group came to a non-evidence–based conclusion that anterior surgery is preferred in certain situations).

4. ACDF and TDR produce similar short-term outcomes for single-level disease.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

Lumbar

22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)

Cervical

22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical

22858 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectyomy for nerve root or spinal cord decompression and microdissection); second level, cervical

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
2/2/23	For Commercial Plan Policy, modified contraindication #B in Lumbar Contraindications section to now read, “Severe lumbar spinal stenosis” instead of “Significant bony lumbar spinal stenosis.”

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MEDICAL POLICY

ATHLETIC PUBALGIA (SPORT'S HERNIA) REPAIR

Policy # 487
Implementation Date: 9/30/11
Review Dates: 11/29/12, 12/19/13, 12/18/14, 12/10/15, 5/22/16, 6/15/17, 6/21/18, 6/20/19, 6/18/20, 6/17/21, 5/4/22, 6/8/23, 6/6/24, 6/7/25
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

A sports hernia, also known as athletic pubalgia, Gilmore's groin, and slap shot gut, is an uncommon but often missed cause of groin pain in high level athletes. It is poorly understood and poorly defined in the medical community. It is also very difficult to identify based on history and physical exam of an athlete with groin pain. The name sports hernia is a misnomer as well because there is no discernable hernia (or protrusion of abdominal cavity contents) present in this condition. Sports hernias may result from chronic, repetitive trauma or stress to the musculotendinous portions of the groin. They typically develop in an insidious fashion without sudden or dramatic pain. Symptoms typically come from overuse of the lower abdominal musculature and the muscles of the upper thigh.

Sports hernias are more common in men than in women and are more common with sports such as hockey, soccer, rugby, and football, in which the athlete bends or leans forward. However, virtually all sports can produce sports hernia because leaning or bending forward into the typical "athletic stance" is a common pose in any athletic endeavor. Additionally, high-speed twisting and turning and torquing the groin, likely contribute to the development of the condition.

Diagnosis of athletic pubalgia can be elusive but is established by history and physical examination. In a 2004 study by Susmallian et al., 35 professional soccer players underwent laparoscopic inguinal exploration and repair of sports hernias. This article suggests that with close enough examination, surgeons could typically find athletic pubalgia in most patients (97%). There is still neither consensus as to what exactly athletic pubalgia is nor how to treat it.

Treatment is initially conservative with rest, ice, nonsteroidal anti-inflammatory drugs, physical therapy, and fluoroscopically-guided injections. Once an adequate trial of conservative treatment fails, surgery is often considered.

Two surgeries are most performed in the treatment of a sports hernia. The first is a pelvic floor repair. In this procedure the inferolateral edge of the rectus abdominus muscle is reattached to the pubis and adjacent anterior ligaments. In the other, the patient undergoes an adductor release. In this procedure the anterior epimysial fibers of the adductor longus muscle are divided about 2 to 3 cm from pubic insertion; the muscle belly is left intact. This can be performed independently, or concomitantly, with pelvic floor repair—it is rarely successful independently.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover athletic pubalgia (sport's hernia) repair due to ill-defined nature of the condition and lack of consensus as to the approach to treatment. This meets the plan's definition of experimental/investigational.

Select Health

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A Medical Technology Assessment performed in September 2011 identified a systematic review from Hayes on surgery for treatment of athletic pubalgia in December of 2006. The technology brief concluded that although there appear to be benefits to performing surgery for the treatment of athletic pubalgia, the scarcity of randomized controlled trials is concerning. Hayes notes that the procedure appears to be safe and reasonably effective.

Since the Hayes review, nine peer-reviewed journal articles were identified concerning surgical treatment for athletic pubalgia. Of these, only one article (Paajanen et al.) was prospective and comparative. Given that the standard treatment for sport's hernia is conservative physiotherapy, it is concerning that no other article compared surgery to this standard of care. All the articles identified in this review reiterate that there is no one definition for what athletic pubalgia is. Likewise, there is no consensus for patient selection, postoperative rehabilitation duration, preoperative screening, or if preoperative therapy should be considered before being a candidate for surgery—none of the papers discussed revision surgery rates. With that said, it is evident that after conventional therapies have failed, surgery may be the only viable option for many patients.

A Hayes review completed in April 2016, noted that based on a low-quality body of evidence there is insufficient evidence to determine whether a laparoscopic or open surgical technique is superior to another. More rigorous studies are needed to establish the relative benefits and harms of different laparoscopic and open surgical procedures for this patient population; comparative evidence was limited to 5 observational studies and 2 RCTs.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy
49999	Unlisted procedure, abdomen, peritoneum and omentum
49650	Laparoscopy, surgical, repair initial inguinal hernia

HCPCS CODES

No specific codes identified

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Disclaimer

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

AUTOLOGOUS CHONDROCYTE TRANSPLANTATION (ACT) OR IMPLANTATION (ACI)

Policy # 195
Implementation Date: 10/15/03
Review Dates: 11/18/04, 11/20/05, 12/21/06, 12/20/07, 12/18/08, 12/16/10, 12/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24
Revision Dates: 12/19/09, 6/5/19, 2/21/20, 3/4/21

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Damaged articular cartilage can be associated with pain, loss of function, disability, and can lead to debilitating osteoarthritis over time. These manifestations can severely impair an individual's activities of daily living and quality of life. Autologous chondrocyte implantation (ACI) or transplantation (ACT) has been proposed as a surgical treatment for patients who have clinically significant, symptomatic, focal defects of the articular cartilage of the knee. It is hypothesized that the implanted chondrocytes will stimulate regeneration of a hyaline-like cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the generation of a hyaline-like cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

ACI has 4 components:

1. Debridement of the injured area
2. Coverage of the injured area with a periosteal tissue flap
3. Implantation of cultured chondrocytes
4. Physical rehabilitation

The defining and unique feature of ACI is the implantation of autologous cultured chondrocytes that have been harvested from the patient, grown in a culture medium, and then transplanted to the injured area. The use of a periosteal flap to cover the lesion, which is also hypothesized to promote cartilage repair, has also been investigated as a potential treatment. While the use of a periosteal flap is novel, it is not unique to ACI. The remaining 2 components of ACI, debridement and rehabilitation, are standard procedures commonly used to achieve symptomatic relief.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers autologous chondrocyte transplantation (ACT) or implantation (ACI) in *limited circumstances.*

Criteria for coverage, must meet ALL the following guidelines:

1. Age 15 to 55 years
2. BMI < 35

Autologous Chondrocyte Transplantation (*ACT) or Implantation (ACI), continued

3. Disabling knee pain with significant symptoms of pain, swelling, catching, and limitation of daily activities are documented
4. Focal articular cartilage defect down to but not through the subchondral bone
5. Size of the cartilage defect is at least 2 centimeters across (or 3 cm^2 in total area)
6. Stable knee with intact meniscus and normal joint space on x-ray
7. No active inflammatory or other arthritis, clinically, and by x-ray
8. Failure of conservative therapy (minimum of 2 months of physical therapy) and prior arthroscopic or other surgical repair procedure (e.g., microfracture, drilling, abrasion, osteochondral autografts)

Select Health considers autologous chondrocyte transplantation (ACT) or implantation (ACI) for ages below 15 and above 55 to be experimental/investigational, as these age groups are not FDA approved for these procedures.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The evidence continues to be limited primarily to case series: i.e., uncontrolled, and non-randomized studies that support only limited confidence in understanding the contribution of implantation of autologous chondrocytes distinct from the other components of the total procedure (e.g., use of periosteal flap, extensive rehabilitation, limitation of physical activities for 6–12 months). Thus, even though the current body of evidence (i.e., case series) consistently points to good outcomes, it is not yet known whether this represents the benefit of the implantation of autologous chondrocytes, other components of the total procedure, natural history of the disorder, bias of studies, or placebo effect. In fact, in a recent study published by Shelbourne et al., it is suggested that little is known about the natural course of chondral defects, thus, uncontrolled studies tell us little.

However, attempts by Genzyme to enroll patients in placebo-controlled trials have failed, at least in part, due to apparent unwillingness of prospective patients to be randomized into placebo-controlled trials with moderately difficult demands (i.e., surgery, extensive rehab) with no guarantee of receipt of the ACI procedure. Consequently, guided by discussions with the FDA, Genzyme has agreed to conduct a prospective, longitudinal “within patient” study, plus a registry-based study; the latter complete and submitted to the FDA, and the former in progress. Another methodology-related issue is that for many indications, the only alternative is continuing to avoid physical activity (involving the knee) combined with pain medications, or knee replacement surgery (i.e., other surgical options have been exhausted). Additionally, the surgical procedures that may be considered alternatives to ACI (e.g., mosaicplasty, microfracture, OATS procedure) have limited evidence against which to compare ACI.

Autologous Chondrocyte Transplantation (*ACT) or Implantation (ACI), continued

Since the BCBS TEC review in March 2003, which states that ACI does not pass their criteria, 2 controlled studies of ACI versus alternative surgical procedures have been published. These suggest that ACI is superior to mosaicplasty and similar to (or inferior to) osteochondral cylinder transplantation in cartilage repair of the knee joint. Neither of these RCTs had a placebo or control (i.e., do nothing) group.

A 2008 literature review found a published study by Zaslav et al. with 126 (82%) patients completing the protocol. Seventy-six percent of patients were treatment successes at study-end, while 24% were deemed treatment failures. Results did not differ between patients whose primary surgery had been a marrow-stimulating procedure and those whose primary procedure had been a debridement alone. The median difference in duration of benefit between autologous chondrocyte implantation and the failed non-autologous chondrocyte implantation prior procedure was at least 31 months ($P < .001$). Seventy-six patients (49%) had subsequent surgical procedure(s), predominantly arthroscopic. Need for a subsequent surgical procedure was not predictive of failure. It found, patients with moderate-to-large chondral lesions, with failed prior cartilage treatments, can expect sustained and clinically meaningful improvement in pain and function after autologous chondrocyte implantation. The subsequent surgical procedure rate observed in this study (49% overall; 40% related to autologous chondrocyte implantation) appears higher than generally reported after autologous chondrocyte implantation. ACI remains promising but important questions remain unanswered, as is the case with all the other surgical procedures for treating traumatic articular cartilage defects of the knee.

Billing/Coding Information

Covered: for the indications outlined above

CPT CODES

27412	Autologous chondrocyte implantation, knee articular surface defect; autografts
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)

HCPCS CODES

J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

Key References

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MEDICAL POLICY

AXIAL LUMBAR INTERBODY FUSION (AXIALIF)

Policy # 450

Implementation Date:8/9/10

Review Dates: 9/15/11, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 9/15/18, 8/8/19, 8/20/20, 7/29/21, 7/5/22, 8/22/23, 9/18/24

Revision Dates: 5/1/12

Related Medical Policies:

#320 Interspinous Distraction Devices/Spacers
#513 Interbody Spinal Fusion Devices
#558 Interspinous Fixation (Fusion) Devices

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The spine is subject to multiple conditions which may lead to pain, functional impairment, and disability. The two most common conditions involving the spine are degenerative disc disease and spinal stenosis. Spinal stenosis can involve the spine in various locations. Approximately 75% of cases of spinal stenosis occur in the lumbar spine. Spondylosis or degenerative arthritis affecting the spine is the most common cause of lumbar spinal stenosis and typically affects individuals over the age of 60 years. Progressive disc degeneration due to aging, trauma, or other factors can lead to disc protrusion and/or loss of disc height with attendant loading of the posterior elements of the spine, including the facet joints.

The traditional surgical treatment of lumbar stenosis entails an extensive resection of posterior spinal elements, such as the interspinous ligaments, spinous processes, bilateral lamina, and portions of the facet joints, capsule, and the ligamentum flavum. Additionally, wide muscular dissection and retraction is usually employed to achieve adequate surgical visualization. The classic operations of a wide decompressive laminectomy, medial facetectomy, and foraminotomy have been used for decades with varying degrees of success. The extensive resection and injury of the posterior osseous and muscular complex can lead to significant iatrogenic pain, disability, and morbidity. Such iatrogenic injury can lead to paraspinal muscle denervation and atrophy, which may correlate with an increased incidence of "failed back syndrome" and chronic pain.

As an alternative to standard surgical management of spinal stenosis, Axial Lumbar Interbody Fusion (AxiaLIF) has been developed. This is an anterior stabilization and interbody fusion technique via a retroperitoneal access. The AxiaLIF system is a multi-component system including titanium implantable devices as well as instrumentation made of biocompatible materials such as titanium alloy, stainless steel, and nitinol. The nitinol cutters are made to debulk the nucleus pulposus and scrap the endplates in order to create a bleeding bed for fusion. The various sizes of cutters allow the surgeon to control and direct the radial cutters to best prepare the disc space. Tissue extractors are used to remove the diseased disc in order to prepare the disc for bone grafting, are made of stainless steel, and allow the surgeon to twist and grab the disc after it has been debulked by the nitinol cutters. The TranS1 3D Axial Rod is a titanium alloy implant that utilizes a differential thread pitch to attain distraction of the disc space during implant insertion.

During the procedure, the surgeon makes an incision lateral to the tip of the coccyx and advances the dissecting tool to the docking point on the sacrum. A series of dilators is used to drill through the sacrum to the L5/S1 disc space. With the last dilator, a cannula is docked in the sacrum. The radial cutters and

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tissue distractors are used to remove the intervertebral disc. Bone graft is inserted into the disc space. After measurements of the newly drilled hole have been made, the surgeon selects and inserts the AxiaLIF 3D rod with the rod driver. Antibiotics are flushed in the space and the skin at the operation site is closed.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover axial lumbar interbody fusion (AxiaLIF). While the short-term evidence suggests equal, if not superior efficacy and safety for this procedure compared to standard lumbar single level fusion procedures, long-term evidence on the durability and cost-effectiveness do not exist.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

A Medical Technology Assessment performed in May 2010 identified only 5 peer-reviewed journal articles discussing the efficacy and implementation of Axial Lumbar Interbody Fusion (AxiaLIF). One of the 5 is a general review article which lacked a systematic analysis of the procedure. All told, only 64 patients have received the AxiaLIF procedure as reported in the primary literature. Each of the 5 papers report percutaneous method to be safe and effective, but none of the studies provides long-term data to support their conclusions. Three of the 5 papers specifically involved the AxiaLIF procedure, but none of these trials presented long-term outcomes data. Anand et al. identified postoperative follow-up times being as little as 2.5 months, while Aryan et al. found such a maximum reported time of 17.5 months. This does not constitute a broad enough time window to draw significant conclusions regarding long-term postoperative outcomes. Lubansu indicates: "Despite these encouraging early clinical results, no prospective, randomized published scientific study has proved that minimally invasive techniques are better than standard techniques. Larger clinical series with a longer follow-up could fill this gap."

An updated Medical Technology Assessment performed in April 2012 identified 2 systematic reviews and 7 peer-reviewed journal articles since the last review in 2006. At the time of the last review, only 64 patients' outcomes had been reported in the literature. Since then, the results of an additional 369 AxiaLIF procedures have been published. Though the systematic reviews and primary literature articles indicate that transaxial percutaneous lumbar interbody fusion is safe and effective for most patients, it is evident that these conclusions are based upon relatively short-term outcomes. Follow-up times range from 12–34 months, with a mean follow-up of 21.7 months.

The question as to how AxiaLIF compares to standard interbody fusion is not well addressed in the literature. There are currently no head-to-head trials comparing this technique to standards of care. Tobler et al. noted, however, that there were no severe adverse events associated with the presacral approach, and those outcomes and fusion rates were comparable with those of reports of other methods of interbody fusion.

Axial Lumbar Interbody Fusion (AxiaLIF®), continued

In a trial of 68 patients undergoing AxiaLIF, Lindley et al. published a list of complications associated with the procedure. Oddly, other than Tender et al. who reported no complications, this was the only paper identified in this review which explicitly noted complications and their rates. This is peculiar given the route needed to access the surgical space and the potential for superficial infection, pelvic hematoma, pseudoarthrosis, sacral fracture, rectal injury, and bowel perforation.

Three articles noted statistically significant improvements in Oswestry Disability Index (ODI)* scores. The analysis was used in 58% of all AxiaLIF procedures. Tender et al. noted largest improvement (80.5%) in ODI, though, the patient population was exceptionally small (n = 3). Nonetheless, even Tobler et al. noted significant improvements in both ODI as well as fusion percentage in nearly half of all patients who received the AxiaLIF procedure.

The following table (Table 1) illustrates significant metrics common to the primary literature. As noted, there have been 5 and one half-times as many patients who have undergone AxiaLIF since the last time this technology was reviewed. Most significantly, the table demonstrates revision rates and fusion rates that are similar to other methods of interbody fusion.

Table 1: Outcome Data for AxiaLIF Procedure

Study	N	Follow-up	Revision	Complication	ODI* Pre/Post Op	Fusion**
Bohinski et al.	50	12 mos	2%	2%	56%/28%	100%
Gerszten et al.	26	24 mos	15%			100%
Lindley et al.	68	34 mos	11.8%	26.5%		
Liu et al.	40					
Tender et al.	3	12 mos	0%	0%	67%/13%	100%
Tobler et al.	26	24 mos			49%/27%	96%
Tobler et al.	156	24 mos			37%/19%	94%
Mean	**53**	**21.7 mos**	**7.2%**	**9.5%**	**56% Decrease**	**98%**

* The Oswestry Disability Index (ODI) is a common measure based on a series of questions to evaluate patient lower back pain. Scoring is divided as follows:
1. 0%-20%: Minimal Disability
2. 21%-40%: Moderate Disability
3. 41%-60%: Severe Disability
4. 61%-80%: Crippled
5. 81%-100%: Bedridden

** % of fusions maintained at follow-up

In the Australia and New Zealand Horizon Scanning Network's (ANZHSN) 2010 systematic review, they noted the AxiaLIF procedure appears to be relatively safe and effective, and where complications do arise, such as bowel perforation, they are readily treated with no apparent residual problems. Unfortunately, there is no evidence illustrating AxiaLIF's benefits or weaknesses when compared with current methods of interbody fusion. No conclusions can be drawn regarding AxiaLIF's use in patients with multilayer disc disease. Given the difficulty of the retroperitoneal approach, another systematic review performed by the National Institute for Health and Clinical Excellence (NICE) in 2011 concluded that though symptoms may be alleviated for some patients with the AxiaLIF procedure, it should only be carried out by surgeons with specialized training using this procedure.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this condition

CPT CODES

22586 Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes none graft when performed, L5-S1 interspace

22899 Unlisted procedure, spine

Axial Lumbar Interbody Fusion (AxiaLIF®), continued

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

BONE GROWTH STIMULATORS: ELECTRICAL

Policy # 107

Implementation Date:7/98

Review Dates: 2/01, 5/01, 5/20/02, 6/25/03, 6/24/04, 5/20/05, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/17/24

Revision Dates: 6/1/03, 6/24/04, 3/17/06, 3/11/08, 1/10/22, 4/3/23, 5/25/23, 12/27/23

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Approximately 5% of the 2 million long bone fractures that occur in the United States each year will not achieve union. Standard management of fractures includes stabilization of the fracture site by use of internal or external fixation devices, compression devices, and/or casting. In some cases, insufficient blood supply, inadequate immobilization at the fracture site, too large of a gap between ends of the fracture, infection, bone-tissue loss, poor nutrition, certain diseases, or metabolic problems can interfere with normal healing, resulting in delayed or nonunion of the fracture. Diagnosis of fracture nonunion is based on pain and motion at the fracture site and on findings using radiography (x-ray), fluoroscopy, intraosseous venography, technetium scintigraphy, or magnetic resonance imaging.

Treatment of nonunion generally consists of stabilization of the fracture site and induction of osteogenesis. Stabilization may be achieved with casting, or with internal or external fixation devices to realign and closely approximate fracture fragments. Osteogenesis (bone growth stimulators) may be induced and enhanced through use of bone grafting or by exposure of the fracture site to electrical, electromagnetic, or ultrasound energy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers electrical bone growth stimulators, *only when the following guidelines are met.*

1. Fractures of the long bones that have failed to heal ("nonunions") may be treated with either invasive or non-invasive electrical bone growth stimulators, when all the following criteria are met:
   a. The fracture was acquired secondary to trauma or surgery
   b. The fracture is predominantly of the shaft (diaphysis) of the long bone
   c. The fracture gap is 1 cm or less
   d. There is documented evidence of adequate fracture care (e.g., casting, immobilization, internal fixation)

Select Health

e. At least 3 months have passed since the date of fracture or the date of surgical treatment of the fracture

f. Serial radiographs for the preceding 3-month period show no signs of progression of healing

g. Provider has supplied a written interpretation stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs

h. The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing

2. Congenital (infantile) pseudoarthroses may be treated with non-invasive electrical bone growth stimulators, when all the following criteria are met:

   a. The fracture gap is 1 cm or less

   b. The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing

   c. There is documented evidence of more conservative medical care

3. Degenerative disease of the hip post-osteotomy may be treated with non-invasive electrical bone growth stimulators, when all the following criteria are met:

   a. The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing

   b. There is documented evidence of more conservative medical care

4. Spinal fusion, adjunct to fusion surgery: Either invasive or non-invasive methods of electrical bone growth stimulation may be considered medically necessary, at the time of spinal fusion surgery (or up to 6 months post-operative if there appears to be lack of progression of healing), for patients with any of the following risk factors for subsequent failed fusion:

   a. One or more previous failed spinal fusion(s)

   b. Fusion to be performed at more than 1 level

   c. Grade III or worse spondylolisthesis

   d. Current smoking habit

   e. Diabetes

   f. Renal disease

   g. Alcoholism

5. Spinal fusion, failed fusion: Non-invasive electrical bone stimulation may be considered medically necessary as a treatment of patients with failed spinal fusion. Failed spinal fusion is defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over the course of 3 months.
6. Non-spinal arthrodesis fusion: Failed fusion of a joint other than the spine when ≥ 3 months has elapsed since joint fusion was performed.

Contraindications (any of the following):

1. Implanted cardiac pacemaker or defibrillator close to the area of nonunion
2. Severe osteoporosis
3. Epiphyseal fractures (of a long bone)
4. Pregnancy
5. Presence of tumor(s), autoimmune, metabolic, or neoplastic diseases

6. Current use of systemic steroids (relative contraindication)
7. Unresolved synovial pseudoarthrosis
8. Necrotic (dead) bone or avascularity at the fracture site
9. The presence of infection or actively draining osteomyelitis with invasive stimulators

Investigational (not covered):

10. Nonunion fractures of scaphoid and other carpal bones
11. Nonunion fractures of "short," "flat," or "irregular" bones; unless stated otherwise
12. Semi-invasive stimulators

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The use of electrical bone growth stimulators to assist in the healing of fractures has become common practice. However, several issues continue to arise with the use of these bone growth stimulators. These issues include, when is the optimal timeframe shown in the medical literature to initiate therapy, and what fractures have been proven in the medical literature to respond to electrical bone growth stimulation. Additionally, the role of electrical bone growth stimulators in spinal surgery continues to evolve.

Regarding the appropriate timeframe for the application of electrical bone growth stimulators, post-long bone fracture, no direct evidence supporting a reduction was identified. However, the CMS National Coverage Analysis of Electrical Stimulation for Fracture Healing (#CAG-0042N) provides insight into the complexities surrounding this issue.

Time Frame Definition of Nonunion

Currently, the published literature is inconclusive with respect to a universally recognized timeframe definition for nonunion. Various timeframe definitions have been used to define nonunion. Campbell's Operative Orthopedics reports that: "The time when a given fracture should be united cannot be arbitrarily set" but notes that "a fracture of the shaft of a long bone should not be considered a nonunion until at least 6 months after injury because often union requires more time…" Adams and Hamblen states that: "In adults, the time usually required for consolidation of a fractured long bone, in favorable conditions, is about 3 months; though in many cases it extends to 4 or 5 months, especially in the case of a large bone such as a femur. Other sources describe nonunion as "a lack of healing at 6−8 months."

Orthologic submitted nearly 500 references gathered from a review of nonunion literature spanning the last three decades. This review included published articles, abstracts, presentations, and textbook citations regarding various nonunion definitions. From this review, it is clear that two different components are used to describe nonunion: 1) Time-referent descriptions that identify the time elapsed since injury, and/or 2) Radiographic accounts describing healing activity at the fracture site.

The Orthologic review stated that of the nonunion definition and descriptions included in their analysis, 36% of the articles cited identified a time equal to or less than 6 months post-fracture, 17% included

descriptions of nonunions between 6−9 months, and 47% described a time since injury of 9 months or greater as their criteria for union classification. Of the 91 articles that identified a definition for nonunion, 19% used a lack of radiographic progression in their definition, with a minimum of 3 months with no progression toward healing as criteria.

In 3 randomized double-blind clinical trials that have involved electrical stimulation for fracture healing, Parnell and Simonis supplied no definition for nonunion, Borsalino's study used patients 3 days post-intertrochantic osteotomy, and Sharrard's investigation determined nonunion by the presence of movement at the fracture site and radiologically by the presence of a fracture line. In an early case series by Bassett, all patients had to have had no change in the clinical and radiographic features of the nonunion for a minimum of 4 months. In this study, Bassett defined delayed union as occurring when: "… no clinical or radiographic evidence of union at 4-9 months after fracture." Nonunion was described as "a fracture that had not united by 9 months after the fracture." A retrospective case series published by Brighton et al. in *Clinical Orthopaedics and Related Research* stated that: "Diagnosis of nonunion was made radiographically when no progressive signs of healing of the callus were seen during a 3 month period."

Both EBI and Orthologic provided HCFA with unpublished patient registries which examined the "heal" rates of patients who had received electrical stimulation for various nonunions. This unpublished data indicated that success rates for patients with nonunions less than 6 months in duration were equal to, if not better, than those of patients who had nonunions older than 6 months. However, these registries do not equate to rigorously controlled scientific studies. The possible biases that exist in these types of registries make it difficult to make any statements about causality, and coverage NCDs cannot be based on these registries alone.

Further analysis by HCFA and discussions with the orthopedic community confirmed that there were no established criteria for determining when a fracture has reached a stage of nonunion. Most clinicians agreed that a strict timeframe limitation for considering nonunion was unreasonable given the differing nature of fracture patterns and existing patient comorbidities. Many agreed that the 6-month limitation appeared arbitrary and was not based on the limited research there has been to date.

Because clinical indications of nonunion such as motion, pain, and tenderness at the fracture site are subjective measures which are difficult to measure validly and reliably, it is evident that radiographic studies over a fixed time period are a better indication of nonunion. Repeated AP and lateral images showing no progressive healing in a fracture over a 3-month period has become the standard which most large commercial payers use to define nonunion. Coupled with clinical evidence gathered from patient interview and examination, this radiographic evidence can provide a clinical picture of nonunion which requires further intervention.

The second issue to address is what fracture types have been clinically proven to respond to electrical bone growth stimulation. Of note, is the issue of efficacy in the treatment of the so-called "short bones" of the appendicular skeleton. Following is CMS/Medicare's narrative about this issue.

<u>Electrical Stimulation for Nonunion Fractures in the Appendicular Skeleton Other Than Long Bone</u>

There is limited scientifically valid evidence to support electrical stimulation for fracture nonunions in bones of the appendicular skeleton other than the long bones. Both the Sharrard and Parnell randomized double-blind studies related to only tibial fractures, and Borsalino et al. examined only intertrochantic osteotomies.

Bassett et al. found an overall heal rate of 77% in 1,007 patients with ununited fractures. This case series involved patients from the US and international locations, with long bones representing 97% of the total ununited fractures treated (65% tibia). A follow-up study of a subset of these patients published in the Journal of Bone and Joint Surgery found a success rate of 87% in 125 patients with 127 tibial lesions. This study did not involve any fracture nonunions of other bones of the appendicular skeleton.

Another case series published by Dunn and Rush in the Southern Medical Journal investigating PEMF technology found a success rate of 81%, with union determined by examining x-rays taken at 6-week intervals to evaluate healing. This study examined 35 nonunion patients, with the tibia, femur, and humerus representing 83% of all nonunions. Nonunions of the carpal navicular, metacarpal, and proximal phalanx of the thumb were reported in only 5 patients.

Garland et al. published results from a prospective non-randomized trial using PEMF therapy in patients who had established nonunions that underwent a bone grafting procedure or internal fixation. Of the 181 subjects enrolled, 139 patients completed treatment (defined as use of a pulsed electromagnetic stimulation device for a minimum of 8 hours per day for 6 months or until union). Of these 139 patients, the success rates in 13 patients (14 fractures) of those patients who averaged less than 3 hours of daily device use was found to be statistically different from those patients who underwent the entire course of treatment. The authors concluded that this difference implied a dosage threshold and excluded these patients from further analysis. Of the remaining 126 patients (135 fractures), only 34 fractures were classified as non-long bone (scaphoid, metatarsal, ankle fusion, other fusion, and "other"). Although heal rates in these bones ranged from 60%−80%, these fractures represent only a small percentage of the total number of nonunions in this trial. Furthermore, the limited statistical analysis, no mention of intent to treat analysis on the dropouts, and no randomization or matching utilized in this study raises serious methodological questions.

Although Holmes provided an analysis comparing his study to others involving surgical intervention, the 9 Jones fractures with clinical and radiographic signs of delayed union and nonunion treated with PEMFs (resulting in a 100% heal rate) represent a very small sample size in an uncontrolled case series. Furthermore, of these 9 patients, 5 were classified as having delayed union.

Beckenbaugh provided results of a case series in *Orthopaedic Transactions* describing 24 patients with 24 established nonunions of the scaphoid treated with electrical stimulation and casting. In this series, 10 patients were treated in a short arm cast for a stimulation period of 2−9 months and 14 patients were treated in a long arm cast for a stimulation period of 4.5−6 months. Because the short arm casted group had an initial heal rate of less than 50%, a protocol change to a long arm cast for the remainder of treatment led to an eventual heal rate of 87% for the combined group. This was a short report without statistical analysis or any description of exclusion/exclusion criteria or patient characteristics.

Frykman et al. retrospectively reviewed 50 patients with nonunited scaphoid fractures treated with PEMFs from 1979−1984. Forty-four patients were included in the analysis, which showed a heal rate of 80%. The study provided good analysis of the failures and included follow-up to 33 months. However, patient selection and the possibilities of bias resulting from the uncontrolled nature of this review bring into question its validity.

Calandra et al. provide a good review of scaphoid fractures, but other than concluding that under certain conditions a scaphoid nonunion "may effectively be treated with pulsed electromagnetic stimulation combined with cast immobilization," this article provided little comment or review about electrical stimulation for fracture healing in the rest of the appendicular skeleton.

Both EBI and Orthologic included unpublished patient registry data in their requests to HCFA. Although these registries were reviewed by HCFA staff as part of the overall analysis, this type of data alone is generally not adequate for us to use to make coverage NCDs. The possibilities for biases in these uncontrolled registries make it difficult to make any statements about causality, and therefore, they cannot be relied upon to provide valid scientific data.

We recognize that it is difficult to perform controlled, prospective, randomized, double-blind studies of electrical stimulation vs. surgery or other treatment modalities. Given this limitation, we carefully considered the studies presented, along with information gathered from the clinical community, in examining this issue. However, the quality and quantity of the evidence cited above is not enough for us to make a positive determination on expanding coverage of electrical bone growth stimulators to nonunions, other than for long bones. Furthermore, because of the paucity of studies surrounding this therapy and its current application, the current policy restricting coverage of this device to only those indications outlined in the CIM is necessary for protecting the integrity of the Medicare program and ensuring that its beneficiaries receive the most appropriate care.

HCFA's analysis suggests that maintaining the current coverage limitation of electrical bone growth stimulators to long bones while shortening the time frame definition of nonunion is a reasonable and necessary action.

In conclusion, the panel recommended the removal of the "9 month" clinical study timeframe from the definition of nonunion in bone growth stimulator labeling. After this recommendation, the FDA has granted approval to several bone growth stimulator manufacturers to change the labeling of their devices to read

"nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing." This change resulted from general agreement among panel members that the timeframe definition for nonunion differed clinically from that of the original FDA document. According to FDA personnel, the original timeframe definition was essentially determined based on the need in clinical trials for patients to act as their own controls, and current clinical applications of this timeframe were inappropriate.

Finally, the issue of electrical bone stimulation as an adjunct to spinal surgery has not been addressed directly by CMS/Medicare. Available systematic reviews are inconsistent in their conclusions (see below), reflecting the variable results seen in even the controlled trials, including animal studies. The weight of current evidence about radiographic and histologic fusion-related outcomes, however, points to improvements in these outcomes. Direct patient ("clinical") outcomes, are "all over the board." In fact, many of the studies did not even attempt to measure clinical outcomes. Consequently, those outcomes that, arguably, best reflect patients' concerns (outcomes) remain in question. Following are summaries of available systematic reviews.

Hayes, Inc., in its 2 reviews of electrical bone growth stimulation in 2001; i.e., invasive and non-invasive, rated all spinal indications as either 'C' or 'D.' Most notably, electrical bone growth stimulation as an adjunct to spinal fusion for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for patients undergoing multilevel fusion was rated a 'C.' A 'D' rating was given for other factors generally considered to substantially increase risk of pseudoarthrosis (i.e., patients with spondylitis, infection, Paget's disease, cancer, diabetes mellitus, renal disease, or osteoporosis; patients lacking skeletal maturity; pregnant patients; and patients with certain types of pacemakers or implantable defibrillators).

The technology assessment done by AHCPR (Hotta SS) in 1994 on "Electrical Bone Growth Stimulation and Spinal Fusion" indicates that improved surgical technique may obviate the need for using electrical stimulators. On the other hand, an implantable bone-growth stimulator may be a useful adjunct that could enhance the probability of fusion success in patients who have had previous fusion failure or need extensive bone grafting for multiple-level fusion. The only controlled study that gave data on patients identified with specific high-risk criteria showed that direct-current stimulation appeared to influence spinal fusion only in patients with 2 of the 4 entry criteria for high risk. However, overall, there are insufficient data available at the present time to include high-risk patients (e.g., severe spondylolisthesis, obesity, smokers) among those who may benefit from electrical stimulation.

The technology assessment by ECRI states that invasive, direct-current electrical bone growth stimulation appears to promote bony healing in conjunction with spinal fusions, yielding 81%−93% fusion rate compared to control case rates of 54%−67%. The differences appear to be most pronounced among patients who did not have fixation. In a blind, controlled study, PEMF noninvasive stimulators appear to yield comparable healing rates (92%) with invasive units. The effectiveness of invasive and noninvasive stimulation for treating failed spinal fusions ranges from 77%−87% in uncontrolled studies. However, blind, controlled studies, using placebo stimulators, are needed to determine their effectiveness for failed spinal fusion cases.

BCBS TEC performed a review in September 1993 in which electrical bone growth stimulation as an adjunct to spinal fusion surgery among patients at high risk for pseudoarthrosis met the BCBS TEC evaluation criteria. High-risk factors included previous failed fusion, multi-level fusion, grade II or worse spondylolisthesis, current smoking habit, diabetes, and renal disease.

Virtually all the early studies performed fusions without instrumentation, thus, the results may or may not be applicable to current fusion methods, which virtually all use instrumentation (e.g., cages, screws); apparently introduced in the U.S. in the early 1990s.

A review article was published in the *Journal of the American Academy of Orthopaedic Surgeons*) with the following summary: "Although many studies of the use of electrical stimulation to enhance spinal fusion have shown promising results, they exhibit numerous limitations, including poor patient randomization, retrospective design, and, for some of them, financial support from device manufacturers. The most crucial limitation is the lack of an accurate means of assessing the presence of solid fusion. Radiographic criteria used to demonstrate fusion are inconsistent; thus, any reported success achieved by the electrical stimulators graded by radiographic criteria must be cautiously interpreted. Also, no direct comparisons of the 3 techniques have been made. As a result, the benefits and limitations of each must

be weighed to determine appropriate indications and methodology. Future research should provide further insight into the specific mechanisms by which electrical stimulation results in bone growth and thereby lead to further advances in these techniques."

The issue of use of electrical stimulators for spinal fusion is less clear. The best evidence supporting electrical bone growth stimulation for fusion appears to be in the use of invasive stimulators in patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for patients undergoing multilevel fusion (i.e., extensive grafting). Evidence of the effectiveness of electrical stimulation for other high-risk patients is mixed; perhaps confounded by the large variation in outcomes due to surgical methods/technique and in measurement of outcomes. There is at least one controlled trial demonstrating approximate equivalence between invasive stimulators and non-invasive PEMF and CC stimulators; however, compliance with the non-invasive stimulators seems to be problematic even during highly structured clinical trials.

A Hayes review performed in September 2011 identified 1 systematic review and 1 multi-center randomized trial. The trial was focused on low-intensity pulsed ultrasound and was not applicable. The systematic review, from the Cochrane Database reviewed electromagnetic field stimulation for the treatment of non-union in long bones. Four studies, involving 125 participants were identified with delayed union and non-union of the long bones was included, but most data related to non-union of the tibia. The overall pooled effect size was small and not statistically significant (risk ratio 1.96; 95% confidence interval 0.86 to 4.48; 4 trials). There was substantial clinical and statistical heterogeneity in this pooled analysis (I(2) = 58%). A sensitivity analysis conducted to determine the effect of multiple follow-up time-points on the heterogeneity amongst the studies showed that the effect size remained non-significant at 24 weeks (risk ratio 1.61; 95% confidence interval 0.74 to 3.54; 3 trials), with similar heterogeneity (I(2) = 57%).There was no reduction in pain found in 2 trials. No study reported functional outcome measures. One trial reported 2 minor complications resulting from treatment. The authors concluded that though the available evidence suggests that electromagnetic field stimulation may offer some benefit in the treatment of delayed union and non-union of long bone fractures, it is inconclusive and insufficient to inform current practice. More definitive conclusions on treatment effect await further well-conducted randomized controlled trials.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

20974	Electrical stimulation to aid bone healing; non-invasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS CODES

E0747	Osteogenesis stimulator, electrical noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Key References

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Select Health

MEDICAL POLICY

COMPUTER-ASSISTED ORTHOPEDIC SURGERIES

Policy # 277
Implementation Date:8/10/05
Review Dates: 8/17/06, 12/20/07, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/20/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/17/24
Revision Dates: 12/12/06, 8/11/08, 8/13/09, 11/30/17, 2/2/24

Related Medical Policies:
#431 Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental)
#579 Ligament-Sparing Knee Replacement Surgery
#506 Joint Replacements Using Makoplasty
#598 Total Knee Arthroplasty
#599 Total Hip Arthroplasty

Description

Total hip and knee replacement are among the most common and successful orthopedic operations. The indications for joint replacement are well-established and the quality of patient outcomes is well-documented. Pain relief, increased joint motion, improved joint function, and durability are predictably achieved in most patients. Surgical goals are accomplished using techniques that mechanically or visually reference anatomical landmarks to reconstruct the damaged joint. Computer-assisted orthopedic surgery (CAOS) is designed to either compliment or add information during joint replacement surgery.

CAOS is surgical technology that assists surgeons through creation and display of images showing the replacement components in their relationships to the bones and ligaments of the joint being replaced. CAOS is also called Imaged Guided Surgery or Surgical Navigation. CAOS has 2 basic components:

1. A special camera designed to see the surgical joint and limb and create a picture or image of the hip or knee
2. Computer programs which integrate these images with surgical information and assist the surgeon during the operation

CAOS can use actual images of the joint (x-rays/fluoroscopic, ultrasound, or CT images) or can create virtual images of the damaged joint. The camera and computer are given information by the surgeon about the normal and abnormal anatomic landmarks of the joint and limb. This information can be transmitted in several ways. Some CAOS systems use special cameras to identify and record the position of photo reflective spheres or infrared light emitting devices. Some other systems use ultrasonic devises to identify bony landmarks. The surgeon uses the computer-generated information and images to reconstruct, accurately and reproducibly, the damaged joint and limb.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover computer-assisted guidance/navigation systems for orthopedic procedures of the pelvis and appendicular skeleton, as the medical literature is inadequate to determine the efficacy of this technology. This therapy meets the plan's definition of experimental/investigational.

Select Health does *NOT provide additional reimbursement* for computer-assisted guidance/navigation systems for orthopedic procedures of the pelvis and appendicular skeleton. This is considered part of the primary procedure and would not be subject to additional reimbursement on the part of the surgeon or the facility.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A 2005 M-Tech review found the literature to be, limited-to-small, and primarily prospective studies measuring whether use of computer assisted techniques improve knee alignment over conventional techniques. “Improved alignment” remains the primary focus of the literature identified for this update. As with the earlier report, the recent literature, including several randomized controlled trials, consistently demonstrates that use of computer navigation for total knee arthroplasty (TKA) improves alignment postoperatively compared to conventional techniques.

However, the clinical significance of improved alignment remains unknown. There continues to be a dearth of published literature describing clinical endpoints of importance to patients and third-party payers namely, pain, mobility, knee revisions, and other complications. A few studies have begun to examine potential clinical advantages of computer assistance. In Kalairajah et al., 60 patients were randomly assigned to either computer-assisted or standard knee arthroplasty. Mean blood loss in the computer-assisted group was significantly lower at 1351 ml than with the standard group at 1747 ml. The authors estimated that computer-assistance with all patients in the study would have reduced the mean transfusion requirement from 2.1 units to 1.2 units per arthroplasty. A 2006 study by Kalairajah et al. of 24 patients randomly assigned to standard (n = 10) or computer-assisted (n = 14) arthroplasty measured the presence of post-surgical emboli. Post-surgery, computer-assisted patients had an average of 0.64 ± 0.74 emboli (range = 0-2) vs. an average of 10.7 ± 13.5 emboli (range = 1-43) in the standard group. The source of the emboli could not be determined by transcranial Doppler. The patients did not differ on a mental test score given at one and three days after surgery. The authors speculated that use of intramedullary rods in standard surgery led to the higher rate of systemic emboli.

A 2-year follow-up by Luring et al. of 80 patients who underwent computer-assisted knee arthroplasty reported that pain, stiffness, and functioning were the same for patients regardless of type of bearing platform used. Without baseline values or a comparative control group, however, the significance of these outcomes cannot be evaluated. At a 3-month follow-up by Decking et al. of patients randomly assigned to standard (n = 25) and computer-assisted (n = 27) surgeries, there was no significant difference between the 2 groups in terms of surgical complications, range of motion, pain, stiffness, or functioning. In an abstract from the International Society for Computer Assisted Orthopaedic Surgery 2005 Annual Meeting, Swank describes clinical outcomes from 30 patients who underwent computer-assisted and 20 cases that underwent standard minimally invasive knee arthroplasty. The abstract does not indicate whether these were randomly assigned to surgical groups. The computer-assisted group required fewer intraoperative or postoperative blood transfusions (0%) than did the standard group (15%). Moreover, 90% of computer-assisted patients were discharged to home, whereas 50% of standard surgery patients required skilled nursing after care either in a SNF or in a hospital-based program after surgery. The computer-assisted

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group had a 10% complication rate versus 15% for the standard group. Finally, Anderson et al. found no difference in postoperative blood loss (103 mL vs. 105 mL), length of stay, or range of motion at 2 weeks, 2 months, 3 months, or 6 months in 142 patients who underwent computer-assisted knee arthroplasty and 61 matched standard surgery controls.

In 2007, Ecker et al. published results of clinical trials suggesting the application of surgical navigation to hip arthroplasty improves the surgeon's ability to place components more reliably and with improved consistency. In a prospective case series, 344 THA were performed with CT-based surgical navigation. Following surgery radiographs were obtained including anterior-posterior (AP) pelvis, AP-hip, lateral and false profile views. Acetabular cup abduction was calculated and compared to the abduction measurement by navigation. Leg-length was compared by obtaining pre- and postoperative radiographs, and compared to change, measured by navigation. Guided by the navigation system, cups were placed 40.8° ± 2° of operative abduction and 30.8° ± 3.2° of operative anteversion. The authors reported that 97.1% measured radiographically and 99.1% calculated radiographically were inside the safe zone regarding abduction, and 92.4% of the cups were placed in the safe zone regarding anteversion. Leg length change measured intraoperatively was 6.6° ± 4.1 mm and was similar to radiograph measurements Computer navigation increased the consistency of component placement and allowed reliable measurement of leg-length change during surgery.

Additionally, in 2008, Gandhi et al. conducted a systematic review and meta-analysis evaluating whether navigation increased the precision of acetabular components. The authors reviewed 3 randomized controlled trials involving 250 patients that met the inclusion criteria. The results of the meta-analysis indicate that computer navigation improved the surgeon's ability to place the acetabular cup within the desired alignment, although it was unclear if improved alignment would translate into improved long-term clinical outcomes. The authors noted that additional well-designed randomized controlled trials are needed to clearly establish clinical and radiographic outcome parameters, complications, survival rates, quality of life, years gained, and cost analyses.

Like hip and knee arthroplasty, success of shoulder arthroplasty also depends on technique. Incorrect component alignment can lead to loosening, instability, and sub-optimal function of the joint. Computer navigation has been employed to determine if systems similar to those used in hip and knee surgery are safe and effective for use during shoulder arthroplasty. There are few published clinical studies in the medical literature evaluating computer-aided shoulder navigation and limited published articles. A single published study by Edwards et al. consisted of a cadaver and an initial cohort of shoulder arthroplasty patients (n = 27). Preliminary results have shown the technique is safe and may enhance correction of deformity. While preliminary results are encouraging, the evidence is insufficient to support conclusions regarding improved clinical health outcomes and further studies are warranted.

In summary, while the literature supports improved results through computer-assistance, there are insufficient data to conclude that such improvements would result in better clinical outcomes. The limited data from a few small study samples suggest that there is no improvement in functioning, pain, and range of motion when computer-assistance is used. While discharge to home can certainly be considered an important clinical outcome, the apparent lack of random selection and assignment, small sample size, and the lack of validation from any other literature source, raise questions about the reliability of these findings.

In July 2009, the Medical Technology Committee reviewed the technology to include the hip as well as the knee. Since the 2008 M-Tech review, several systematic reviews were to have been completed related to this topic. All concluded that computer-assisted surgery (CAS) offers improved placement of prostheses but data on clinical outcomes are limited and inconsistent. A 2008 Hayes' review on imageless CAS TKA gave a 'C' rating to the procedure. This rating reflected Hayes' conclusion of limited and inconsistent evidence of improved clinical outcomes with computerized surgery. The review also cited a lack of clear patient selection criteria as a limitation of this procedure. Blue Cross Blue Shield TEC also reviewed CAS TKA in 2008, concluding that the evidence is not sufficient to conclude that the improvement in alignment associated with computer-assisted navigation leads to meaningful differences in health outcomes, such as pain, function, and revision surgery. A 2007 review from the Danish Centre for Health Technology Assessment also evaluated CAS TKA, noting that a clear connection between a more precisely placed prosthesis and an improved early range of movement has not been established. A 2007 meta-analysis by Mason et al. concluded that CAS offers significant improvement in component

orientation and mechanical axis over conventional techniques. The study did not evaluate clinical outcomes.

In another review by Brophy et al. (2007), on behalf of 2 teaching hospitals in Quebec, Canada, noted that studies showed a small average difference of about 1° between conventional and CAS techniques for TKA, with wider variation of malalignment with the conventional techniques. The authors concluded that CAS may improve alignment by the avoidance of the occurrence of outliers as these are observed more frequently with the conventional technique than with the computer-assisted device. The authors concluded that there is no convincing evidence that demonstrates improved clinical outcomes with the computer-assisted navigation systems in total knee replacement surgery. However, expert opinion believes that this technology is likely to decrease malalignment in some patients. For this reason, it is recommended that funding for a limited number of cases (Max. 40) annually should be approved for use in patients at the highest risk of malalignment. The specific patient types to consider, however, were not established.

In the one systematic review specific to CAS for THA, a 2004 Ontario Heath Technology Assessment found one, Level 2 evidence (i.e., small randomized controlled trial) short-term study found no statistically significant difference in the variation of the abduction angle between navigation-assisted and conventional total hip arthroplasty.

In addition to the systematic reviews, 56 studies met criteria for inclusion in this report. As with the earlier report, the recent literature on TKA continues to demonstrate that use of CAS for TKA improves alignment postoperatively compared to conventional techniques. Indeed, computerized assistance appears to reduce the number of cases with final mechanical axes greater than 3° with the implication that this may lead to a reduction in early device failures. Likewise, computer assistance can improve cup positioning in total hip arthroplasty.

Studies reporting clinical outcomes remain sparse. Studies examining outcomes often used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a 24-item questionnaire focusing on joint pain, stiffness, and loss of function related to osteoarthritis of the knee and hip. Some studies also used the Knee Society rating system (KSS), which evaluates outcomes of TKA and consists of a Knee Score and a Function Score; these 2 scores, rather than one summation score, are usually reported for the KSS. The Hospital for Special Surgery (HSS) rating system is an instrument evaluating various measures of knee function. The Oxford Knee Score consists of 12 questions related to knee function and activities of daily living. Each question is answered on a scale from 1−5, 5 being the worst outcome. The Bartlett Patellar score is composed of four subcategories assessing anterior knee pain, quadriceps strength, ability to rise from a chair and to climb stairs; the maximum score is 30.

Biasca et al. reported on 40 consecutive patients who underwent minimally invasive CAS TKA or conventional CAS TKA. The minimally invasive group experienced shorter duration of hospital stay and range of motion at 3 months; after 6 months differences were minimal. Clinical outcome scores (KSS) were identical for both groups 6 months after surgery. Operating time and blood loss were similar in both groups. Comparisons with traditional TKA were not done. Bonutti et al. reported on outcomes of TKA alone relative to a group treated by computerized TKA. The 2 groups did not differ in mean estimated blood loss, mean pain scores, and functional scores in a matched-control retrospective study by Ek et al. Two groups of 50 patients underwent conventional or computer-assisted TKA. The computer-assisted group experienced better SF-12 and International Knee Society scores. Ensini et al. randomly assigned patients to conventional or computer-assisted TKA. Though the computer group had better alignment postoperatively, this radiographic improvement did not necessarily result in a better clinical outcome at 28 months follow-up. Additionally, Kim et al. did not report any difference in range of motion at 2 years in 100 patients randomly assigned to conventional and CAS TKA. Matziolis found the same results in 60 TKAs randomly assigned to CAS or conventional surgery. Martin et al. reported on 200 patients randomly assigned to CAS or conventional surgery and found that the Insall score, anterior knee pain, feeling of instability, and the step test did not differ between groups.

Adding to the above findings, studies by Spencer and Luring failed to demonstrate improved clinical outcomes with the use of CAS technology. Spencer et al. reported no difference in the frequency of mild-to-severe anterior pain, Bartlett Patellar score, or the Oxford knee score at 2 years postoperatively in 71 patients randomly assigned to conventional or CAS TKA. Whereas, Luring et al. randomly assigned patients to conventional TKA (n = 30), a minimally invasive (MIS) group (n = 30), or a computer assisted -

MIS group (n = 30). At follow-up, Knee Society and WOMAC Score were similar in all 3 groups after 1, 6, and 12 weeks, no significant differences were seen between groups at any point of time. Similarly, studies by Seon and Molfetta found no change in clinical outcomes for CAS assisted TKA for patients followed from 12 months (Seon) to 5 years (Molfetta). Seon et al. evaluated functional outcomes 3, 6, and 9 months, and 1 year postoperatively in 42 patients who underwent bilateral TKA using conventional TKA on one leg and minimally invasive CAS TKA on the other. At 6 months, CAS yielded better HSS and WOMAC total scores conventional surgery and a better WOMAC pain score up to 9 months. At 1 year, these differences were not significant. ROM was comparable in both groups throughout. Patients preferred the CAS side to the conventional side. Radiological results showed no differences in mean values between the 2 surgical groups, though the CAS group contained fewer outliers. Molfetta et al. reported a 5-year follow up comparing CAS and conventional TKA using case control matching. At follow-up, there was no statistical difference between the two groups in knee function or range of motion.

Saragella et al. reported the longest period of follow-up, an 8−10-year evaluation of 26 CAS TKA surgeries. Two of these were revised prior to the follow-up period and 4 patients were lost to follow-up. Of the 20 remaining cases, the mean alignment angle was 179.2° ± 1.67° (range, 176°- 185°), with 92.3% of the knees aligned between 177° and 183°. In 9 patients who underwent radiographic examination at follow-up, there was no evidence of loosening of the implants. Two tibial plateaus showed an obvious wear (2−3 mm). Seventeen (85%) patients reported being satisfied or very satisfied with their prosthesis.

Only one study examined the cost-effectiveness of CAS for TKA. The study assumed an incremental cost of $1,500 more for CAS TKA and a 14% improvement in coronal alignment precision, and cumulative incidence of revision of 0.54 at 15 years with coronal malalignment. The incremental of CAS is $45,554 per quality-adjusted life-year gained.

No studies on THA reported clinical outcomes.

In summary, while the literature supports improved knee alignment and acetabular cup placement through computer-assistance, there are insufficient data to conclude that such improvements would result in better clinical outcomes. The data for TKA are inconsistent but tend to show little difference in functional outcomes in the years following surgery. No clinical outcome data are available for THA. The primary rationale for using CAS, therefore, would be to reduce revision rates. However, long-term studies are not yet published. Also, the primary method for improving alignment for both procedures is by eliminating outliers, i.e., arthroplasties in which the outcome alignment is significantly different from that observed with most patients. This suggests that for most patients, CAS would have little impact on improving alignment and reducing risk for revision, further highlighting the need for patient selection criteria to identify individuals at greatest risk for misalignment. In conclusion, while the literature supports a consistent improvement in the technical performance of TKA and THA, when using CAS, there is little evidence to support that this procedure would offer any meaningful improvement in outcomes over time.

Billing/Coding Information

CPT CODES

Not covered: Investigational/Experimental/Unproven for this indication

0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

Computer-Assisted Orthopedic Surgeries, continued

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MEDICAL POLICY

CORE DECOMPRESSION FOR AVASCULAR NECROSIS

Policy # 523
Implementation Date:5/20/13
Review Dates: 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/17/24
Revision Dates:

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Osteonecrosis, also known as aseptic necrosis, avascular necrosis (AVN), atraumatic necrosis, and ischemic necrosis, is a pathologic process that has been associated in patients in whom there is direct damage to blood vessels feeding the bone (e.g., femoral neck fracture) or direct injury of bone or marrow elements (e.g., radiation injury, dysbarism, or caisson disease); the cause is clearly identifiable. However, in many patients, the mechanisms by which this disorder develops are not fully understood. Compromise of the bone vasculature, leading to the death of bone and marrow cells (bone marrow infarction), and ultimate mechanical failure appear to be common to most proposed etiologies. The process is most often progressive, resulting in joint destruction within a few months to two years in most patients.

The exact prevalence of osteonecrosis is unknown. In the United States, there are an estimated 10,000 to 20,000 patients newly diagnosed each year. Osteonecrosis is the underlying diagnosis in approximately 10 percent of all total hip replacements. The male-to-female ratio varies depending upon the associated comorbidities. The mean age at diagnosis also depends upon comorbidities but is typically less than 40 years.

The optimal treatment for osteonecrosis has not been determined. The treatment also depends upon the region affected. For non-traumatic AVN, the disease is often bilateral, which further increases the extent of disability. Various approaches have been employed for treating different stages of AVN of the hip. Non-operative treatments include rest, non-weight-bearing exercises, protected weight-bearing, pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs and bisphosphonate medications such as alendronate or residronate), and electrical stimulation. Operative treatments include fusion, osteotomy, hemi-resurfacing, hemi-arthroplasty, debridement and grafting, core decompression with or without grafting, as well as total hip arthroplasty.

Core decompression of the hip is usually employed before collapse and fracture of the femoral head and/or neck to delay or avoid reconstructive surgery of the affected joint. It is generally carried out to preserve the function and the structure of the hip as well as to relieve pain associated with AVN. Core decompression entails repair of the necrotic site by coring, followed by filling the cored area with a bone graft, which is optional. A lateral trochanteric approach is used in this procedure: an 8-mm to 10-mm cylindrical core of bone is removed from the antero-lateral segment of the femoral head, which creates an open cylindrical channel; this open channel serves to relieve pressure. The open channel may be filled with either a vascularized or a non-vascularized bone graft. The former is used to aid in the ingrowth of vascular cellular tissue into the necrotic area; thus, enhancing re-vascularization. This may arrest the progression of the necrosis. The latter is used to provide structural stability to the hip during the healing process.

Select Health

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers core decompression of the hip as proven for the treatment of early (pre-collapse stage I and II)* avascular necrosis of the femoral head.

Select Health DOES NOT cover core decompression as it is unproven for the treatment of late avascular necrosis of the femoral head or for avascular necrosis elsewhere. This also includes the humeral head, the distal femur, the talus, or the mandibular condyle as investigational. The quality and quantity of the evidence for core decompression for these conditions is limited and insufficient. There is insufficient data to allow conclusions regarding the safety and efficacy of core decompression in these patient populations.

*Ficat classification of avascular necrosis

Stage	Name	Clinical features	Radiography
Early			
0	Preclinical		
I	Preradiographic	+	
II		+	Osteoporosis, sclerosis, cysts
Transition			Flattening and crescent sign
Late			
III	Collapse	++	Irregular contour of head, sequestrum, normal joint space
IV	Osteoarthritis	+++	Flattened femoral head, narrowed joint space; collapse of head (see image)

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Core Decompression of the Femoral Head (Hip)

The majority of published literature is focused on core decompression for hip avascular necrosis (AVN). In a systematic review conducted in 2009 to compare the effect of surgical treatment to non-surgical treatment of avascular necrosis (AVN) in individuals with sickle cell disease (SCD), only 1 trial was identified involving core decompression. This trial included 46 participants, eight of whom withdrew after randomization, as they declined to participate in the trial. The remaining 38 patients were randomized to receive either hip core decompression and physical therapy, or physical therapy alone. After a mean follow-up of 3 years, the surgical group showed no clinical improvement compared to the non-surgical

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group. The author's concluded that the addition of core decompression to physical therapy did not improve outcomes for patients with SCD and AVN. Additional studies, preferably randomized controlled trials, are necessary to evaluate the role of hip-core depression in patients with SCD.

In another trial from 2007, other investigators identified osteonecrosis of the femoral head eventually led to its destruction if it remains untreated. This study noted, depending on the location and the extent of the osteonecrosis, several surgical options are available. For early small and medium-sized pre-collapse lesions, core decompression was identified as the treatment of choice.

Two studies calculated Kaplan-Meier survivorship curves, which consider the follow-up time for each hip. In the first study, 37 hips and compared Kaplan-Meier curves were compared between hips of 37 patients at stage I or pre-cystic stage IIA, with hips in all other more advanced stages (cystic IIA, IIB, IIC, and III). This study found a statistically significant difference, with survival of 166 months for the first group and 57 months for the second. The second study, (n=94 hips) demonstrated Kaplan-Meier probabilities of joint survival of 84% at 4 years and 78% at 6 years for patients with hips at stage I or II, excluding patients who had a history of corticosteroid use because it was shown to be predictive of failure. Those probabilities dropped to 63% at 4 years and 56% at 6 years for patients with hips at stage III, IV, or V.

A few studies afford some evidence that, within a given stage, larger lesions and lesions in a central or lateral, as opposed to a medial position, are less likely to be treated successfully with core decompression. These studies found that hips in the pre-cystic phase of stage II were dramatically more likely to survive than hips with stage II lesions that were cystic or sclerocystic. They also noted patients treated with core decompression (94 hips) were 67% more likely than patients treated with osteotomy (83 hips) to require subsequent total hip replacement over a mean follow-up of 9 years, although the relative risk calculation was not significant. This may not be a useful comparison for a number of reasons. As the authors acknowledge, osteotomy patients may be more likely to postpone further surgery, having already endured the morbidity associated with a more complicated procedure. Another bias potentially in favor of the osteotomy results was that about half of the patients treated with osteotomy also had a core decompression procedure, although the authors do report that the relative risk of failure did not differ significantly between patients treated only with osteotomy and those who received the double procedure. Furthermore, core decompression is not generally considered to be an alternative to osteotomy, or partial joint arthroplasty; rather, it is intended to delay both osteotomy and complete arthroplasty.

Further evidence supporting core decompression in the treatment of hip AVN looked at the effect of core decompression combined with an allogeneic, antigen-extracted, autolyzed fibular allograft and autologous impacted bone grafting on hip survival outcomes. The study included 162 patients (223 hips; 61 females, 101 males; mean age 33.5 years, range 19–54 years) with stage II–III avascular necrosis of the femoral head. The outcome was determined by changes in the Harris hip score, by progression in radiographic stages, and by the need for hip replacement. The mean follow-up was 24 months. Excellent and good results were obtained in 93.3% of cases in stage II, and 87% in stages III, with a survivorship of 81% in all cases. According to the authors, core decompression combined with an allogeneic, antigen-extracted, autolyzed fibular allograft, and autologous impacted bone grafting, may be the treatment of choice, particularly in the pre-collapse stage.

Although the majority of the studies have a weak study design with a lack of controlled comparisons and small sample sizes, results were consistent and support the conclusions of earlier research: core decompression is safe and may result in prevention or deferral of partial or complete arthroplasty if performed in hips with avascular necrosis (AVN) at stage I or II, with a substantially higher likelihood of success at stage I. Joint survival rates for hips at stage I were quite high (92% to 100%). In all studies, joint survival declined with increasing baseline disease stage.

Core Decompression in the Shoulder, Knee, and Ankle

While available evidence indicates that core decompression is effective in treating early stages of AVN of the hip, there is currently insufficient evidence that this procedure is effective in treating AVN of the knee, ankle, and shoulder. The following sections outline the limit to current available evidence.

Humeral Head (Shoulder)

Studies of core decompression of the humeral head are particularly limited in their size and are primarily composed of single arm cohort studies. In one small 2009 study to evaluate humeral head core decompression involving percutaneous perforations of the shoulder, arthroplasty was avoided in all 15 patients (26 shoulders) for a mean follow-up of 32 months. Of the 26 shoulders, 25 had successful clinical

and functional outcomes, and 1 showed radiographic progression of the disease, but has not needed further operative treatment. Decompression results were compared with those of a nonoperative historical control group, identified through a literature search. There was a 48% (143/299) rate of progression to arthroplasty in the control group at a follow-up ranging from 2 to 4.5 years. According to the authors, percutaneous decompression appears to be a low-morbidity method for relieving symptoms and deferring shoulder arthroplasty in patients with symptomatic osteonecrosis of the humeral head. This study is limited by lack of randomization, and small sample size. Another small (n=46 patients, 67 shoulders), retrospective, uncontrolled study, provided weak but positive evidence of the long-term effectiveness of core decompression in delaying secondary surgery for avascular necrosis (AVN) of the humeral head, not only in the pre-collapse stages but also in stage III. Joint survival rates for stages I, II, III, and IV were 94%, 88%, 70%, and 14%, respectively, after a mean follow-up of 10 years. However, other investigators identified that because the glenoid is shallower and less conforming than the acetabulum and the shoulder is not a weight-bearing joint, deterioration of shoulder function may not occur until advanced stages of AVN. They postulated that core decompression for stage III or even stage IV AVN may be more appropriate for the shoulder than for the hip.

Overall, the evidence is weak and limited, and still developing for use of core decompression in shoulder/humeral head AVN.

Femoral Condyle or Distal Femur (Knee)
The knee is the second most common location for osteonecrosis with about a 10% incidence of the disease in the hip. Similar to core decompression of the shoulder, this literature is limited by significant methodological weaknesses. One retrospective, uncontrolled study (n=248 knees), provided weak but positive evidence of the long-term effectiveness of core decompression in delaying secondary surgery in the early stages of avascular necrosis (AVN) of the femoral condyle. A second core decompression procedure was performed in 16% of patients; the criteria for repeat core decompression were not reported. Only 7 knees were at stage III at the time of diagnosis. The overall survival rate for knees included in the 2000 report (stages I through III) was 79%, based on a mean of 7 years of follow-up (minimum of 2 years). Comparability of these results with those of future studies may be limited. First, patients were selected for core decompression only after 3 months of conservative treatment failed to relieve symptoms. This is a reasonable selection process but not one reported by other authors. Results from core decompression might have been more favorable in patients whose symptoms had not already been shown to be unresponsive to conservative treatment. Secondly, 16% of patients had two, rather than one, core decompression procedures for AVN in the knee, which may have inflated results.

Talus (Ankle)
Only 2 studies were identified which evaluated core decompression of the talus. The first study from 1998 was a retrospective analysis of 32 ankles. It provides weak but positive evidence of effectiveness in treating avascular necrosis (AVN) of the talus. The rate of joint survival over a mean follow-up period of 7.3 years was 91%. Five ankles were at stage III AVN at the time of diagnosis; the remainder were at stage II. As in the knee studies, comparability with future studies is limited because core decompression was performed only in patients who had not responded to conservative treatment. However, because AVN in the talus appears to be rare, the authors had to start the time frame for their retrospective review in 1974, which may make it difficult to study this condition.

In the second study from 2010 a non-randomized study was performed to examine the results of percutaneous drilling to treat osteonecrosis of the ankle in 31 patients (44 ankles). At a mean follow-up duration of 45 +/- 12 months, 40 (91%) ankles had achieved a successful clinical outcome. There were no perioperative complications, although 3 ankles subsequently collapsed and required arthrodesis. According to the authors, the percutaneous drilling technique appears to be a useful method for the relief of symptomatic ankle osteonecrosis. This study is limited by lack of randomization, control, and small sample size.

The lack of high-quality studies limits any conclusion regarding the effectiveness of core decompression on ankle AVN.

Mandibular Condyle
Similar to all other areas other than hip, mandibular condyle core decompression has few published studies. The only study identified for this review was published in 1995. In 8 of 9 patients (16 joints) with histologically confirmed osteonecrosis of the mandible, core decompression resulted in substantial pain

reduction over a mean follow-up period of 34 months. In a second group of 8 patients (15 joints) with more severe lesions, core decompression with bone grafting resulted in significant clinical improvement in 11 joints during the follow-up period (mean 28 months). This single study, though promising, does not allow conclusion regarding the safety and efficacy nor the long-term outcomes for core decompression of the mandibular condyle.

Billing/Coding Information

CPT CODES

No specific CPT code for core decompression procedures

27299	Unlisted procedure, pelvis or hip joint
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
29999	Unlisted procedure, arthoscopy

HCPCS CODES

S2325	Hip core decompression

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Core Decompression for Avascular Necrosis, continued

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MEDICAL POLICY

CRYOANALGESIA USING THE IOVERA SYSTEM FOR KNEE PAIN

Policy # 632
Implementation Date:6/18/19
Review Dates: 1/11/22, 2/16/23, 3/3/24, 2/15/25
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The Myoscience iovera system is intended to target peripheral sensory nerves with extremely cold temperatures to ablate nerves and temporarily provide pain relief. The iovera system is a handheld device that enables the use of closed-end needles (called Smart Tips) to treat the targeted peripheral nerves for a particular application. During a patient treatment, the iovera Smart Tip needles are inserted into the target tissue and liquid nitrous oxide (N_2O) is delivered from a pressurized cylinder at > 850 psi through a control valve and into the closed-end needles of the iovera Smart Tip. Within each closed-end iovera Smart Tip needle, the liquid nitrous oxide flows to the tip through an inner channel (lumen).

A combination of rapid pressure decreases, and evaporation of the nitrous oxide causes an endothermic event that rapidly draws heat from the surrounding tissue, thus, causing focused cooling at the point of the inserted iovera Smart Tip needles. The focused cooling can reach temperatures below -20°C (-4°F). By incorporating a skin warmer, the iovera system focuses precise subdermal cooling while protecting the skin. Sensors within the iovera handpiece monitor the automated delivery of nitrous oxide and the rate of cooling to ensure consistency during treatment cycles. The iovera Smart Tip closed-end needles leave nothing in the patient's body. The gas created from the evaporating N_2O is vented back up through the needle and released harmlessly into the atmosphere.

U.S. Indications for use: The iovera system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days.

The iovera system is not indicated for treatment of central nervous system tissue. The iovera system's "1 x 90" Smart Tip configuration (indicating one needle, which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover Iovera as there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management. Iovera is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria

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available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

CPT CODES

0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)
64600	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, metal, or inferior alveolar branch
64605	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale
64610	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring
64620	Destruction by neurolytic agent, intercostal nerve
64632	Destruction by neurolytic agent, plantar common digital nerve
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint
64640	Other peripheral nerve or branch

Key References

1. Hayes, Inc. (2018, September 26). Cryoanalgesia Using the iovera° System (Myoscience, Inc.) for Knee Pain. doi: 10.1053/j.trap.2015.10.014.

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Cryoanalgesia Using the Iovera System for Knee Pain, continued

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MEDICAL POLICY

CRYOSURGICAL ABLATION OF PLANTAR FASCIITIS, MORTON'S NEUROMAS AND OTHER CONDITIONS OF THE FEET

Policy # 237

Implementation Date: 3/1/04

Review Dates: 1/13/05, 2/28/06, 7/12/07, 8/21/08, 8/13/09, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24

Revision Dates: 7/24/06, 7/19/17

Related Medical Policies:

#103 Benign Skin and Subcutaneous Lesions

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Cryogenic neuroablation by the application of a cold-generating probe inserted into the lesion believed to cause pain and/or dysfunction is being proposed for such podiatric pathologies as Morton's neuroma and plantar fasciitis. The application of a cold-generating probe (to -70˚C) is another way to ablate/destroy tissue; it can be permanent or temporary, depending on the temperature and exposure time. In the case of neuromas, it is hypothesized that proper application of extreme cold will temporarily ablate the nerves associated with pain, leaving intact part of the nerve structure, allowing the nerves to regrow after several months. In plantar fasciitis, it is less clear what the therapeutic effect is derived from (there is not yet any literature published on this indication); however, it is another way to ablate the plantar fascia tissue in an effort to ameliorate the pathology occurring within that tissue.

All procedures are performed in an office setting. The procedure involves anesthetizing the overlying skin with approximately 0.5 cc of xylocaine to anesthetize the underlying neuroma. A 12-gauge cannula is then passed percutaneously into the vicinity of the symptomatic nerve. A nerve stimulator, located in the tip of the cryoneedle, is activated to elicit a pain response. Several short activations ensure that the probe is as accurately placed near the nerve as possible. Each nerve then undergoes 2, 3-minute freeze cycles with a 30-second thaw period interspersed. The nerve stimulator is again activated to determine if there is any residual pain. If there is, the procedure is repeated. Once the pain response is eliminated, a dry, sterile dressing is applied to the operative site and the patient can leave.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover cryosurgical ablation of plantar fasciitis, Morton's neuroma, or other foot conditions (exclusive of warts). This treatment is considered investigational due to the lack of evidence supporting its efficacy and safety. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Cryosurgical Ablation of Plantar Fasciitis, Morton's Neuromas, and Other Conditions of the Feet, continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Search of various databases revealed only 2 studies, both identified in Medline, on this topic. Both studies reported on cryoablation of neuromas. The first was a small case series (n = 20, follow-up at 2-weeks post-procedure), and the second a review with a case study (n = 1). Additionally, in studies by Dockery and Masala, et al., alcohol sclerosing injections appear to be much more effective for neuromas of the foot than what was reported by Caporusso, et al. with cryogenic neuroablation of neuromas.

Billing/Coding Information

CPT CODES

0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
28899	Unlisted procedure, foot or toes
64632	Destruction by neurolytic agent; plantar common digital nerve
64640	Destruction by neurolytic agent; other peripheral nerve or branch

HCPCS CODES

No specific codes identified

Key References

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2. Caporusso EF, Fallat LM, Savoy-Moore R. Cryogenic neuroablation for the treatment of lower extremity neuromas. J Foot Ankle Surg. 2002 Sep-Oct;41(5):286-90. PMID: 12400711
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Cryosurgical Ablation of Plantar Fasciitis, Morton's Neuromas, and Other Conditions of the Feet, continued

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MEDICAL POLICY

CUSTOM COMPONENTS FOR TOTAL KNEE REPLACEMENT (TKA)

Policy # 511

Implementation Date:11/12/12
Review Dates: 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/18/23, 2/20/24, 12/19/24
Revision Dates: 11/30/17

Related Medical Policies:

#598 Total Knee Arthroplasty

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Osteoarthritis of the knee is common, affecting almost a tenth of the population over age 55. Osteoarthritis can affect one or more compartments of the knee joint. Of the three compartments of the knee: medial, lateral, and patellofemoral, the medial compartment has the greatest susceptibility to age-related wear and tear. Lateral compartment osteoarthritis may accompany medial compartment disease, but isolated lateral involvement typically results from previous injury (e.g., lateral meniscus tear, tibial plateau fracture, or grade 3 ligament tears).

After medical treatment has failed, surgical intervention may be required. Many patients end up progressing to the point of requiring total knee arthroplasty (TKA). Total knee replacement is a well-established treatment for patients with severe osteoarthritis, with long-term results comparable to those of total hip replacement. Studies have shown survival rates for the standard implant of between 84% and 98% at 15 years.

A key aspect of TKA is achieving proper alignment of the femur and tibia post-procedure. Mechanical alignment of the leg as it relates to the technique of primary TKA is defined as center of hip, through center of knee, to center of ankle. Mechanical alignment should be restored to a neutral mechanical alignment. Various techniques have been employed to improve alignment with standard TKA including computer-assisted navigation. Though evidence has demonstrated significantly statistic improvement alignment using these devices, no evidence has shown improvement in health outcomes, revision rates, or complications.

Recently, the use of custom-designed patellofemoral/tibiofemoral prosthetic devices versus off-the-shelf designs has been utilized with the goal of improving alignment of the femoral and tibial components of the knee replacement and clinical outcomes. Many manufacturers produce a "custom" knee platform. The essential element of any custom knee is the metal or composite surface that is designed specifically for a particular patient. Typically, after a CT scan or MRI has been performed and the patient's anatomy is understood, a new custom surface can be created and attached where the diseased surface used to be. Custom knee replacements can be defined in 3 ways: 1) an "off the shelf" knee prosthetic that has been custom fit to the patient's native anatomy using patient-specific cutting tools, 2) a custom-made prosthesis that is designed specifically for a particular patient, and 3) customized knee replacements that are gender specific.

Another component to "custom knee replacements are the cutting blocks or "jigs." Most total knee replacements depend on a jig system to guide bone sawing. The implant is provided with a set of patient-specific, disposable cutting jigs. Biomechanical and anatomic axes are factored into jigs from either a CT or MRI scan of the joint obtained weeks prior to the procedure. This effectively achieves pre-navigation of

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the cut planes without the need for a navigation system. The placement of the jig is based on the surgeon's visual cues from the exposed bone surfaces. Inaccuracies in total knee placement can produce patellofemoral pain and limited flexion in 40% of patients when conventional approaches are used. As an example, displacements of 2.5 mm can produce a 20º alteration in the range of motion of a joint. Custom jigs are designed to eliminate this misalignment.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover custom components for total knee arthroplasty. The current evidence does not demonstrate improved health outcomes and standard total knee arthroplasty is the current accepted gold standard. This meets the plan's definition of experimental/investigational.

Select Health *does NOT provide additional reimbursement* for custom components for total knee arthroplasty. This is considered part of the primary procedure and would not be subject to additional reimbursement on the part of the surgeon or the facility.

SELECT HEALTH MEDICARE (CMS)

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Summary of Medical Information
A Select Health Medical Technology Assessment in October 2012 identified one systematic review and nine peer-reviewed journal articles; 858 were examined with follow-up from 6 weeks to 73 months.

A Hayes review from 2012 did not support custom knee arthroplasty as efficacious or cost-effective as it compares to traditional knee arthroplasty (TKA). This review highlighted only one studies which examined outcomes beyond surgery and no meta-analyses were identified in the literature. This review pointed out that much of the published literature focuses on knee alignment axis and range of motion but fails to look at clinically relevant endpoints such as revision rates, pain reduction, or improved function compared to standard TKA procedures. The Hayes review goes on to point out even with regards to knee alignment there are conflicting results. Three studies, including one randomized controlled trial, one prospective nonrandomized study, and one retrospective study found better alignment with custom TKA, yet two retrospective studies by one author found no difference between custom TKA and conventional approaches.

The findings of the Hayes review are validated in the primary studies. Very little information is given regarding prosthetic failure rates or improvements in clinical outcomes. To these points, Hayes noted that controversy concerning knee alignment and its effects on prosthesis survival remain. However, no evidence was given by either the Hayes group or any of the primary study authors about device survivability. Additionally, study endpoints such as hip-knee-ankle alignment and femorotibial angles, are very inconsistent with some studies reporting neutral, positive, and negative outcomes, when custom TKA was compared with conventional TKA. There is a surprising lack of outcomes data reported throughout all the literature.

Custom Components for Total Knee Replacement (TKA), continued

The literature also suggests the lack of cost-effectiveness of using custom knee replacement devices. Slover et al. found in completing a cost analysis study that routine use of custom cutting blocks for TKA will not be cost-effective unless it results in a significantly reduced revision rate. However, current evidence is insufficient to conclude that revision rates will be reduced, and thus, is insufficient to determine if cost-effectiveness can be achieved using these blocks. Watters et al. and Nunley et al. further noted in their review that custom TKA was not cost-effective. Nunley et al. showed that for all valgus outliers in conventional TKA there were more valgus outliers in patient-specific TKA. The group acknowledged that although it is clear these instruments add cost, it is unclear whether they improve alignment.

In summary, the literature supporting the benefit of custom knee arthroplasty is weak. Most of the studies are uncontrolled with no randomization. These studies tend to acknowledge that further studies need to be completed to illustrate cost-effectiveness and improvements beyond the standard of care in the clinical setting. Furthermore, studies demonstrating prosthetic survival rate and comparative revision rates need to be completed.

Billing/Coding Information

HCPCS CODES

C1776 Joint device (implantable)

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MEDICAL POLICY

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS

Policy # 120
Implementation Date: 7/1/03
Review Dates: 6/24/04, 5/20/05, 4/29/06, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 9/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24
Revision Dates: 5/5/04

Related Medical Policies:

#592 Percutaneous Tenotomy or Percutaneous Fasciotomy (Tenex Health Tx System or TX1, TX2)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Plantar fasciitis and epicondylitis are common musculoskeletal conditions which frustrate patients and practitioners alike because of their resistance to treatment. Although normally managed with conservative treatment, both conditions are frequently resistant to the wide variety of treatments commonly used, such as nonsteroidal anti-inflammatory drugs, rest, pads, cups, splints, orthotics, corticosteroid injections, casts, physical therapy, ice, and heat. There is no consensus on the efficacy of any particular conservative treatment regimen; there is agreement that nonsurgical treatment is ultimately effective in approximately 90% of patients.

Extracorporeal shock wave therapy (ESWT) devices use either piezoelectric electrohydraulic or electromagnetic technology, to generate low- or high-energy shock waves. Delivery of energy also varies with the size of the "footprint"; i.e., the size and shape of the energy pattern. These devices use ultrasound, fluoroscopy, or "clinical focusing" in an attempt to locate the best site for application of the shock wave energy. When ultrasound or fluoroscopy is used, the provider will generally charge an additional fee for this component of the service. In contrast, use of clinical focusing is a manual method of locating the best site that involves the technician (or physician) and patient working together to find the site that elicits the most pain upon application of the shock energy. The best method of focusing shock energy is currently controversial.

The therapy head contacts the patient's body via a water cushion or water-based conductive gel, and shock waves are released from 70–20 times per minute. Therapy usually consists of 1–3 sessions, during which between 1000–3000 pulses of low- or high-energy shock waves are administered to the site of pain. Each treatment takes approximately 20 minutes. Extracorporeal shock wave therapy can be performed as an outpatient procedure, with general, regional, local, or no anesthesia as needed.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover extracorporeal shock wave therapy (ESWT) for any musculoskeletal indication; the published medical literature has not demonstrated unequivocal efficacy for its approved uses. This therapy meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the

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Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The body of literature on ESWT is large, heterogeneous, and mixed. Most of the reported studies are case series but there are also multiple RCTs, with mixed results. The variability in outcomes, from strongly positive to equivalent to placebo/sham, is explained by differences in shock wave energy level, method of focusing the shock energy, size of the "foot print" of the machine, and, of course, study design (e.g., patient selection, blinding). There is, clearly, no consensus in the medical literature on the meaning of the highly variable outcomes or differences in protocols (e.g., focusing method, size of the shock wave "footprint").

There seems to be "near consensus," however, about the use of low- vs. high-energy ESWT protocols with respect to benefits of the procedure; i.e., it doesn't seem to matter whether the energy is applied via high-energy ESWT in one session or whether it's applied with lower energy over 3 sessions. That is, there is no reason to believe the healing process differs between low- and high-energy protocols. It is clear, however, that negative outcomes (complications) are minimal to non-existent with low-energy protocols and substantial with high-energy protocols. No head-to-head trials between different protocols/devices have been reported.

Focusing of shock wave energy: There is evidence suggesting that neither MRI nor ultrasound (US) are reliable methods of identifying the presence or absence or precise location of pathological tissue in tendinopathies. Thus, use of US as the sole means of focusing ESWT or use of either US or MRI to determine the presence or absence of tendinopathy or inflammation may not be reliable (i.e., OssaTron and Donier machines/protocols).

The second component of focusing relies on the size of the ESWT head, which varies widely between the multiple devices in use (3 in U.S.). Though there doesn't seem to be any consensus expressed in the literature about the relative merits of the different footprints, it seems logical that if ESWT does indeed influence biological processes that a larger footprint would increase the likelihood of hitting the target.

The third important component of "hitting the target" involves the use of anesthesia. High-energy protocols (OssaTron) require the use of local as well as regional anesthesia; without which, the high-energy shock waves are too painful to withstand. These protocols require focusing by ultrasound or fluoroscopy, which again, may not be a reliable means of identifying the specific site of pathology.

Though there isn't yet consensus on all these components of ESWT protocols, numerous pieces of indirect evidence suggest that the different ESWT machines/protocols would be expected to yield different outcomes. Indeed, this seems to be the case.

Though the OssaTron machine has the biggest footprint, to accommodate the high-energy levels this protocol requires, substantial anesthesia and fluoroscopic or US guidance is used; which may be unreliable as a means of focusing the shock waves. The large focal footprint may partially compensate for the unreliable focusing method. In fact, the large double-blind RCT that led to FDA approval (Ogden et al.) did demonstrate effectiveness but not in all measures and only about 17% points higher than the placebo/sham (47% vs. 30%), with substantial complications.

The machine with the next largest footprint, the Siemens Sonocur, is the only device/protocol that uses "clinical focusing," with or without US to help locate the depth of the offending "lesion." Focusing relies on intimate interaction between the patient and technician or physician to determine the focal point of pain.

This low-energy protocol calls for 3 sessions, with no reported substantive complications. This device is the most studied of the FDA-approved devices.

Use of the Donier machine/protocol, which utilizes intermediate to high-energy shock waves, anesthesia and ultrasound focusing, has led to mixed outcomes.

BCBS TEC completed a technology assessment in March 2003; this review did NOT differentiate between devices/protocols. The review suggests that the current combined evidence base is inconclusive for all indications. Since that review, there has been another small RCT (n = 45), using low-energy ESWT (the Sonocur device) on patients with plantar fasciitis of at least 12-month duration. Though this reasonably well-conducted trial reported positive results; the improvements were modest and statistical analysis failed to account entirely for dropouts (i.e., didn't use intention-to-treat analysis). Additionally, the primary author "has received financial benefit from research in this study." Consequently, BCBS TEC's conclusions would not be altered significantly by this recent study.

Following is a summary from the March 2003 BCBS TEC review:

Plantar fasciitis: In summary, the available evidence consists largely of good quality studies; there are 3 double-blind, randomized controlled trials that included over 600 patients. Overall, the results of the trials are inconclusive. If ESWT provided a clinically significant improvement in plantar fasciitis, one would expect consistent improvement across multiple ways of measuring pain and function (e.g., morning pain, use of pain medications, ability to walk without pain). However, the results of various measures within studies and across studies do not give a consistent picture concerning the effect of ESWT on health outcomes for plantar fasciitis.

Non-FDA approved indication: Tendinitis of the shoulder: There is not sufficient evidence to permit conclusions on whether ESWT improves outcomes for patients with tendinitis of the shoulder. The highest quality evidence, 2 randomized, placebo-controlled (n = 114 total) trials including one that was double-blinded found no significant differences between treatment and control groups. Outcomes measured were shoulder pain and disability index, Constant and Murley score for functional assessment of the shoulder, pain at rest, and pain with activity.

Two other studies (n = 159 total) were non-randomized and uncontrolled, including 1 that compared ESWT with surgery. These studies reported significant results favoring ESWT but represent a poor quality of trial design.

An additional (positive) study of this clinical indication has been reported since completion of BCBS TEC's review in March.

Tendonitis of the elbow: There are 2 trials that evaluated ESWT for tendinitis of the elbow. Both were randomized, double-blind, placebo-controlled trials. The first (n = 114) reported statistically significant improvement in pain on resisted extension and the upper extremity function score. The second (n = 75) reported no group differences on elbow pain during the day or at night. This study appeared to have some group differences at baseline, although none were reported as statistically significant. Thus, the existing evidence from randomized controlled trials does not permit conclusions on the effect of ESWT for tendinitis of the elbow.

The Hayes report, which is dated April 2001, suggests a 'C' rating at best.

Multiple other systematic reviews (see below) are mixed with regards to their conclusions. However, since the BCBS TEC report is the most recent and relied only on randomized, blinded, controlled trials, it likely represents the most reliable summary of the evidence.

On the other hand, the evidence supporting both conservative and surgical therapies for both chronic plantar fasciitis and epicondylitis (tennis elbow) is also weak. Currently, there are no published controlled studies of surgical treatment for either chronic plantar fasciitis or epicondylitis.

Evidence on Treatment Options/Reports of Recent Systematic Reviews

Plantar fasciitis: Although numerous interventions have been used for heel pain, very few have been subjected to rigorous evaluation. There is limited evidence upon which to base clinical practice. Although the effectiveness of corticosteroid injections has not been demonstrated against a placebo, there is limited evidence for their superiority over certain types of orthotic device. There is limited evidence that the use of night splints may benefit chronic plantar heel pain. There is limited evidence for the

effectiveness of low-energy shock extracorporeal shock wave therapy in reducing pain. There is no evidence to support the effectiveness of therapeutic ultrasound, low-intensity laser therapy, or exposure to an electron generating device or insoles with magnetic foil. No randomized trials evaluating orthotic devices, surgery, or radiotherapy against a control population have been identified.

Tennis elbow (lateral epicondylitis): There are no published controlled trials of surgery for lateral elbow pain. Without a control group, it is not possible to draw any conclusions about the value of this modality of treatment. There is some support for the use of topical NSAIDs to relieve lateral elbow pain, at least in the short-term. There remains insufficient evidence to recommend or discourage the use of oral NSAIDs, although it appears injections may be more effective than oral NSAIDs in the short-term. A direct comparison between topical and oral NSAIDs has not been made and so no conclusions can be drawn regarding the best method of administration. No definitive conclusions can be drawn concerning effectiveness of orthotic devices for lateral epicondylitis. More well-designed and well-conducted RCTs of sufficient power are warranted.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproven for this Indication

CPT CODES

20999	Unlisted procedure, musculoskeletal system, general
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

FEMOROACETABULAR IMPINGEMENT (FAI) SYNDROME

Policy # 449
Implementation Date:8/9/10
Review Dates: 11/29/12, 12/19/13, 12/18/14, 12/10/15, 2/16/17, 2/15/18, 2/18/19, 2/19/20, 2/18/21, 1/20/22, 2/16/23, 3/4/24, 4/17/25
Revision Dates:

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Hip pain can be caused by several different conditions. One condition which is increasingly being recognized as a cause of debilitating hip/leg pain is femoroacetabular impingement. The cause of impingement in the osseous hip can be developmental, as a result of childhood conditions such as Legg-Calvé-Perthes disease and slipped capital femoral epiphysis; it may also result from post-traumatic or post-osteotomy morphologic changes in inclination and anteversion angles. Extra-articular impingement of the intertrochanteric bone of a deformed proximal part of the femur can occur. Impingement caused by structural deformities (morphologic dysplasia) may still be the single most common cause of osteoarthritis.

Two distinct types of femoroacetabular impingement have been identified. The first type, *cam impingement*, is more common in young athletic men. It is caused by the jamming of an abnormal femoral head, or head-neck junction (resulting in a reduced head-neck ratio or offset), against the acetabulum, especially with flexion and internal rotation.

The second type, *pincer impingement,* is most common in middle-aged athletic women. It is the result of linear contact between the prominent anterior aspects of the acetabular rim and the femoral head or femoral head-neck junction such as occurs with coxa profunda, acetabular protrusion, or retroversion of the acetabulum. The femoral head may have normal morphologic features or may have an indentation caused by the abutment against the prominent anterior aspect of the acetabular rim. The repeated microtrauma may result in the labrum becoming ossified, which stiffens the labrum and compounds the impingement.

Cam and pincer impingement rarely occur in isolation, and the combination has been termed mixed cam-pincer impingement. With this disorder, an abnormal femoral head or head-neck junction joins with an abnormal acetabulum.

FAI can often be resolved with rest, modifying one's behavior and a physical therapy and/or anti-inflammatory regimen. Such conservative treatments have been successful in reducing the pain and swelling in the joint. Chronicity of signs and symptoms along with radiographic evidence of impingement and chondral and/or labral lesions are clear indications for operative intervention.

The 3 choices of treatment are arthroscopy, arthroscopy combined with a limited open operation, and an open operation with surgical dislocation of the hip. The operative treatment is chosen according to the specific disease pattern being corrected and the technical preferences and treatment philosophy of the surgeon. Open operative treatment is the original and best documented method for treatment of femoroacetabular impingement, and it is the standard against which other joint-preserving treatment methods must be measured. This surgical approach has the advantage of a very large exposure and visualization, but the disadvantage of significant muscle disruption. There is also a higher risk of blood clots because of twisting the vessels.

Hip arthroscopy, or a “hip scope,” is a minimally invasive procedure. The use of an arthroscope means that the procedure is done using 2 to 3 small incisions (approximately 1/4–1/2-inch long) rather than a more invasive “open” surgery that would require a much larger incision. The surgeon is also aided by fluoroscopy to ensure that the instruments and arthroscope are inserted properly. The instruments include an arthroscope, which allows the surgeon to view the inside of the joint, and a variety of “shavers” that allow the surgeon to cut away (debride) the frayed cartilage or labrum that is causing the pain. The shaver is also used to shave away the bump(s) of bone that are responsible for the cartilage or labral damage. In addition to removing frayed tissue and loose bodies within the joint, occasionally, holes may be drilled into patches of bare bone where the cartilage has been lost. This technique is called "microfracture" and promotes the formation of new cartilage where it has been lost. The procedure is normally performed on an outpatient basis under local anesthetic.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN’S HEALTH INSURANCE PROGRAM)

Select Health covers both open and arthroscopic repair for femoroacetabular impingement (FAI) syndrome. Current evidence demonstrates surgery to treat femoroacetabular impingement is a proven method to relieve hip pain in an appropriately selected population.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A technology assessment in May 2010 failed to identify any comparative trials assessing both the open and arthroscopic FAI surgery. The systematic review by Bedi et al. attempted a comparative assessment of the 2 techniques demonstrating high levels of patient satisfaction with both procedures with significant overlap. The NICE report from 2007, however, concluded that evidence at the time was inadequate to assess safety and efficacy of the procedure, and recommended coverage only in an investigational trial. Thus, direct conclusions regarding the comparative efficacy and safety cannot be reached.

Studies, otherwise identified, tended to be of moderately large size ranging from 24–200 patients, though, most studies suffered from the limitations of retrospective study designs and the lack of randomization or blindin,g allowing investigator bias to have a greater impact on the outcomes and conclusions from these trials. Study duration range for the most part was adequate to reach reasonable conclusions regarding safety, efficacy, and durability of this procedure.

Seven of the 12 studies, including Phillippon et al. (2007), noted a substantial number of patients (> 10%) underwent revision surgery, and indicated that a substantial portion of the patients had total hip arthroplasty only 12–24 months later.

In summary, current evidence is limited as to the comparative safety and effectiveness of arthroscopic surgery for FAI. This limited evidence suggests equivalent outcomes compared to the open procedure and does not address aspects of recovery or early return to function important to patients.

Femoroacetabular Impingement (FAI) Syndrome, continued

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

29914	Arthroscopy, hip, surgical; with femoroplasty (ie, treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (ie, treatment of pincer lesion)
29916	Arthroscopy, hip, surgical; with labral repair
27299	Unlisted procedure, pelvis or hip joint
29862	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum
29999	Unlisted procedure, arthroscopy

HCPCS CODES

No specific codes identified

Key References

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Select Health

Femoroacetabular Impingement (FAI) Syndrome, continued

Select Health

MEDICAL POLICY

INSPACE

Policy # 691
Implementation Date:4/8/25
Review Dates:
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The InSpace biodegradable subacromial spacer (Stryker) is a minimally invasive biodegradable subacromial spacer intended to restore the subacromial space to improve pain and function, for use in arthroscopic treatment of massive irreparable rotator cuff tears (MIRCTs). It is a resorbable shoulder spacer intended to act as a temporary spacer to restore the subacromial space without requiring sutures or fixation devices. The presence of the spacer lowers the head of the humerus and reduces pain by decreasing the amount of friction that occurs between the humerus and the acromion.

The InSpace biodegradable subacromial spacer received de novo clearance as a class II device under product code QPQ (resorbable shoulder spacer) on July 12, 2021 (DEN200039). The clearance was originally granted to Ortho-Space Ltd. which was acquired by Stryker in 2019. The InSpace biodegradable subacromial spacer is cleared for use in "patients with massive, irreparable full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age." The included studies had a mean or median age ≥ 65 years, and the severity of osteoarthritis was not reported, so the effectiveness of InSpace in younger patients or those with more severe osteoarthritis is unclear.

The de novo clearance document also states that InSpace should be used with patients who "would benefit from a shorter surgical time compared to partial rotator cuff repair." This suggests that use of InSpace as an adjunct to partial repair is off-label. Although use of the InSpace device appears to be associated with substantial improvements in pain severity and global shoulder measures compared with baseline, if the device is not shown to confer benefit beyond partial repair alone, it will not be worth the risks inherent in lengthening the surgical procedure and inserting a foreign body into the shoulder. More and higher quality research is needed to determine the incremental benefit of the InSpace device in addition to partial repair of rotator cuff tears.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover subacromial balloon spacers (e.g., InSpace) for the treatment of rotator cuff tears as they are considered experimental/investigational due to insufficient evidence of efficacy.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

Select Health

InSpace, continued

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

Not covered for the indications listed above

CPT CODES

C9781 Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed

Key References

1. Hayes, Inc. Evolving Evidence Review. InSpace Biodegradable Subacromial Spacer as an Adjunct to Partial Repair of Rotator Cuff Tears. Jan 3, 2025.
2. Hayes, Inc. Evolving Evidence Review. InSpace Biodegradable Subacromial Spacer Alone or With Debridement of Rotator Cuff Tears. Jan 3, 2025.

Disclaimer

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MEDICAL POLICY

INTERSPINOUS DISTRACTION DEVICES/SPACERS

Policy # 320

Implementation Date: 10/25/06

Review Dates: 10/18/07, 10/23/08, 8/16/11, 8/16/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/15/18, 8/8/19, 8/20/20, 7/29/21, 7/27/22, 8/22/23, 9/18/24

Revision Dates: 5/26/10, 10/8/14

Related Medical Policies:

#450 Axial Lumbar Interbody Fusion (AXIALIF)

#513 Interbody Spinal Fusion Devices

#558 Interspinous Fixation (Fusion) Devices

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Spinal stenosis refers to a narrowing of the spinal canal with compression of the nerve roots in the central spinal canal or in the neural foramina. Spinal stenosis may be due to acquired or degenerative processes, or to congenital stenosis.

Conservative management is usually attempted first and includes a variety of physical and pharmacological techniques to strengthen muscles and reduce pain. If conservative management does not produce pain relief, several more invasive options are available, which include lumbar epidural injections, soft-tissue injections, and surgical decompression. Surgical techniques include standard wide laminectomy and decompression; and foraminal enlargement surgery is used to address refractory foraminal stenosis-induced radicular pain. Other surgical decompressions include laminotomy, medial facetectomy, and medial or lateral foraminotomy.

Decompressive laminectomy is the most common type of surgery done to treat spinal stenosis. This surgery is done to relieve pressure on the spinal cord or spinal nerve roots caused by age-related changes in the spine and to treat other conditions, such as injuries to the spine, herniated discs, or tumors. In many cases, reducing pressure on the nerve roots can relieve pain and allow you to resume normal daily activities. Laminectomy first removes lamina and ligamentum flavum from the lateral borders of one lateral recess to the other and then decompresses entrapped nerve roots.

More recently, interspinous process decompression (IPD) procedures have been developed as a less invasive surgery option. This is a surgical procedure in which an implant is placed between the spinous processes (the bony protrusion from the back of each vertebra) of adjacent vertebrae. It works by limiting the spine extension that compresses the nerve roots while still allowing flexion, axial rotation, and lateral bending: that is, the device limits pressure on the spinal nerves and the resulting pain symptoms when the patient is in an upright position or leans backward, while also preserving the patient's ability to turn side-to-side, bend forward, and to turn to either side.

Many interspinous distraction devices have been FDA approved or are in the process of receiving FDA approval. These include: Aperius-PercLID System (Kyphon/Medtronic), Coflex-F (Paradigm Spine), CoRoent System (NuVasive), DIAM Spinal Stabilization System (Medtronic Sofamor Danek), Falena Interspinous Decompression Device (Mikai Spine), FLEXUS (Globus Medical), Helifix Interspinous Spacer System (Alphatec Spine), In-Space (Synthes), NL-Prow Interspinous Spacer (Non-Linear Technologies), Stenofix (Synthes), Superion ISS Interspinous Spacer System (VertiFlex), Wallis System, (Zimmer Spine [formerly Abbott Spine]), X-STOP Interspinous Process Decompression (IPD) System

(Kyphon/Medtronic Spine), and X-STOP PEEK [polyetheretherketone] (Medtronic).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover interspinous distraction devices/spacers. Concerns continue related to long-term outcomes and device failure rates. These devices remain unproven and meet the plan's definition of investigational.

Excluded interspinous and interlaminar distraction devices, include but are not limited to:

- Aperius PercLID System (Kyphon/ Medtronic Spine)
- Coflex Interlaminar Technology Implant (Paradigm Spine)
- CoRoent Extensure (Nuvasive)
- DIAM Spinal Stabilization System (Medtronic Sofamor Danek)
- ExtenSure (Nuvasive)
- FLEXUS (Globus Medical)
- Falena Interspinous Decompression Device (Mikai Spine)
- Helifix Interspinous Spacer System (Alphatec Spine)
- In-Space (Synthes)
- NL-Prow Interspinous Spacer (Non-Linear Technologies)
- Stenofix (Synthes)
- Superion ISS Interspinous Spacer System (VertiFlex)
- Wallis System (Abbott Spine/ Zimmer Spine)
- X-STOP Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)
- X-STOP PEEK Interspinous Process Decompression (IPD) System (Kyphon/ Medtronic Spine)

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health

Summary of Medical Information

Only two of the interspinous distraction devices are FDA approved (X-Stop and Coflex), though, several are approved for use in clinical trials and have been available in Europe for several years. Thus, a significant body of evidence is available for review. Two systematic reviews and twenty-six primary literature articles were identified which met inclusion criteria for review. Data published to date include outcomes of 2,187 patients with information dating between 2002 and 2014. The average follow-up period was 24.4 months (range = 6−51 months).

Evidence from the published literature illustrates important shortcomings of the devices. Some of the studies are a bit dated such as the NICE review in 2010 which suggested adequate efficacy and safety, though, the need for re-operation was noted. As newer studies have been published, however, concerns related to complications, spinous process fractures, and other issues have arisen, calling into question the role for these devices. Of note, is the systematic review by Wu et al. published in 2014. The group found no significance difference between interspinous spacer surgery and traditional decompression surgery in patients with low back pain. The group also noted a significantly lower incidence rate of reoperation in the patients who underwent traditional decompression. They concluded: "Although patients may obtain some benefits from interspinous spacers implanted through a minimally invasive technique, interspinous spacer use is associated with a higher incidence of reoperation and higher cost. The indications, risks, and benefits of using an interspinous process device should be carefully considered before surgery." These findings are also noted in studies by Bowers et al.

Bowers et al. found the following at a mean follow-up time of 42.9 months (range = 3−48 months):

- 28% of patients did not experience an improvement in pain
- Pre-operative pain returned in 77% of the patients
- Overall complication rate of 38%
- 23% of patients experienced an interspinous fracture
- 15% experienced a new onset of radiculopathy
- The ultimate failure rate was 85%

Though the data acknowledges that there may be some benefit to interspinous spacer use, such as with X-Stop or Coflex, the data does not explicitly address appropriate patient selection criteria or demonstrate a substantial improvement in patient outcomes commensurate with the documented risks. Additionally, many of the studies suffer from methodological issues such as small size, the lack of randomization, are retrospective assessments, and lack comparison to surgical interventions. This adds to the weight of the conclusions noted above in the recent systematic review by Wu et al.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
22899	Unlisted procedure, spine

HCPCS CODES

C1821 Interspinous process distraction device (implantable)

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Interspinous Distraction Devices/Spacers, continued

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

Select Health

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MEDICAL POLICY

INTERSPINOUS FIXATION (FUSION) DEVICES

Policy # 558

Implementation Date: 10/6/14

Review Dates: 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/28/21, 9/15/22, 10/13/23, 9/27/24

Revision Dates: 9/27/22

Related Medical Policies:

#320 Interspinous Distraction Devices/Spacers

#450 Axial Lumbar Interbody Fusion (AXIALIF)

#513 Interbody Spinal Fusion Devices

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Low back pain is a common affliction affecting over 80% of the general population at some time during life. Although much of low back pain does not have a precisely identifiable cause, low back pain can be caused by a variety of conditions including degenerative disc disease, muscle strain, skeletal trauma, infection, and tumor. Most cases of low back pain without an identifiable cause improve with conservative therapy including physical therapy, exercise, and/or analgesics. When the spine becomes unstable, for example, due to spondylolisthesis, trauma, infection or tumor, and for certain other identified causes of chronic, unremitting back pain, a fusion procedure is often recommended to provide stability or pain relief to the affected portion of the spine.

Arthrodesis (fusion) procedures in the lumbar (lower) spine are surgical procedures that join two or more lumbar vertebrae together into one solid bony structure. These procedures may be used to treat spine instability, cord compression due to severe degenerative disc disease, fractures in the lumbar spine or destruction of the vertebrae by infection or tumor. There are several methods or approaches to this surgery. These include a posterior approach (most common), anterior/anterolateral approach, anterior/posterior lumbar fusion, lateral extracavitary approach and posterior lumbar interbody fusion (PLIF)/transforaminal lumbar Interbody fusion (TLIF).

Contemporary models of interspinous fixation devices have evolved from spinous process wiring with bone blocks and early device designs (e.g., Wilson plate, Meurig-Williams system, Daab plate). The newer devices range from paired plates with teeth to U-shaped devices with wings that are attached to the spinous process. These newer devices are intended to be an alternative to pedicle screw and rod constructs to aid in the stabilization of the spine with interbody fusion. Interspinous fixation devices are placed under direct visualization, while screw and rod systems may be placed either under direct visualization or percutaneously. Use of an interspinous fixation device in combination with a unilateral pedicle screw system has also been proposed. Interspinous fixation devices are not intended for standalone use.

Interspinous fixation (fusion) devices contrast with interspinous distraction devices (spacers), which are used alone for decompression and are typically not fixed to the spinous process. In addition, whereas interspinous distraction devices may use dynamic stabilization, interspinous fixation devices are rigid. However, the fixation devices might also be used to distract the spinous processes and decrease lordosis. Thus, the fixation devices might be used off-label without interbody fusion as decompression (distraction) devices in patients with spinal stenosis. If fixation devices are used alone as a spacer, there is a risk of spinous process fracture.

Interspinous Fixation (Fusion) Devices, continued

The current list of Food and Drug Administration (FDA) cleared devices includes but may not be limited to Affix (NuVasive), AILERON Expandable (Life Spine), AILERON (Life Spine), Aspen (Lanx), Axle (X-Spine), BacFuse (Pioneer Surgical), BridgePoint (Alphatec), Coflex-F (Paradigm Spine), Inspan (Spine Frontier), PITBULL Interspinous Process Fixation Device. (BM Korea Co., Ltd.), PrimaLOK (OsteoMed), Spire (Medtronic), SP-Fix (Globus), Romeo2 PAD (SpineArt), and ZIP ULTRA MIS Interspinous Fusion System (Aurora Spine).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover interspinous fixation devices for decompression of spinal stenosis, alone or in combination with spinal fusion, as they are considered experimental and investigational.

Interspinous Fixation Devices excluded from coverage for any indication include, but may not be limited to the following:

1. Affix II and Affix II Mini Spinous Process Plating System (NuVasive)
2. Aileron Interspinous Fixation System (Life Spine)
3. Aspen Spinous Process Fixation System (Lanx)
4. Axle (X-Spine)
5. BacFuse (Pioneer Surgical)
6. BridgePoint (Alphatec)
7. CD Horizon Spire Fixation System (Medtronic Sofamor Danek)
8. Coflex-F (Paradigm Spine)
9. Inspan (Spine Frontier)
10. Minuteman Interspinous Interlaminar Fusion Device (Spinal Simplicity)
11. PrimaLOK (OsteoMed)
12. Octave (Life Spine)
13. SP-Fix Spinous Process Fixation System (Globus Medical)
14. Zip Ultra (Aurora Spine)

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. Select Health applies this policy after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

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Summary of Medical Information

A search of the published clinical literature was performed on April 28, 2014. Currently no systematic reviews and only seven primary literature articles related to all the different technologies have been identified which met inclusion criteria. In all, results from only 184 patients who underwent interspinal fusion/fixation have been published.

Though current evidence suggests some potential efficacy of spinal fixation devices in specific measures such as anterior/posterior mobility, current studies have not demonstrated superior clinical outcomes with use of any spinal fixation device over the current standards of care. None of the published studies to date were prospective, randomized, or sham controlled. Additionally, identified studies lack control group, were of small size, and in many instances lacked clinically meaningful endpoints.

Billing/Coding Information

CPT CODES

22899 Unlisted procedure, spine

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

INTRADISCAL ELECTROTHERMOPLASTY (IDET)

Policy # 136

Implementation Date:3/11/03

Review Dates: 4/1/03, 5/1/03, 4/24/04, 3/30/05, 3/11/06, 12/21/06, 12/20/07, 12/18/08, 9/15/11, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 11/14/18, 10/15/19, 10/14/20, 11/28/21, 9/15/22, 10/17/23, 10/29/24

Revision Dates: 5/5/03, 9/28/10

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Up to 84% of adults have low back pain at some time in their lives. The long-term outcome of low back pain is generally favorable, but given how common low back pain is, persistent symptoms affect millions of individuals. Subacute low back pain is commonly defined as back pain lasting between 4–12 weeks and chronic low back pain as pain that persists for 12 or more weeks.

With age, or due to injury, cracks or fissures may develop in the wall of the intervertebral disc. Filled with small nerve endings and blood vessels, these fissures are a chronic source of pain in many patients. Additionally, the inner disc tissue (nucleus) will frequently cause the disc to bulge, or herniate, into these fissures in the outer region of the disc, likewise, stimulating pain sensors within the disc.

To treat chronic low back pain, various treatment methods have been developed. Intradiscal electrothermoplasty (IDET) is a minimally invasive surgical procedure in which thermocoagulation of one or more defective intervertebral discs are accomplished using a percutaneously inserted catheter with a heating element enclosed in the tip. In general, it is performed as an outpatient procedure under local anesthesia. A specially designed catheter is used in conjunction with a programmable heat source that monitors temperatures at the tip of the catheter. Both devices are approved by the FDA for use together in treating patients with symptoms resulting from one or more contained degenerative discs, those that have not ruptured through the protective annular covering.

IDET uses a flexible catheter with a navigable tip incorporating a copper wire heating element. It is inserted into the disc through a 17-guage needle using fluoroscopic guidance. The tip of the catheter is placed at the site where the patient's pain is suspected to originate, usually an annular tear or fissure. Once the catheter is in place, the temperature at the tip is gradually raised to 60°–90°C and maintained for a specified predetermined period; the manufacturer's total heating protocol is 17 minutes long. Application of heat to the disc in this manner has been shown to cause coagulation of the disc nucleus and annular wall tissues.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover intradiscal electrothermoplasty (IDET) as current evidence poses significant unanswered questions as to the efficacy of intradiscal electrothermoplasty in treating low back pain. This meets the plan's definition of experimental/investigational.

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SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Studies by Bogduk and Pauza completed since above referenced systematic reviews suggested that, at least in the short-term (defined as less than 6 months), IDET has the potential to improve the pain and possibly function in patients meeting specific criteria. This improvement may be as high as 50% in 50% of the patients, with upwards of 20% of patients noting nearly complete relief of their chronic back pain. However, despite these encouraging studies, many questions remain regarding the chronic efficacy of this procedure, particularly, in a broad patient population.

Histological studies have also been done to help determine if IDET is safe and effective. They concluded that temperatures developed during IDET were insufficient to alter collagen architecture or stiffen treated motion segments acutely. They showed no significant alteration of the annular fiber morphology in the vicinity of the catheter canal. Thus, the mechanism of action of the IDET procedure remains controversial.

An updated Medical Technology review completed in August 2010 identified several uncontrolled studies and nonrandomized controlled or comparative studies. They suggest that intradiscal electrothermoplasty therapy (IDET) may lead to a significant reduction in pain, disability, a significant improvement in function, and mobility in some patients with chronic discogenic low back pain. But, less than 20% of patients reported a complete resolution of pain and disability. However, results of 2 randomized, placebo-controlled studies were conflicting; one study reported a benefit of IDET compared with placebo, while the other did not. No other randomized controlled trials of IDET were identified in the literature.

While there is not much risk with the procedure, there is also very little reward as indicated by the literature. In a study of 50 patients observed over 2 years, Assietti et al. only report a 79% success rate and a 66% reduction in pain; Derby et al. only exhibited a 63% post-IDET improvement in pain.

In summary, IDET, though a relatively safe procedure, and despite case series suggesting effectiveness, prospective placebo controlled randomized studies do not demonstrate any compelling evidence of superior efficacy to placebo/sham therapy.

Billing/Coding Information

CPT CODES

22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

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Intradiscal Electro-thermoplasty (IDET), continued

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MEDICAL POLICY

JOINT REPLACEMENTS USING MAKOPLASTY

Policy # 506

Implementation Date: 8/6/12

Review Dates: 8/15/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24

Revision Dates: 4/8/16, 12/2/20, 5/13/22

Related Medical Policies:

#277 Computer-Assisted Orthopedic Surgeries

#431 Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental)

#579 Ligament-Sparing Knee Replacement Surgery

#598 Total Knee Arthroplasty

#599 Total Hip Arthroplasty

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

The normal hip functions as a "ball and socket" joint. The femoral head (ball) articulates with the acetabulum (socket), allowing smooth range of motion in multiple planes. Any condition that affects either of these structures can lead to deterioration of the joint. This, in turn, can lead to deformity, pain, and loss of function. The most common condition affecting the hip in this way is osteoarthritis. Osteoarthritis (degenerative joint disease) results from progressive erosion and degeneration of the articular cartilage induced by a complex interplay of genetic, metabolic, biochemical, and biomechanical factors with secondary components of inflammation. In most patients, the initiating mechanism is damage to normal articular cartilage by physical forces, which can be either single events of macrotrauma or repeated microtrauma. Chondrocytes (cartilage-producing cells) react to this injury by releasing degradative enzymes and elaborating inadequate repair responses. Osteoarthritis most commonly presents in patients over 40 years of age.

For patients with hip pain due to a variety of conditions, total hip arthroplasty (THA) can relieve pain, restore function, and improve quality of life. It is estimated that over 150,000 THAs are performed each year in the United States and over 500,000 are performed worldwide. THA removes diseased articular surfaces and are replaced with synthetic materials. In general, over 90% of THAs are working successfully, are pain-free, and are without complication 10−15 years postoperatively. Some patients continue with their original implant even after 25 years of use. All THAs consist of a femoral component, an acetabular component, and a bearing surface. Most systems are modular with a separate femoral stem, femoral head, acetabular liner, and acetabular shell.

A new version of performing a THA involves the use of robotic technology and computer navigation. The MAKOplasty Total Hip Arthroplasty procedure uses diagnostic images to reconstruct the joint. MAKOplasty uses CT scans and computer software to create a 3D model of the pelvis and femur to plot ideal implant placement. During surgery, a proprietary robotic arm, the Robotic Arm Interactive Orthopedic (RIO) System, assists the surgeon in preparing the hip anatomy and positioning the implants. The patient-specific procedure is intended to provide a higher level of patient–specific implant alignment and positioning to accurately reproduce the surgical plan. Implants that have not been properly aligned can lead to loosening, undue wear, pain and post-op hip dislocation.

MAKOplasty may also be used in partial knee resurfacing for early to midstage OA in the medial (inner), patellofemoral (top), or lateral (outer) compartments of the knee. The procedure is performed through a 4-

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6 incision. The computer image and robotic arm assist in the removal of affected bone and proper alignment using the RESTORIS series of compartmental implants.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT reimburse separately for the use of MAKOplasty or any robotic assisted device for total joint replacement surgery. Current evidence has not demonstrated clinical utility of this method as it compares to standard total hip arthroplasty, unicompartmental knee arthroplasty, and total knee arthroplasty procedures. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A June 2012 Medical Technology Assessment identified that only 1 systematic review and 1 peer-reviewed journal article exist concerning MAKO hip arthroplasty. In April 2012, Hayes published an overview of the MAKOplasty procedure for THA and indicated that increased marketing and media coverage has driven interest in this procedure despite the absence of evidence indicating improved patient outcomes. Hayes further noted that MAKO is currently undergoing 70 clinical studies and that none of these trials are registered on ClinicalTrials.gov.

No studies have compared MAKOplasty of the hip to manual THA techniques. The only peer-reviewed journal article available offers little to the determination as to whether MAKOplasty of the hip is clinically beneficial to patients who otherwise would have undergone traditional THA or conservative therapies.

In a study published in 2014 for both UKA and THA, Werner et al. concluded: "The benefits of this technology are evident but have not been shown to improve patient outcomes and justify the added financial burden imposed. Further research is needed to determine if this technological advancement will translate into improvements in longevity and clinical outcomes. A metaanalysis for TKA published by Thienpont et al. reviewing computer-assisted navigation with conventional instrumentation and assess the current evidence for patient-matched instrumentation and robot-assisted implantation. They concluded: "For all three technologies, clinical benefits cannot currently be assumed, and further studies are required. Although current technologies to improve alignment during TKA appear to result in intra-operative benefits, their clinical impact remains unclear, and surgeons should take this into account when considering their adoption. Based on these and other studies, a Hayes review published in 2016 concluded there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of Makoplasty for osteoarthritis of the knee.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

S2900 Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

JUVENILE CARTILAGE ALLOGRAFT TISSUE IMPLANTATION

Policy # 481

Implementation Date:4/11/11
Review Dates: 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 9/18/18, 4/17/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/19/24, 4/17/25
Revision Dates: 5/16/17, 5/8/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Normal articular cartilage is a complex tissue composed of matrix, chondrocytes, and water. Cartilage has a poor intrinsic ability to heal itself. When a full-thickness cartilage injury occurs, the joint surface does not usually regenerate on its own. This may result in a defect in the joint surface resulting in pain, effusion, or mechanical symptoms. The defect often becomes more severe over time since even small defects involving the full thickness of articular cartilage may progress to osteoarthritis (a debilitating joint disease marked by degeneration of the articular cartilage).

Initial therapy for joint pain usually involves nonsurgical therapies such as nonsteroidal anti-inflammatories, physical therapy, and intra-articular injections such as corticosteroids and/or viscosupplementation. As the problems persist, or worsen, various surgical procedures are performed in an attempt to slow or reverse the problem. These include arthroscopic debridement, microfracture procedures, and cartilage transfer procedures, such as mosaicoplasty and autologous cartilage implant (ACI). The last procedure, ACI, utilizes a patient's own cells (***autologous***), in an effort to repair damage to articular cartilage with the goal of improving joint function and reducing pain. The procedure involves 2 procedures, the first to collect articular cartilage cells (i.e., chondrocytes) which are shipped to a remote facility for culturing and are then implanted into the cartilage defect in a second procedure. The intent is that the cultured cells will contribute to the regeneration and repair of the articular surface.

As an alternative to ACI, transplants of ***allogenic*** osteochondral plugs have been developed. By using allogenic cells derived from a treated juvenile cartilage source the procedure offers the chance at true hyaline cartilage resurfacing, can be performed in a single procedure, is performed using reusable equipment, and does not require the use of a remote facility to grow the cartilage. However, unlike microfracture, osteochondral grafts are not always amenable to the arthroscopic technique and may require an arthrotomy.

DeNovo NT Natural Tissue Graft (Zimmer, Warsaw, IN) consists of particulate natural articular cartilage with living cells. The tissues are recovered from juvenile donor joints. The procedure is performed arthroscopically in a single-stage procedure with fibrin fixation that eliminates the need for harvesting a periosteal flap or a second procedure to reimplant harvested cartilage cells.

BioCartilage *Cartilage Extracellular Matrix* (Arthrex, Naples, FL) is developed from allograft cartilage and contains the extracellular matrix that is native to articular cartilage including key components such as type II collagen, proteoglycans, and additional cartilaginous growth factors. It is a clot stabilizer that consists of hypothermic dehydrated allograft articular cartilage that is micronized to particles 100–300 µm in size. The principle of BioCartilage matrix is to serve as a scaffold over a microfractured defect, providing a tissue network that can potentially signal autologous cellular interactions, and improve the degree and quality of tissue healing within a properly prepared articular cartilage defect. Microfracture provides

access channels for mesenchymal stem cells (MSCs) present within the subchondral bone to populate a scaffold that has been implanted over the prepared defect.

This is delivered as an injectable after being mixed with equal parts of an autologous blood solution that is typically covered with fibrin glue. Benefits of this technology are its 5-year shelf life and that it can be utilized at the time of the index arthroscopy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover juvenile cartilage allograft tissue implantation, including *DeNovo* NT, BioCartilage, or Prochondrix osteochondral allograft, due to the lack of published literature identifying efficacy, safety, and durability of this procedure. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

In a 2017 technology review, there has been a limited number of studies published related to the DeNovo NT implant since 2011. No studies were identified related to the use of Biocartilage Cartilage Extracellular Matrix in humans. 11 primary studies, and 1 systematic review (Hayes 2016), were identified which met inclusion criteria for this review. Most of these studies were single case studies or small case series with no study evaluating more than 25 members. In total, the number of individuals included in these studies was only 101.

The longest duration of any of the studies was by Tower et al. in 2015, which reported outcomes to a mean follow-up period of 42.8 months, though this study only involved 7 patients. Several studies reported outcomes to 24−28 months. The studies in general reported positive outcomes, though this is not uncommon for small case series and may reflect publication bias.

Five of the 11 studies (36 patients) focused on use of DeNovo NT on ankle/talus defects with the largest study assessing 23 patients.

Given the evidence, it is difficult to feel confident in the conclusions drawn by the authors in the DeNovo NT studies. The complete lack of identifiable published evidence regarding Biocartilage also limits any evidence-based conclusions regarding the efficacy, safety, or durability of this product. This is exemplified by the findings of the recent Hayes review from 2016 which provided a D2 recommendation (their lowest) signifying there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

The updated evidence regarding safety, efficacy, and particularly the durability of osteochondral allografting for osteochondral defects remains limited and focused primarily on the knee. Adequate evidence of efficacy and safety is lacking for any joint beyond the knee except for a few single or small case studies of the ankle.

Select Health

In summary, the lack of published literature related to this technology is concerning and does not allow for the ability to draw any conclusions regarding this technology in treating cartilage defects of the knee and the safety of the procedure in human patients. Multiple articles have been published in animal models, which suggest this technique is safe and results in few problems with implant rejection.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for the indications listed above

CPT CODES

29999 Unlisted procedure, arthroscopy

HCPCS CODES

No specific codes identified

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Juvenile Cartilage Allograft Tissue Implantation, continued

Revision History

Revision Date	Summary of Changes
5/8/25	For Commercial Plan Policy, added the Prochondrix osteochondral allograft as an excluded technology to list of products not covered for this procedure.

Select Health

Select Health

MEDICAL POLICY

LATERAL INTERBODY FUSION (XLIF)/(DLIF)

Policy # 445

Implementation Date:5/26/10

Review Dates: 6/21/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 9/15/18, 8/8/19, 8/20/20, 8/19/21, 7/5/22, 8/22/23, 9/18/24

Revision Dates: 4/11/11, 9/19/18

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The spine is subject to multiple conditions which may lead to pain, functional impairment, and disability. The two most common conditions involving the spine are degenerative disc disease and spinal stenosis.

Spinal stenosis can involve the spine in various locations. Approximately 75% of cases of spinal stenosis occur in the lumbar spine (low back). When symptoms of pain or radiculopathy become severe, and patients have failed conservative therapy, spinal surgery may be performed. Various surgical approaches are commonly used to complete this surgery. The procedures described are commonly referred to as posterior lumbar interbody fusion PLIF, and transforaminal lumbar interbody fusion TLIF.

Recently, lateral Interbody fusion (XLIF) has been developed as a technique for performing spinal fusion surgery. It involves the use of specialized instruments to perform the procedure. During the XLIF procedure, the surgeon positions the patient on their side rather than their back or stomach. Then the surgeon makes a very small incision in the flank, inserts their finger and uses it to push away the peritoneum from the abdominal wall. A second incision is then made directly on the side of the patient. The surgeon then inserts a dilator into this incision. The surgeon inserts a probe through the psoas muscle. Neuromonitoring of the probe used to create the surgical track helps to reduce the potential for nerve damage during this portion of the procedure. The NeuroVision probe is designed to detect the position of the nerves so they are not disturbed during surgery.

Once the muscles are split apart, a retractor (MaXcess) is put into place to give the surgeon direct access to the spine. When this direct access is achieved, the surgeon is then able to perform a standard discectomy with tools designed to cut and remove the disc. Once the disc material is removed, the surgeon is then able to insert the implant through the same lateral incision. This spacer will aid in holding the vertebrae in the proper position, making sure the disc height is correct, and that the spine is properly aligned. This spacer (CoRoent XL) together with the bone graft will allow the spine to fuse. Sometimes, depending on the diagnosis of the patient, additional support is needed to hold the vertebrae in place. In this case, the surgeon may also decide to put in additional implants, such as screws, plates, or rods. A single-level XLIF procedure takes approximately one hour to perform.

Direct Lateral Interbody Fusion (DLIF) is a minimally invasive surgical procedure for treating leg or back pain caused by degenerative disc disease. Unlike traditional anterior or posterior approaches to back surgery, DLIF approaches the lumbar spine through the patient's side. Approaching through the side helps the surgeon to avoid major muscles of the back.

DLIF is recommended for patients of degenerative conditions, deformities, and injuries that can lead to spinal instability. If the instability of the spine exerts pressure on the spinal cord or spinal nerves, it can cause back pain, leg pain, or muscle weakness. These symptoms can extend into the hips, buttocks, and

legs. DLIF is recommended only if these symptoms persist for a long period of time and have failed to be treated with conservative treatments such as rest, exercise, physical therapy, and medication.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers lateral interbody fusion (XLIF) and Direct Lateral Interbody Fusion (DLIF). This is considered a modification to the standard approach for lumbar fusion.

Select Health *does NOT provide additional reimbursement* for lateral interbody fusion (XLIF) or Direct Lateral Interbody Fusion (DLIF). This is considered part of the primary procedure and would not be subject to additional reimbursement on the part of the surgeon or the facility.

SELECT HEALTH MEDICARE (CMS)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A Medical Technology Assessment performed in March 2011 identified 14 studies which met the criteria for inclusion for review. The evidence table below summarizes key clinical endpoints identified from these studies along with the reported rates for the same endpoints reported for posterior lumbar interbody fusion (PLIF), anterior lumbar interbody fusion (ALIF), posterior interbody fusion (PIF), and anterior interbody fusion (AIF).

	Article	OR Time (min)	Blood Loss (mL)	Hospitalization (days)	Major Complications (%)	Failed Fusion/Revisions (%)
XLIF	Yousesef (2010)	199	155	2.6	2.4-6.1	
	Isaacs (2010)	178	50-100	3.8	12.1	
	Karikari (2010)		227.5	4.8		
	Karikari (2011)				7.4	
	Oliveira (2010)	47	23			9.5
	Pimenta (2011)	130	60		0	5.6
	Rodgers (2011)				0.7-6.2	1.8
PLIF	Kunze (2011)				23	15
	Singh (2010)			3.4	33.3	
	Zhao (2011)	115	150	10		
	Matsumoto (2010)	135	66.6			
	Tormenti (2010)					25
ALIF	Li (2010)	126	134	3.3		

Select Health

	Mehren (2010)	50-92	67.3			
	Garg (2010)		143			
	Gumbs (2007)			6		4.1
PIF	Pradhan (2002)	261	634	6.1	4.7	9
AIF	Pradhan (2002)	162	200	4.7	3.4	4

As can be seen from the table with regards to the various clinical endpoints, the updated literature supports XLIF as equivalent if not superior on many of the endpoints. Additionally, the volume of patients studied since the last review included in this review exceeds > 1,400 patients allowing for confidence in the legitimacy of the findings.

Essentially, current literature demonstrates at least equivalent outcomes with XLIF procedures as compared to standard surgical fusion approaches and may be reasonably considered as a viable surgical option for surgical fusion candidates.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

22558 Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar

HCPCS CODES

No specific codes identified

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Select Health

MEDICAL POLICY

LIGAMENT-SPARING KNEE REPLACEMENT SURGERY

Policy # 579

Implementation Date:3/22/16
Review Dates: 2/16/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/13/23, 2/20/24, 12/19/24
Revision Dates: 11/30/17

Related Medical Policies:
#277 Computer-Assisted Orthopedic Surgeries
#431 Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental)
#506 Joint Replacements Using Makoplasty
#598 Total Knee Arthroplasty

Disclaimer:
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Description

Osteoarthritis of the knee is common, affecting almost a tenth of the population over age 55. Osteoarthritis can affect one or more compartments of the knee joint. Of the three compartments of the knee, medial, lateral, and patellofemoral, the medial compartment has the greatest susceptibility to age-related wear and tear. Treatment of OA most commonly begins with rest of the affected joint, bracing, physical therapy, and medications. Steroid injections or viscosupplementation may also be employed. If the condition progresses and becomes unresponsive to conservative measures, they may become candidates for surgical intervention. Most commonly, the patient undergoes a total knee arthroplasty, though, unicompartmental arthroplasty is also performed when only one compartment is involved.

More recently, ligament sparing joint implants have been developed. The implants are composed of femoral and tibial components and maintain the patient's native knee ligaments. Maintenance of the AC and PC ligaments has been suggested to improve joint stabilization post-total knee arthroplasty. The clinical benefits of this joint stabilization are not well-defined in the literature; however, there are several ligament-sparing knees on the market.

The procedure for placement of a ligament sparing knee is similar to that for traditional total knee replacements other than modification of the procedure to allow for retention of the anterior and posterior cruciate ligament.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover ligament-sparing knee replacement surgery as it is considered not medically necessary.

Select Health *does NOT provide additional reimbursement* for the use of ligament-sparing joint implants. This is considered part of the primary procedure and would not be subject to additional reimbursement on the part of the surgeon or the facility.

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SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Current evidence regarding ligament sparing knee implantation is limited. A recent literature review identified no systematic reviews and only 5 primary literature studies were identified which met criteria for review. Papers reported on the outcomes of 2,389 patients (> 2,616 knees). Follow-up periods ranged from 6 months to 23 years. The literature used varying prostheses to preserve the cruciate ligaments.

Only 1 of the 5 papers randomized patients into treatment groups. However, this was only done to illustrate differences in surgical time, not to demonstrate improvements in patient outcomes at follow-up. Most of the literature was retrospective and was primarily designed to demonstrate survivability of the prostheses at follow-up. The current body of literature shows device survivability commensurate with conventional TKA.

Because there have been no head-to-head trials designed to illustrate the benefits of bicruciate-sparing TKA versus conventional TKA in terms of an improvement in patient outcomes, it is difficult to draw meaningful conclusions pertaining to the merits of one method over another. Randomized, controlled, and blinded studies are needed. At best, the literature to date shows non-inferiority of bicruciate-sparing TKA to conventional TKA.

Billing/Coding Information

CPT CODES

27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medical AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27599	Unlisted procedure, femur or knee

HCPCS CODES

C1776	Joint device (implantable)

Key References

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12. Sabouret, P., F. Lavoie, and J.M. Cloutier, Total knee replacement with retention of both cruciate ligaments: a 22-year follow-up study. Bone Joint J, 2013. 95-B(7): p. 917-22.
13. Schroer, W.C., D.M. Stormont, and W.S. Pietrzak, Seven-year survivorship and functional outcomes of the high-flexion Vanguard complete knee system. J Arthroplasty, 2014. 29(1): p. 61-5.
14. Vermesan, D., et al., Reduced operating time but not blood loss with cruciate retaining total knee arthroplasty. J Clin Med Res, 2015. 7(3): p. 171-5.

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MEDICAL POLICY

MENISCAL ALLOGRAFT TRANSPLANTATION

Policy # 208

Implementation Date: 12/9/03
Review Dates: 7/22/04, 6/16/05, 4/29/06, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 8/16/11, 8/16/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24
Revision Dates: 7/22/04

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Meniscal allograft transplantation (MAT) is a surgical treatment for patients who have irreparable tears of the meniscus, or who have undergone previous meniscectomy, and involves grafting a donor meniscus into the knee of the patient.

Meniscal allograft transplantation was introduced as a way to prevent or reverse the joint deterioration that occurs when the meniscus has been destroyed or removed; this joint deterioration often leads to early degenerative osteoarthritis. Many meniscal allograft candidates need to undergo additional procedures, such as anterior cruciate ligament (ACL) repair, performed in conjunction with the allografting to correct knee instability.

Donor menisci are obtained from non-genetically related individuals, usually through commercial suppliers (i.e., organ procurement entities) but also through coroner's offices, hospitals, and morgues. The allografts may be implanted fresh from the cadaver donor, although this presents problems regarding the timing of the surgery and increases the risk of disease transmission. Cryopreservation, in which the graft is treated with a cryoprotectant and frozen after removal, preserves the greatest number of viable fibrochondrocytes and does not distort the graft. However, this method has the disadvantage of expense and the technical problem of freezing and thawing the graft material. Fresh-freezing is another technique used in the preservation of the allograft and has all the advantages of cryopreservation without the freezing and thawing issues. Freeze-drying (lyophilizing) is a method similar to fresh-freezing, except that the graft can be stored indefinitely, transported easily, and kept at room temperature. The disadvantage of freeze-drying is that the graft becomes brittle. There are reports that fresh-frozen grafts produce better results than freeze-dried ones.

After the meniscal transplantation has been completed, the surgeon then performs a realignment osteotomy and/or anterior cruciate ligament (ACL) reconstruction, as required. Immediately following surgery, the patient is usually placed in a locking knee brace for at least 8 weeks, with limited flexion and weight-bearing permitted. During the next 4 weeks, lower extremity strengthening exercises and range of motion (ROM) activities are used to restore normal gait and increase muscle strength. For 3–9 months after transplantation, additional strengthening exercises are performed while activities that place high stress on the menisci are avoided. Thereafter, the patient can gradually return to full activity while continuing to avoid cutting and pivoting motions that might lead to reinjury. Rehabilitation programs may vary according to the surgeon's experience and the procedures performed.

Meniscal Allograft Transplantation, continued

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers meniscal allograft transplantation. This procedure has been shown to improve health outcomes in appropriately selected patient populations.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Overall, the quality of the available evidence from the peer-reviewed literature is poor, consisting only of small case series and limited prospective studies. Patient populations were mixed, including young and older patients ranging in age from 15–55 years who had undergone meniscectomy many years before and had marked arthritic changes, or had sustained a sports injury resulting in a torn meniscus. Outcome measures across studies differed widely, with some using measures of structural change, others using functional rating scales, and still others using a combination of the two. In many instances, outcome was measured by subjective clinical impression alone using pain and general health assessment surveys. Most studies were also flawed by heterogeneity in many other areas, including allograft preservation method, collateral surgery, and location of menisci (medial or lateral). Long-term follow-up was lacking in most of the studies; the longest follow-up reported for any study was 14 years.

There is some evidence that meniscal allografting can be successfully performed and that the graft can become vascularized and incorporated into the joint tissues. However, there is little evidence that meniscal allografting can prevent or slow the degenerative changes in the joint that commonly occur after meniscus injury. In addition, since meniscal allografting is often accompanied by ACL reconstruction or other interventions to improve knee stability, it is difficult to evaluate the effect of meniscal allografting alone on joint pain and disability. The level of performance that can be expected from the meniscus allograft has not been well-defined; in some patients, restoration of knee function involves the ability to perform at a high level of athleticism, while other patients merely need to be able to perform activities of daily living. In addition, the durability of the grafted tissue has not been established; only a limited number of patients have been followed for more than 5 years.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

HCPCS CODES

No specific codes identified

Meniscal Allograft Transplantation, continued

Key References
1. ASERNIP-S. Meniscal Transplantation. 11/2001.
2. BCBS TEC – Meniscal allograft transplantation. 8/1997.
3. Cochrane Database of Systematic Reviews: Howell JR, Handoll HHG. Surgical treatment for meniscal injuries of the knee in adults. Issue 2. Review completed in 2001.
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MEDICAL POLICY

MYOELECTRIC LIMB PROSTHESES

Policy # 695
Implementation Date:6/26/25
Review Dates:
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Amputation presents a significant disability that can have profound physical, psychological, and vocational consequences in a person's life. Trauma is the most common cause of upper limb amputation, with cancer or vascular complications of disease also contributing to amputations. Risk factors associated with amputation include trauma, vascular disease, exposure to chemicals, radiation therapy, infection, diabetes, high blood pressure, and soft tissue or bone tumors. Upper limb amputation includes the removal of the hand, digits, arm, or forearm. Myoelectric prostheses offer a potentially helpful technology for amputees.

Myoelectric prostheses are controlled through the acquisition and processing of the electrical signal that generates muscle contractions. This signal is known as the myoelectric or electromyographic (EMG) signal and may be recorded intramuscularly or from the skin surface. Prosthesis control using the EMG signal is typically accomplished through surface recording from electrodes placed on the skin covering target muscles or muscle groups.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers myoelectric upper limb prostheses and hand prostheses for members with traumatic amputation or congenital absence of upper limb at the wrist or above (e.g., forearm or elbow) when all the following criteria are met:

1. The member has adequate cognitive and neurologic ability to utilize a myoelectric prosthetic; and
2. The member has a traumatic or surgical amputation distal to a trans humeral amputation or congenital limb loss; and
3. The prosthetic replaces all or part of a missing limb; and
4. The prosthetic will help the member regain or maintain function; and
5. The prosthetic needs have been evaluated for the member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician; and
6. The member has the ability to operate the simulator of the computerized prosthetic or microprocessor; and

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7. The member with expected rehabilitation potential undergoes functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation; and
8. Remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic device (usually 3 to 5 muscle groups must be activated to use a computerized hand), no external switch.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Billing/Coding Information

Covered for the indications listed above when criteria are met

CPT CODES

L6925 Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

L6935 Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

L6945 Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

L6955 Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device

Terminal Device

L6880 Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)

L6881 Automatic grasp feature, addition to upper limb electric prosthetic terminal device

L6882 Microprocessor control feature, addition to upper limb prosthetic terminal device

L6890 Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment

L7007 Electric hand, switch or myoelectric controlled, adult

L7008 Electric hand, switch or myoelectric, controlled, pediatric

L7009 Electric hook, switch or myoelectric controlled, adult

L7045 Electric hook, switch or myoelectric controlled, pediatric

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Elbow

L7180 Electronic elbow, microprocessor sequential control of elbow and terminal device

L7181 Electronic elbow, microprocessor simultaneous control of elbow and terminal device

L7190 Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled

L7191 Electronic elbow, child, Variety Village or equal, myoelectronically controlled

Wrist

L6621 Upper extremity addition, flexion/extension wrist, with or without friction, for use with external powered terminal device

L7259 Electronic wrist rotator, any type

Other Additions

L6611 Addition to upper extremity prosthesis, external powered, additional switch, any type

L6629 Upper extremity addition, quick disconnect lamination collar with coupling piece, Otto Bock or equal

L6632 Upper extremity addition, latex suspension sleeve, each

L6677 Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow

L6680 Upper extremity addition, test socket, wrist disarticulation or below elbow

L6682 Upper extremity addition, test socket, elbow disarticulation or above elbow

L6686 Upper extremity addition, suction socket

L6687 Upper extremity addition, frame type socket, below elbow or wrist disarticulation

L6688 Upper extremity addition, frame type socket, below elbow or wrist disarticulation

L6694 Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism

L6695 Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism

L6696 Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism initial only (for other than initial, use code L6694 or L6695)

L6697 Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism initial only (for other than initial, use code L6694 or L6695)

L6698 Addition to upper extremity prosthesis, below elbow/above elbow, lock mechanism, excludes socket insert

L7400 Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)

L7401 Addition to upper extremity prosthesis, above elbow disarticulation, ultralight material (titanium, carbon fiber or equal)

L7403 Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material

L7404 Addition to upper extremity prosthesis, above elbow disarticulation, acrylic material

L8465 Prosthetic shrinker, upper limb, each

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Key References
1. Hayes, Inc. Evidence Analysis Research Brief. Myoelectric Multigrip Prosthetic Hands for Upper Extremity Amputation. Nov. 16, 2023.
2. Powell, M.A. & Thakor, N.V. A Training Strategy for Learning Pattern Recognition Control for Myoelectric Prostheses. *J Prosthet Orthot*. 2013 Jan 1;25(1):30-41. doi: 10.1097/JPO.0b013e31827af7c1. PMID: 23459166; PMCID: PMC3581303.

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

PARTIAL KNEE REPLACEMENT/RESURFACING (UNICOMPARTMENTAL AND BICOMPARTMENTAL)

Policy # 431

Implementation Date: 12/27/09
Review Dates: 4/25/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24
Revision Dates: 5/19/11, 2/14/12, 10/18/24

Related Medical Policies:
#277 Computer-Assisted Orthopedic Surgeries
#506 Joint Replacements Using Makoplasty
#511 Custom Components for Total Knee Replacement (TKA)
#579 Ligament-Sparing Knee Replacement Surgery
#598 Total Knee Arthroplasty

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Osteoarthritis is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. It is the most common form of arthritis, affecting over 20 million people in the United States. Most patients with osteoarthritis of the knee can manage their symptoms without medical treatment, but a large proportion of those referred to orthopedic surgeons have debilitating disease, presenting chiefly with pain and stiffness. Classically, the pain depends on activity, and in severe cases not only limits the distance patients can walk and their daily activities, but also disrupts sleep.

There are 3 compartments to the knee: the medial (inside) compartment, the lateral (outside) compartment, and the patellofemoral (kneecap) compartment. Osteoarthritis can affect one or more compartments of the knee joint. When a knee has been damaged extensively, total knee replacement surgery, in which the entire knee is replaced with a prosthetic joint, may be required.

When only the medial or lateral compartment of the knee has been damaged, partial knee replacement/resurfacing is a surgical procedure for helping to relieve osteoarthritis. With partial knee replacement/resurfacing, only the damaged surface of the knee joint is replaced, helping to minimize trauma to healthy bone and tissue.

There are 2 options for partial knee replacement/resurfacing. In unicompartmental knee replacement/resurfacing, the femur and tibia in the medial or lateral compartment are reshaped to facilitate implantation of a prosthetic knee joint in a single compartment. In bicompartmental knee replacement/resurfacing, the implant is placed in 2 of 3 compartments, though, most commonly it is used in the medial and lateral compartments. Bicompartmental replacement surgery represents an intermediate procedure between unicompartmental knee replacement and total knee replacement. Bicompartmental knee replacement can replace only the inside (medial) joint and kneecap joint (patello-femoral) joint.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health

Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental), continued

Select Health covers unicompartmental knee resurfacing/replacement for the treatment of osteoarthritis in the knee when the following criteria are met:

Must meet either criteria 1 or 2.

1. Advanced joint disease demonstrated by all the following:
    a. Radiographic supported evidence or when conventional radiography is not adequate, magnetic resonance imaging (MRI) and/or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed) supported evidence (subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis); **and**
    b. Pain or functional disability from injury due to trauma or arthritis of the joint; **and**
    c. Unsuccessful conservative therapy (non-surgical medical management) lasting at least 12 weeks that is clearly addressed in the pre-procedure medical record. Includes one or more of the following:
        i. Anti-inflammatory medications or analgesics, or
        ii. Flexibility and muscle strengthening exercises, or
        iii. Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care], or
        iv. Weight reduction as appropriate, or
        v. Therapeutic injections into the knee as appropriate.
    d. If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
    e. BMI is less than 45.
    f. Hemoglobin A1C (Hgb A1C) is less than 8 in diabetics.
    g. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping of any other substances, must be discontinued for at least four weeks prior to knee arthroplasty.
2. The patient has severe deformity, pain or significant disability with interference in activities of daily living, and the surgeon determines that nonsurgical medical management would be ineffective or counterproductive due to:
    a. Failure of a previous osteotomy; or
    b. Distal femur fracture; or
    c. Malignancy of the distal femur, proximal tibia, knee joint or adjacent soft tissues; or
    d. Failure of previous unicompartmental knee replacement; or
    e. Avascular necrosis of the knee; or
    f. Proximal tibia fracture

Select Health will NOT cover unicompartmental knee resurfacing/replacement if any of the following contraindications or relative contraindications are present:

a. Active infection of the knee joint or active systemic bacteremia
b. Active urinary tract or dental infection
c. Any skin infection which may cause an adverse event
d. Rapidly progressive neurological disease

e. Insufficiency of extensor mechanism/quadriceps
f. Any process that is rapidly destroying bone
g. Neurotrophic arthritis

Select Health does NOT cover unicompartmental knee resurfacing/replacement for any other indication as it is considered experimental/investigational.

Select Health does NOT cover robotic-assisted unicompartmental knee resurfacing/replacement such as makoplasty or RIOS, as there is a lack of evidence to demonstrate meaningful clinical differences in outcomes for patients undergoing TKA using these technologies; use of these technologies is considered experimental/investigational.

Select Health will NOT reimburse additionally for custom knee components (see medical policy #511) as current evidence has not demonstrated any meaningful clinical differences in outcomes for patients undergoing TKA compared to use of standard components. If the procedure otherwise meets criteria for TKA, the procedure will be covered, but the components will only be reimbursed at the standard component reimbursement level.

Select Health does NOT cover bicompartmental knee resurfacing/replacement for the treatment of osteoarthritis in the knee due to the lack of literature demonstrating the efficacy, safety, and durability of bicompartmental knee resurfacing/replacement.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Unicompartmental

In reviewing partial knee replacement/resurfacing, several systematic reviews were identified. The first, by Hayes, was published in 2002. The reviewers determined a "moderate level of evidence" supports replacement of a single condylar compartment as treatment for osteoarthritis or osteonecrosis. The review noted that unicompartmental knee replacement provides pain relief and improvements in joint function comparable to total knee replacement. However, data on prosthesis survival were conflicting. A 'B' rating was given for this indication, specifically, in patients in whom "damage to the joint is completely or almost completely confined to the medial or the lateral compartment of the knee." Unicompartmental knee arthroplasty (UKA) was not recommended in patients with knees with multiple affected compartments, knees with certain deformities, or in patients with rheumatoid arthritis; 'D' ratings were given for these indications.

The Australian Safety and Efficacy Register of New Interventional Procedures reviewed the procedure in 2005 and offered similar conclusions, namely that UKA appears to be at least as efficacious as total knee arthroplasty in terms of knee function and post-operative pain. Knee survival relative to total knee

arthroplasty was less certain, in contrast. Griffin et al.'s 2007 review offered virtually identical conclusions: "UKA is considered at least as safe as TKA and HTO. For function, UKA appears to be at least as efficacious as TKA and HTO. The survival of UKA compared with TKA and HTO cannot be determined based on the available evidence."

Several studies have also examined the cost-effectiveness of UKA versus TKA. Koskinen et al. reviewed outcomes from 1,886 primary UKAs (3 designs) and 48,607 primary TKAs in Finland and found that UKAs had a 60% survival rate while TKAs an 80% survival rate over 15 years. The authors concluded that costs saved by lower implant prices and shorter hospital stays with UKA did not cover the costs of the extra revisions that resulted from shorter survival.

Soohoo et al., in contrast, developed a decision model using quality adjusted life years (QALYs) as the unit of effectiveness. The model determined that UKA is cost-effective, only when prosthesis survival falls within three to four years of the assumed survival of TKA. If this assumption is met, UKA is a cost-effective choice as it results in incremental gains in effectiveness at a cost of less than $50,000 (in 1998, United States dollars) per quality-adjusted life year gained. Similarly, Slover et al. developed a Markov decision model based on Norwegian outcome data using QALYs as the effectiveness outcome. UKA was cost-effective when the annual probability of revision was < 4%.

The following table reports outcomes from the literature on unicompartmental knee replacement, highlighting survival outcomes. These data suggest that survival outcomes within the first 15 years for UKA are perhaps somewhat lower than that for TKA. There is heterogeneity across studies, as there are few trials that directly compare survival outcomes between partial and total knee replacement, particularly over time.

Outcome Survival	Partial Knee Replacement Mean (range)	Total Knee Replacement
5-year	90.6% (74.7–97)	98%
10-year	90.6% (74.7–97)	90%
15-year	82.6% (60–95.7)	84%–98%
20-year	83.08%	
25-year	80%	
KSS-Clinical	84.06(72–94)	90.3
KSS-Functional	74.04 (53–93)	
WOMAC Score	70.22 (20–90)	
HSS	92 (90–94)	

KSS- Knee Society Score: clinical score incorporates pain, stability and ROM; KSS function score rates ability to walk and climb stairs and perform activities of daily living (range: 0-100).
WOMAC- Western Ontario and McMaster Universities Osteoarthritis Index: measure dimensions of pain, stiffness and function in knee and hip osteoarthritis, and the higher the score the more severe impairment (range = 0-100)
HSS- Hospital for Special Surgery knee score: Composite score determined based on pain, function, range of movement, muscle strength, flexion deformity, and instability (range = 0-100)

Overall, a growing body of literature suggests that UKA is an effective alternative to TKA for treatment of knee osteoarthritis. Questions remain about the long-term durability of implants, and additional longitudinal data are needed to address this issue, particularly in younger people who may be more likely to undergo this procedure. Nevertheless, the procedure is safe and appears to produce outcomes similar to those associated with TKA.

Bicompartmental
In 2009, the data on bicompartmental knee replacement was so sparse, that adequate literature related to these procedures was inadequate to evaluate.

An April 2011 literature review identified a follow-up article 5–23 years after bicompartmental knee arthroplasty. Parratte et al., due to renewed interest in bicompartmental arthroplasty, reported their mid- and long-term results of combined medial and lateral UKA and combined medial UKA and patellofemoral arthroplasty. The data suggest this concept improves function and restores limb alignment restoration for moderate deformities. A relatively high revision rate was observed compared to TKA series and these failures may be related to early generation of implant and limited instrumentation. In contrast, they observed few cases of progressive OA confirming the indication for bicompartmental arthroplasty in case of bicompartmental arthritis of the knee. They believe partial knee replacement with less bone loss and

the potential for greater function an important concept. The concept with new implants and appropriate instrumentation will require confirmation using contemporary objective tools to confirm its usefulness.

In January 2012, a Medical Technology Assessment was performed to reassess the literature related to bicompartmental replacement/resurfacing. This review identified 1 systematic review and 3 peer-reviewed journal articles not reviewed previously. In the systematic review, Callahan et al. performed a meta-analysis of 18 studies (884 patients) on bicompartmental knee replacement. The group found an overall complication rate of 30% with a revision rate of 7.2% after 3.6 years. They concluded that improvements in patient outcomes are likely more correlated with proper patient selection than with improvements in technique or device quality. However, it is important that this was published in 1995 because significant modifications to surgical technique and implant design in the last 17 years could easily cause the study conclusion to no longer be applicable; also, no information is given about patient selection criteria.

Though only 3 primary pieces of literature have been published since the 2009 review, each provides some insight into the answers to some of the key questions related to bicompartmental knee replacement, especially as it compares to total knee replacement. For instance, the study by Confalonieri et al. compared bicompartmental knee replacement with total knee arthroplasty. Though the study size was limited, and the duration of follow-up was also short at just 4 years, the study demonstrated equivalence for bicompartmental knee arthroplasty is at least as good as total knee replacement in maintaining higher level function as defined by WOMAC function scores (a measurement of pain, stiffness, and physical function). This implies that the issue of whether total knee replacement or bicompartmental knee replacement is ultimately a question of cost-effectiveness and revision rates of the two procedures.

Durability of the replacement was assessed in the study by Parratte et al. This study found that after a follow-up time of 12 years, 22% of the 100 knees that underwent bicompartmental knee arthroplasty experienced device failure. The group concluded, the high revision rate after these failures, may be related to any one of several factors including patient selection and component malalignment, issues commonly referred to throughout the published literature. Similarly, Morrison et al. noted that though bicompartmental knee replacement patients had less pain and better physical function, these findings did not persist past three months after the operation.

It was concluded, there remains a paucity of literature available to answer key questions related to the efficacy, safety, durability, cost-effectiveness, and complication and revision rates for bicompartmental knee replacements. No data exists delineating patient selection criteria (age, extent of OA, previous knee surgery, etc.). Only 1 of the 4 studies showed comparable outcomes of bicompartmental knee replacement to those of total knee replacement. The 2 other studies show significant post-operative device failure, recurrence of pain, and loss of function.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

Unicompartmental Knee Replacement/Resurfacing

27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy

Not covered: Investigational/Experimental/Unproven for this indication

Bicompartmental Knee Replacement/Resurfacing

27599	Unlisted procedure, femur or knee

HCPCS CODES

C1776	Joint device (implantable)
C8003	Implantation of medial knee extraarticular implantable shock absorber spanning the knee joint from distal femur to proximal tibia, open, includes measurements, positioning and adjustments, with imaging guidance (eg, fluoroscopy)

Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental), continued

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Revision History

Revision Date	Summary of Changes
10/18/24	For Commercial Plan Policy, incorporated the same criteria as listed in medical policy #598 (Total Knee Arthroplasty), to align the requirements for unicompartmental knee resurfacing/replacement procedures.

Select Health

MEDICAL POLICY

PERCUTANEOUS DISC DECOMPRESSION PROCEDURES (NUCLEOPLASTY, PERCUTANEOUS MANUAL, AUTOMATED, LASER DISCECTOMY, AND ENDOSCOPIC)

Policy # 209

Implementation Date: 12/1/03

Review Dates: 11/18/04, 2/16/06, 2/15/07, 12/20/07, 10/23/08, 10/22/09, 5/19/11, 8/16/11, 8/16/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/15/18, 8/8/19, 8/20/20, 7/29/21, 7/5/22, 8/22/23, 9/18/24

Revision Dates:

Related Medical Policies:

#622 Cervical and Spinal Lumbar Fusion With or Without Spinal Decompression

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Percutaneous disc decompression procedures include percutaneous manual discectomy, percutaneous automated discectomy (also referred to as percutaneous nucleotomy), percutaneous laser discectomy, nucleoplasty, and endoscopic. These surgical procedures are proposed for use as a less invasive alternative to open surgical procedures for the treatment of herniated intervertebral discs. All the procedures decrease the volume or remove some of the nucleus pulposus, the gelatin-like substance found in the center of each intervertebral disc. This is thought to decompress the disc and reduce the pressure on the disc and the surrounding nerve roots. Generally, these procedures are performed as outpatient procedures under local anesthesia, with intravenous sedation as needed.

To perform these procedures, a large-bore needle or cannula is inserted through the skin and into the intervertebral disc under fluoroscopic guidance. In laser discectomy, laser energy vaporizes and coagulates the nucleus pulposus tissue; continuous suction removes the smoke that is created. In percutaneous manual or automated discectomy, cutting and/or suction instruments are used to remove some or all the disc material. In nucleoplasty, a radiofrequency device is inserted that first ablates disc material and creates several channels that are intended to reduce the amount of disc material, then the tissue is thermally coagulated with coblation technology as the catheter is pulled back.

Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, which is then followed by visualization of the working space and instruments through an endoscope, and aspiration of disc material. Endoscopic discectomy is also referred to as arthroscopic discectomy. Such procedures include MILD (also known as image-guided minimally invasive lumbar decompression), which is a percutaneous spinal decompression procedure used as a treatment of spinal stenosis. The MILD procedure is performed with the assistance of a contrast medium and fluoroscopic guidance. According to the manufacturer: "*mild* Devices are designed to access the interlaminar space from the posterior lumbar spine, enabling the user to remove small portions of the lamina and preferentially resect and debulk the thickened ligamentum flavum, accomplishing a lumbar decompression." This procedure does not involve a discectomy and can be performed on an outpatient basis under local anesthesia (Vertos Medical Mild Device Kit).

Summary of Research

In 2013, a task force of the American Society of Interventional Pain Physicians (ASIPP) published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence

Percutaneous Disc Decompression Procedures (Nucleoplasty, Percutaneous Manual, Automated Laser Discectomy, and Endoscopic), continued

for percutaneous automated discectomy and for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of "limited" is defined as: evidence insufficient to assess effects on health outcomes because of limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed, when indicated, but did not provide any patient selection criteria. The recommendation was not graded either; the authors indicated only that this recommendation was based on: "… individual experience and the large amount of literature." Therefore, this recommendation is not considered evidence-based.

The 2012 practice guidelines from the North American Spine Society (NASS) on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that percutaneous endoscopic discectomy or percutaneous automated discectomy could be considered for the treatment of these patients. Though, both recommendations were 'grade C' recommendations (based on poor quality evidence). Likewise, a separate recommendation stated that evidence is insufficient to recommend for, or against, use of percutaneous automated discectomy compared with open discectomy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover percutaneous disc decompression procedures, including but not limited to: nucleoplasty, percutaneous manual, automated, laser discectomy, and endoscopic. Current available evidence does not permit conclusions regarding the effectiveness or durability of these procedures compared with the standard surgical treatments for lumbar disc disease. This meets the plan's definition of investigational/experimental.

Select Health does NOT cover percutaneous image-guided lumbar decompression. The lack of evidence related to the long-term efficacy and safety of this procedure, and a complete lack of comparative evidence related to this procedure as it compares to standard surgical intervention for spinal stenosis, leads this therapy to be unproven. This meets the plan's definition of investigational/experimental.

Excluded procedures include, but are not limited to:

1. Minimally invasive lumbar decompression (MILD)
2. Endoscopic decompression
3. Automated percutaneous lumbar discectomy (APLD)
4. Percutaneous discectomy probe, the DeKompressor procedure
5. Percutaneous laser discectomy

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health

Percutaneous Disc Decompression Procedures (Nucleoplasty, Percutaneous Manual, Automated Laser Discectomy, and Endoscopic), continued

Summary of Medical Information

A variety of minimally invasive techniques have been investigated over the years as treatments of low back pain related to disc disease. Techniques can be broadly divided into those techniques that are designed to remove or ablate disc material, and thus, decompress the disc, or those that are designed to alter the biomechanics of the disc annulus. The former category includes chymopapain injection, automated percutaneous lumbar discectomy, laser discectomy, and most recently, discectomy using radiofrequency energy, referred to as a disc nucleoplasty. Techniques in the latter category include intradiscal electrothermal annuloplasty (the IDET procedure) or percutaneous intradiscal radiofrequency thermocoagulation (PIRT).

The primary outcome for disc decompression procedures is pain relief. As such, randomized, controlled trials are particularly important to determine whether the pain relief associated with the procedure exceeds the expected placebo response. A search of the literature based on the MEDLINE database did not identify any controlled trials. One cadaver study and several case series were identified.

Twelve prospective studies of APLD (automated device), with average follow-up of 6 months resulted in an average success rate of 75%. Eight prospective studies of MLPD (manual) with average follow-up of 19 months resulted in 83% success rates. Retrospective analyses included 20 studies of APLD, with average follow-up of 6 months, and a success rate of 75%. Retrospective analyses of MPLD numbered 12, with 25 months average follow-up, resulting in 72% success rate. The outcomes of over 3,200 PLD procedures (automated and manual) report reasonable success rates and minimal complications (< 1%). However, the quality of this evidence is poor. Only 4 studies (n = 187) compared PLD to a control group. The lack of validated outcomes measure, and incomplete reporting of their application, before and after treatment, challenge the conclusions of this study. Uncontrolled studies using subjective measurements are prone to overestimate a treatment's effectiveness. It is unknown how many of these patients would have done well by adhering to conservative therapy. These serious biases do not permit conclusions to be drawn about health outcomes of patients undergoing PLD for herniated disks.

Kleinpeter et al. reviewed the use of percutaneous procedures vs. open procedures. 326 patients limited to disease involving L4−5 discs only were enrolled. Using strict selection criteria, only 13 patients (4%) out of 326, met criteria for percutaneous endoscopic lumbar discectomy (PELD); the rest underwent an open procedure. Of these, only 8 were completely suited to PELD and underwent this procedure. Five of these patients (63%) required open definitive surgery within the first month post-op, while only 4% (14 patients) of the 313 patients who underwent an open procedure required additional surgery. Authors concluded that the PELD method cannot be considered a substitute or alternative to traditional surgery, in most cases.

Chatterjee compared automated percutaneous lumbar discectomy (APLD) compared to lumbar microdiscectomy for radiographically determined small-contained lumbar discal herniations (n = 71). Macnab outcome classification was used at 3 weeks, 2 months, and 6 months out. The same surgeon performed each procedure. In the APLD group, only 9/31 patients had satisfactory results, compared to 32/40 (80%) of those who underwent microdiscectomy. In patients who first underwent APLD and later underwent microdiscectomy, final success was only 65%. The authors concluded that APLD is ineffective in the treatment of contained lumbar disc herniation for this patient group.

Stevenson et al. demonstrated that automated percutaneous lumbar discectomy was less cost-effective than microdiscectomy.

In the US Department of Health and Human Services/Agency for Health Care Policy and Research Clinical Practice Guideline on Acute Low Back Pain in Adults-Quick Reference Guide for Clinicians, it is stated that back surgery is not necessary in the majority of patients. In the first 3 months of acute low back symptoms, surgery is considered only when serious spinal pathology or nerve root dysfunction is obviously due to a herniated lumbar disc. The presence of a herniated disc on imaging does not, in and of itself, imply nerve root dysfunction, as studies of asymptomatic adults commonly demonstrate herniation. Nerve root decompression should be considered if all the following exist: sciatica is both severe and disabling, and persists without improvement for over 4 weeks (or is extremely progressive); and there is strong physiologic evidence of dysfunction of a specific nerve root associated with the corresponding area on imaging. Many patients with strong clinical findings of nerve root dysfunction from disc herniation will recover activity tolerance within a month. There is no evidence suggesting that delaying surgery for 1 month worsens outcomes. With or without surgery, 80% of patients with obvious surgical indications

Percutaneous Disc Decompression Procedures (Nucleoplasty, Percutaneous Manual, Automated Laser Discectomy, and Endoscopic), continued

eventually recover. Surgery benefits fewer than 40% of those with questionable findings and increases the chance of future procedures with higher complication rates. This data is inadequate to permit scientific conclusions on the safety and effectiveness of the procedure.

A technology assessment from the Hayes group in June 2002 concluded that all the studies related to percutaneous discectomy had serious methodologic flaws, including lack of controls or comparison to standard therapy—and all but one study, which had a mean follow-up of 7 years, had a relatively limited mean period of follow-up, ranging from 13–43 months. These methodologic flaws preclude definitive conclusions regarding the efficacy of laser discectomy. Another Hayes report in August 2005 on the Stryker Dekompressor, a device used in percutaneous discectomy, could only locate a single trial (n = 10) in which this device was identified as the one used to treat patients. The summary concluded that there is insufficient evidence to assess the safety and efficacy of the device and that adoption or use could not be recommended at present.

In a Cochrane review completed in 2005, they noted 11 of 27 trials were of different forms or techniques of surgical discectomy. There was only 1 trial that compared surgical treatment of lumbar disc prolapse with any form of natural history, conservative treatment, or placebo. This review did not find any completed RCT of laser discectomy.

Finally, in 2004, the Washington State Department of Labor completed a review of currently available techniques for percutaneous discectomy. They noted that no randomized trials have been conducted to study the efficacy of either percutaneous laser discectomy or nucleoplasty. One study of laser discectomy included a historical comparison group of patients who underwent open discectomy. The authors noted that the comparison group generally showed stronger results, but the laser group would have had a higher success rate if compensation patients had been excluded from the study. Because only case series studies have been conducted to examine the efficacy of these 2 procedures, they concluded that these therapies are still considered investigational.

Billing/Coding Information
Not Covered: Investigational/Experimental/Unproven for this indication
CPT CODES

0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	; lumbar
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)
62292	Injection procedure for chemonucleolysis including discography, intervertebral disc, single or multiple levels, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and or/excision of herniated intervertebral disc; each

Percutaneous Disc Decompression Procedures (Nucleoplasty, Percutaneous Manual, Automated Laser Discectomy, and Endoscopic), continued

	additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system [when specified as percutaneous decompression or laser procedures of cervical or thoracic spine]
77002	Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device)

HCPCS CODES

C2614	Probe, percutaneous lumbar discectomy
S2348	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

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Percutaneous Disc Decompression Procedures (Nucleoplasty, Percutaneous Manual, Automated Laser Discectomy, and Endoscopic), continued

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MEDICAL POLICY

PERCUTANEOUS NEEDLE TENOTOMY FOR THE TREATMENT OF TENDINOPATHIES

Policy # 421

Implementation Date:8/13/09

Review Dates: 8/19/10, 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/18/23, 2/20/24, 12/19/24

Revision Dates: 4/13/23

Related Medical Policies:

#592 Percutaneous Tenotomy or Percutaneous Fasciotomy (Tenex Health Tx System or TX1, TX2)

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Tendinopathy is a generic term used to describe a common clinical condition affecting the tendons, which causes pain, swelling, or impaired performance. Tendinopathy usually results from repeated small tears or degenerative changes (sometimes with calcium deposits) that occur over years in the tendon. Tendinopathy most commonly affects tendons associated with the shoulder (rotator cuff), the tendon of the long head of the biceps muscle (bicipital tendon), flexor carpi radialis or ulnaris, flexor digitorum, popliteus tendon, Achilles' tendon, and the abductor pollicis longus and extensor pollicis brevis, which share a common fibrous sheath (the resulting disorder is de Quervain's syndrome but can involve any tendon subject to repetitive use or strain.

Percutaneous needle tenotomy, sometimes called "dry needling," involves injecting local anesthetic and then using a needle under ultrasound guidance to fenestrate tendonotic tissue, break-up calcifications, and if needed, abrade the surface of underlying bone. An injection of corticosteroid and bupivacaine is performed following the procedure. Patients then perform passive stretching and standard physical therapy exercises at home. This procedure is also commonly performed using an injection of platelet rich plasma to promote healing.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers percutaneous needle tenotomy for the treatment of tendinopathies with barbotage of the shoulder for calcific tendinitis of the rotator cuff.

Select Health DOES NOT cover percutaneous needle tenotomy for the treatment of tendinopathies for other areas, as this is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their

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search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Select Health identified 7 studies for inclusion of percutaneous needle tenotomy for review. (Note: as the primary method of tenotomy being used locally is dry needling, articles on percutaneous longitudinal tenotomy [stab tenotomy] were excluded). The literature consists primarily of single case series examining the outcomes of tenotomy pre-post for lateral epicondylitis. One study evaluated medial epicondylitis and one evaluated patellar tendinosis. There are no comparative studies and none of the studies were blinded. Duration of follow-up varied, the longest being 28 months. These studies all conclude that dry needling is safe and effective for treating a variety of tendinopathies.

In most studies, the procedure was combined with injection of autologous blood or corticosteroids, which limits conclusions about the efficacy of needle tenotomy itself. Connell et al. noted this limitation in their study of 35 patients with lateral epicondylitis who underwent dry needling of the tendon and injection with autologous blood. At baseline, 4 weeks, and 6 months, patients completed pain ratings using Nirschl and Visual Analogue Scores (VAS). Two patients reported no improvement in pain and went on to have surgical repair of the elbow. In the remaining patients, the median VAS pain score decreased from 9 to 6 at four weeks ($p < 0.001$) and to zero ($p < 0.001$). The Nirschl score also decreased significantly from a median of 6 to 4 at 4 weeks ($p < 0.001$) to 0 at 6 months ($p < 0.001$). In their conclusions, the authors note that outcomes of dry needling alone have not been reported in the literature. Based on their clinical experience, they estimate that the procedure alone results in satisfactory outcomes in 60% of patients.

In McShane et al., 58 patients (61 elbows) with lateral epicondylitis were dry needled and injected with a solution of corticosteroid and an anesthetic. Outcomes were measured using the Patient-Rated Forearm Evaluation Questionnaire, which uses a 10-point visual numeric scale to assess pain levels and difficulty performing specific activities. At the average 28-month follow up, 48 (81.4%) of 61 elbows were reported as having no pain at rest over the past week. Fifty-five (93.2%) of 59 elbows never had pain that woke the patients at night. Over the past week, the worst level of pain was “none” or “mild” in 44 (78.5%) of 56 elbows. Functionally, 86.3% (422/489) of the responses were “no difficulty,” 8% “mild difficulty,” 2.2% “moderate difficulty,” and 3.5% “unable to do.” Overall, 63.6% (35/55) of respondents reported excellent outcomes, 16.4% good, 7.3% fair, and 12.7% poor. To summarize, a small body of literature suggests that dry needling in conjunction with injection of autologous blood or corticosteroids is effective in treating lateral epicondylitis. The evidence for treating other tendinopathies is positive but sparse. Overall, patients who undergo the procedure experience reductions in pain and improved functioning. The use of autologous blood and corticosteroids makes it impossible to determine the independent effect of dry needling alone. Also, none of these studies was blinded and there are no comparative trials from which to draw firm conclusions about the efficacy of this treatment. The pre-post design utilized by all studies is a weak method for testing treatment effects as it is susceptible to regression toward the mean. Blinded comparative studies are particularly important in studies on pain to rule out the placebo effect. Thus, larger, blinded, comparative studies are required to determine whether dry needling can be considered a valid alternative in the treatment of tendinopathy.

Billing/Coding Information

Covered: For the indications listed above

CPT CODES

20999	Unlisted procedure, musculoskeletal system, general

Percutaneous Needle Tenotomy for the Treatment of Tendinopathies, continued

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
26060	Tenotomy, percutaneous, single, each digit
27000	Tenotomy, adductor of hip, percutaneous (separate procedure)
27306	Tenotomy, percutaneous, adductor or hamstring; single tendon (separate procedure)
27307	Tenotomy, percutaneous, adductor or hamstring; multiple tendons
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia
27606	Tenotomy, percutaneous, Achilles tendon (separate procedure); general anesthesia
28010	Tenotomy, percutaneous, toe; single tendon
28011	Tenotomy, percutaneous, toe; multiple tendons
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
P9020	Platelet-rich plasma, each unit

HCPCS CODES

J1020	Injection, methylprednisolone acetate, 20 mg
J1030	Injection, methylprednisolone acetate, 40 mg
J1040	Injection, methylprednisolone acetate, 80 mg
J1100	Injection, dexamethasone sodium phosphate, 1 mg
J3301	Injection, triamcinolone acetonide, not otherwise specified, 10 mg

Key References

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Select Health

Percutaneous Needle Tenotomy for the Treatment of Tendinopathies, continued

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MEDICAL POLICY

PERCUTANEOUS TENOTOMY OR PERCUTANEOUS FASCIOTOMY (TENEX HEALTH TX SYSTEM OR TX1, TX2)

Policy # 592

Implementation Date: 11/30/16
Review Dates: 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/18/23, 2/20/24
Revision Dates:

Related Medical Policies:
#421 Percutaneous Needle Tenotomy for the Treatment of Tendonopathies
#120 Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions

Description

Tendonitis is a type of soft tissue injury that is very common in athletes and active individuals. Symptoms can include painful movement and localized joint stiffness. In moderate-to-severe cases, patients might describe a burning that surrounds the whole joint around the inflamed tendon. Other common symptoms are swelling, warmth, and redness, or even a visible knot. Pain is typically worse during, and immediately, after activity. Periods of stiffness can last a day or two. If the symptoms of tendonitis persist beyond the acute phase (4–6 weeks), it is called tendinosis. Tendinosis leads to decreased tensile strength and a higher chance of tendon rupture.

The standard treatment for chronic tendonitis/tendinosis is rest/activity modification, anti-inflammatories, ice/heat and physical therapy including eccentric and heavy load exercises and stretching. Several other less proven modalities are often also employed including prolotherapy, sclerotherapy, dry needling, use of autologous platelet rich plasma, acupuncture, low level laser therapy, and extracorporeal shock wave therapy. Many of these therapies lack strong evidence of efficacy, and in some instances, have been shown to be no better than placebo.

A different approach uses ultrasonic energy to disrupt "scar" tissue, thus, freeing the tendon and reducing pain. Tenex FAST procedure is a minimally invasive method to identify and remove pain generating scar tissue from tendons in the elbow, knee, ankle, foot, and shoulder, which can occur due to various musculoskeletal conditions such as tennis elbow, golfer's elbow, jumper's knee, plantar fasciitis, swimmer's shoulder, and Achilles' tendonitis. The procedure is performed under local anesthesia to numb the affected area. The microtip of the TX1 tissue removal system, the size of a toothpick, is inserted into the affected area under ultrasound guidance. The tip releases ultrasonic energy which breaks and emulsifies the scar tissue which is then aspirated. It takes about 15 minutes, and the tiny opening is covered with an adhesive bandage with no sutures required. Tenex Health received FDA 510(k) clearance of the TX1 Tissue Removal System on March 9, 2011.

On March 29, 2016, Tenex Health won FDA 510(k) clearance for its TX2 MicroTip designed to treat tendinosis of the shoulder and hip. The TX2 differs from the TX1 in that it has a longer needle. The length of the device allows physicians to complete percutaneous tenotomies in regions previously not accessible by the earlier, shorter version. The TX2 MicroTip is a disposable device that uses ultrasonic energy to cut and remove targeted soft tissue.

Select Health

Percutaneous Tenotomy or Percutaneous Fasciotomy (TENEX Health TX™ System or TX1, TX2), continued

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover percutaneous tenotomy or percutaneous fasciotomy (Tenex Health TX System or TX1, TX2), as it is considered unproven in the management of chronic tendonitis/tendinosis.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

As of March 2016, no prospective randomized control trials had yet been published on tendonotomy procedures using the Tenex device. Only three case series were identified on the use of the TX1 device for the treatment of elbow tendinopathy and plantar fasciitis were identified.

In a 2013 case series study, Koh and colleagues explored the safety, tolerability, and early efficacy of the TX1 device in the treatment of recalcitrant lateral elbow tendinopathy. Twenty patients who failed nonoperative therapy underwent the ultrasonic microresection procedure using the TX1 device through a stab incision under local anesthesia. Outcome parameters included patient satisfaction; visual analog scale (VAS) pain scores; Disabilities of the Arm, Shoulder and Hand (DASH) scores at 1, 3, 6, and 12 months; and ultrasound assessment at 3 and 6 months.

A significant improvement in VAS score (from 5.5 to 3.3; $P < .001$) occurred by 1 week, and significant improvements in both DASH-Compulsory (from 21.7 to 11.3; $P = .001$) and DASH-Work (from 25.0 to 6.3; $P = .012$) scores occurred by 1 month. The VAS scores further improved at 3, 6, and 12 months (from 2.0 to 1.0 to 0.50; $P = .003$ and .023). The DASH-Compulsory score improved significantly from 3 to 6 months (from 8.6 to 4.6; $P = .003$), and both the DASH-Compulsory and DASH-Work scores were sustained by 12 months. Sonographically-reduced tendon thickness (19 patients), resolved or reduced hypervascularity (17 patients), and reduced hypoechoic area (18 patients) occurred by 6 months. Nineteen of the 20 patients (95%) expressed satisfaction with the procedure, with 9 patients being very satisfied with their overall experience at 6 months after the procedure, 10 patients somewhat satisfied, and 1 patient neutral. The authors concluded that ultrasonic microresection of diseased tissue with the TX1 device provides a focally directed, safe, specific, minimally invasive, and well-tolerated treatment for recalcitrant lateral elbow tendinopathy in an office-based or ambulatory surgical setting with good evidence of some level of efficacy in 19 of 20 patients (95%) that is sustained for at least 1 year. The limitations of this study are that it involved a small number of subjects, was uncontrolled, and follow-up was short-term (12 months).

In 2015, Barnes and colleagues prospectively studied 19 patients with medial (7), or lateral (12), elbow tendinopathy who had failed conservative management. All patients were treated with percutaneous ultrasonic tenotomy of the elbow using the TX1 device by a single operator. Visual analog scale (VAS) for pain, the 11-item version of the Disabilities of the Arm, Shoulder, and Hand (Quick DASH) index, and the

Percutaneous Tenotomy or Percutaneous Fasciotomy (TENEX Health TX™ System or TX1, TX2), continued

Mayo Elbow Performance Score (MEPS) were assessed by an independent observer before treatment at 6 weeks, 3 months, 6 months, and 12 months after treatment. Average VAS scores were significantly improved from 6.4 to 2.6 at 6 weeks and were 0.7 at 12 months ($P < .0001$). Similar improvement occurred with the Quick DASH (pretreatment, 44.1; 12 months, 8.6, $P < .0001$) and MEPS (pretreatment, 59.1; 12 months, 83.4; $P < .0001$). The authors concluded that sonographically-guided percutaneous ultrasonic tenotomy and debridement using the TX1 device appears to be a safe treatment option for patients presenting with chronic, refractory lateral or medial elbow tendinopathy and provides significant and sustainable improvements in pain and function during a 1-year follow-up period. However, the authors acknowledged several study limitations including a small number of subjects and no control group, does not provide insight regarding the therapeutic mechanism of the TX1 treatment, and that future prospective comparative investigations are warranted. Two of the authors (Barnes DE and Smith J) also disclosed a financial relationship with Tenex Health which is related to the subject of the study.

Also, in 2015, Patel reported on a prospective case series study in which patients were allowed either to continue with noninvasive treatment or to undergo focal aspiration and partial fasciotomy with an ultrasonic probe (TX1). Study inclusion criteria were plantar fasciitis symptoms lasting 12 months or longer. Twelve patients with refractory plantar fasciitis lasting a mean of 19 months chose the procedure. They all had failed conservative care, including physical therapy, casting, shock wave therapy, and invasive procedures such as injections and endoscopic plantar releases. Four of the 12 had undergone an open or endoscopic partial release at a different institution but had experienced no improvement symptoms. American Orthopaedic Foot and Ankle Society (AOFAS) scores were obtained before and after surgery. Follow-up consisted of clinic visits 2 weeks after surgery and monthly thereafter. The 12 patients had a mean preoperative AOFAS score of 30 (range, 17–46) and a mean postoperative score of 88 (range, 25–92). By the 3-month postoperative visit, symptoms were resolved in 11 patients (no activity restricted by plantar fascia pain). On physical examination, 11 patients had no palpable tenderness at the site of preoperative pain. Pain relief was documented as having occurred between 5 and 13 weeks after treatment. One patient had bilateral procedures. One foot was treated, pain resolved by the 3-month postoperative visit, and the patient asked for the other foot to be treated. Three months after the procedure, patient had minimal non-activity-restricting pain. The author concluded that this is the first report of a plantar fascia partial release guided by ultrasonic energy delivered by a percutaneously inserted probe under local anesthesia, that the procedure appears to be a safe, effective, well-tolerated treatment for a condition that is refractory to other options but that more studies are needed to further validate the safety and efficacy of this innovative treatment modality. The author also reported that he is a member of the medical advisory board of Tenex Health, which developed the tissue removal system used in the study.

The currently available published evidence on the safety and efficacy of the TX1 device in the treatment of pain caused by various tendinopathies/tendinitis and fasciitis is limited to case series studies with small number of subjects and short-term follow-up periods. There is insufficient evidence to conclude that the use of the TX1 device results in improved health outcomes, and therefore, its use is considered investigational. Randomized controlled studies with larger number of subjects and longer-term follow-up are needed.

Billing/Coding Information

CPT CODES

23929	Unlisted procedure, shoulder
24999	Unlisted procedure, humerus or elbow
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle
28899	Unlisted procedure, foot or toes
24357	Tenotomy, elbow, lateral or medial (eg, epicondylitis, tennis elbow, golfer's elbow); percutaneous
23405	Tenotomy, shoulder area; single tendon
27000	Tenotomy, adductor of hip, percutaneous (separate procedure)

Percutaneous Tenotomy or Percutaneous Fasciotomy (TENEX Health TX™ System or TX1, TX2), continued

27005	Tenotomy, hip flexor(s), open (separate procedure)
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)
27306	Tenotomy, percutaneous, adductor or hamstring; single tendon (separate procedure)
27307	Tenotomy, percutaneous, adductor or hamstring; multiple tendons
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia
28008	Fasciotomy, foot and/or toe
76881	Ultrasound, extremity, nonvascular, real-time with image documentation; complete
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

HCPCS CODES

No specific codes identified

Key References

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MEDICAL POLICY

PERCUTANEOUS VERTEBROPLASTY/KYPHOPLASTY

Policy # 310
Implementation Date:7/15/03
Review Dates: 8/26/04, 12/15/05, 8/17/06, 8/23/07, 6/11/09, 6/17/10, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/28/18, 12/11/19, 12/17/20, 11/28/21, 11/17/22, 12/20/23, 12/26/24
Revision Dates: 5/30/06, 8/13/08, 10/11/11, 8/22/19, 2/18/22, 4/29/22

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Percutaneous vertebroplasty is a technique in which acrylic cement is injected through a needle into a collapsed or weakened vertebra in an effort to relieve pain and provide stability. Since the mid-1980s in France and the mid-1990s in the United States, radiologists have been successfully treating osteoporotic compression fractures, and pathologic vertebral fractures secondary to malignancy.

This procedure is effective for treating certain types of painful vertebral compression fractures and some painful or unstable benign and malignant vertebral lesions that fail to respond to the traditional conservative therapies. Most experts believe that pain relief is achieved through mechanical support and stability provided by the bone cement. The semisolid mixture of polymethylmethacrylate (PMMA), acrylic cement used in orthopedic procedures, has been shown to restore strength and stiffness in vertebral bodies in postmortem studies.

Vertebroplasty is most performed in the angiography/interventional radiology suite under high-quality fluoroscopy. Midazolam, fentanyl, or other medications may be administered to provide moderate sedation. Patients who are in severe pain may require general anesthesia to tolerate the prone positioning required for this procedure. Using sterile technique and fluoroscopic guidance, an 11-gauge needle is advanced into the vertebral body via a transpedicular or parapedicular approach.

Kyphoplasty was developed in 1997 as a modification to vertebroplasty. It has the additional preliminary step of carefully inserting and inflating a bone tamp (a small balloon-like device) inside the vertebra to create a cavity which can then be filled with polymethylmethacrylate (PMMA). This technique purports to have several advantages over vertebroplasty alone, including helping to realign and restore the lost height of the fractured vertebra, as well as creating a cavity that can allow safer injection of PMMA at lower pressures.

The procedure is performed at a hospital or outpatient facility under fluoroscopic guidance using either local or general anesthesia. The physician makes a small incision in the patient's back and creates a pathway into the fractured bone. A special balloon catheter is placed through the pathway and inflated. The balloon is then deflated and removed, leaving a space within the vertebra. The space is injected with PMMA to support the bone and prevent further collapse, stabilizing the fracture and providing immediate pain relief in many cases. The inflation of the balloon prior to the injection may partially restore vertebral body height and configuration. The procedure generally takes about one hour per vertebrae involved and must be followed by routine post-operative recovery.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers percutaneous vertebroplasty and percutaneous kyphoplasty in *limited* circumstances.

Criteria for coverage:

1. Acute/subacute compression fracture(s) by x-ray or MRI, associated with any one of the following:
    a) Multiple myeloma; or
    b) Painful and/or aggressive hemangiomas; or
    c) Painful vertebral eosinophilic granuloma; or
    d) Painful, debilitating osteoporotic collapse/compression fractures*; or
    e) Primary malignant neoplasm of bone or bone marrow; or
    f) Secondary osteolytic metastasis, excluding sacrum and coccyx; or
    g) Steroid-induced fracture**; and**

2. The patient has debilitating pain and the compression fracture is less than 4 months old**; and**
3. Requested treatment levels are between level T5 – L5**; and**
4. No more than 3 vertebral levels can be treated on any one date of service**.**

*Osteoporosis is defined by T-score ≤ -2.5 standard deviations at any site based upon bone mineral density (BMD) measurement by dual-energy x-ray absorptiometry, **or** fragility fracture (defined as fracture in the absence of major trauma; particularly at the spine, hip, wrist, humerus, rib, and pelvis).

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Vertebroplasty (VP) is a direct injection of bone cement to fill vertebral fracture lines, stabilizing the fracture and reducing pain. Percutaneous vertebroplasty is usually performed under local anesthesia, combined with neuroleptanalgesia, and may be performed as an outpatient procedure or may require a short hospital stay. For this procedure, the patient lies in the prone position and a large-bore (10–15 gauge) needle is placed into the vertebral body lesion under radiological guidance from computed tomography (CT) scanning or fluoroscopy. Acrylic bone cement, usually polymethylmethacrylate (PMMA), is then injected into the affected vertebra until resistance is met or the cement reaches the posterior wall of the vertebral body. This preparation is viscous to reduce leakage of the bone cement into adjacent structures or into the vasculature. The procedure generally takes 1–2 hours. CT may be used several hours after injection to assess vertebral body filling and to detect any leakage of the bone cement. Nonsteroidal or steroidal anti-inflammatory drugs can be used for 2–4 days after vertebroplasty to minimize the inflammatory reaction to the heat of polymerization of the acrylic compound.

Hayes observed that uncontrolled trials demonstrated the procedure to be effective in reducing pain and in improving mobility and quality of life in > 70% of patients with medically refractory, painful osteolytic

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lesions and osteoporotic compression fractures. The review assigned a 'B' rating for medically refractory pain due to osteolytic or osteoporotic lesions of the vertebrae that have no specific contraindications to injection of bone cement. A 'D' rating, reflecting no proven benefit and/or not safe was assigned for patients with specific contraindications.

In Barbero et al., for example, 101 patients (173 vertebrae) were treated with the procedure. At 270 days post-surgery, the authors reported pain relief in 88% of osteoporotic patients and 84% of neoplastic patients. Pulmonary cement emboli were identified in 4 patients, all of whom were asymptomatic. Caudana treated 106 (182 vertebrae), reporting 98% patients with partial or complete pain relief within 24 hours of treatment. One case of pneumothorax and two cases of symptomatic cement leakage. Mild complications included two cases of cement pulmonary embolism. During the follow-up, 8 osteoporotic patients presented a new vertebral fracture, and new vertebral metastases appeared in two oncological patients. He et al. reported on 242 patients (334 procedures). Fifteen patients did not experience pain relief and underwent a second procedure. After 1 month, mean pain VAS rating was reduced from 8.6 to 1.67. At 15 months, complete and partial pain relief were reached in 11 (75%) and 4 (27%) patients. In 98 patients retrospectively evaluated by Lin et al., 62 re-fractures occurred within the 26.9-month follow-up period.

The literature supporting kyphoplasty has demonstrated similar safety and efficacy in treating pain related to vertebral compression fractures. Saliou et al. reported on a case series of 5 patients (7 vertebrae). No complications occurred with balloon inflation with one cement leak occurring afterward. Mean reduction in local kyphosis was 4.4 degrees; at one month, all patients were pain-free. Korovessis et al. prospectively evaluated 23 patients with thoracolumbar A3-type burst fracture with or without neurologic deficit. After surgery, no patient experienced a decline in ASIA grade while 5 patients with incomplete neurologic lesions improved by one or more ASIA grades. Overall sagittal alignment and vertebral body height improved after surgery; 4 cases of cement leakage were reported. A second study of 18 patients with lumbar (L1–L4) burst and severe compression fractures were followed for 22 months. Segmental kyphosis and vertebral body height improved after surgery. Spinal canal encroachment was also reduced. Bone cement leakage was observed in 4 patients without clinical sequelae. In none of these studies were clinical outcomes compared to vertebroplasty.

A literature review performed in October 2011 identified a June 2011 BCBS TEC on vertebroplasty and kyphoplasty. Their review on vertebroplasty identified 2 placebo-controlled, randomized trials, 3 open-label, randomized trials, 1 comparative study, and 6 case series studies. Results of the 2 placebo-controlled randomized trials were similar, with both concluding that vertebroplasty conferred no additional benefit over a sham procedure (injection of local anesthetic into the facet capsule and/or periosteum). These studies were designed to determine short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning in persons with painful osteoporotic vertebral fractures. Results of the 3 open-label randomized trials showed significant differences in immediate pain relief among those receiving vertebroplasty versus those undergoing medical management; 1 concluding that among patients with acute fractures vertebroplasty conferred a benefit over conservative management through 12 months, the other 2 reported immediate drops in pain 1 day after the procedure; however, significant between-group differences in pain were not observed at later time points.

The first placebo-controlled randomized trial recruited 38 participants into the treatment group and 40 into the control arm; 91% completed the 6 months of follow-up. Participants had back pain of less than 12 months' duration, and at least 1, but no more than 2, vertebral fractures. For the primary outcome of overall pain, the authors reported no significant difference in VAS pain score at 3 months, 2.6 vs. 1.9, respectively, mean difference 0.6 (95% CI: -0.7, 1.8).

The second placebo-controlled trial was also a multicenter, randomized, double-blind, sham-controlled trial in which participants with 1–3 painful osteoporotic vertebral fractures of duration less than one year were assigned to undergo vertebroplasty or sham procedure (i.e., injection of local anesthetic into the facet capsule and/or periosteum). Sixty-eight participants had vertebroplasty while 63 received sham; 97% completed 1 month of follow-up and 95% completed 3 months. For the primary endpoints at 1 month, there were no significant between-group differences. Both randomized, controlled trials showed a greater frequency of clinically meaningful improvements in pain.

The largest of the open-label randomized trials was a multicenter, prospective, nonblinded trial where participants with at least 1 painful osteoporotic vertebral fracture of duration of 6 weeks or less were

assigned to undergo vertebroplasty or conservative management (i.e., bed rest, analgesia, and cast and physical support). One-hundred and one participants were randomized to each group. Ninety-three participants received vertebroplasty while 95 received conservative management; 81% of participants completed 1-year of follow-up. For the primary endpoints of pain relief at 1 month and 1 year, there were significant between-group differences in mean VAS scores 2.6 (95% CI: 1.74 to 3.37, $p < 0.0001$) at 1 month and 2.0 (95% CI: 1.13 to 2.80, $p < 0.0001$) at 1 year. Significant pain relief (i.e., 30% change) was quicker (29.7 vs. 115.6 days) and was achieved in more patients after vertebroplasty than after conservative management.

Results of the 2 other randomized trials and one comparative study come from trials of fewer rigors than the previously mentioned randomized trials. These appeared to show an effect favorable to vertebroplasty immediately following the procedure. However, differences between groups quickly diminished. One trial reported no difference at 2 weeks' follow-up; another showed diminished differences at 6 weeks post-procedure, with the third study reporting no differences at 3- and 12-months' follow-up.

The BCBS TEC review on kyphoplasty identified 1 randomized trial and 2 nonrandomized studies comparing kyphoplasty to medical management, 1 study comparing kyphoplasty to vertebroplasty, and 4 case series studies. The randomized trial showed a greater improvement in mean SF-36 physical component score for the kyphoplasty group over medical management. The comparative studies showed greater improvement in pain scores and other outcomes compared to medical management.

In the study that compared kyphoplasty to vertebroplasty, improvements in pain were reported in both study groups, and there were no differences between the 2 procedures. The case series studies showed a consistent 4- to 5-point improvement in VAS pain ratings (0–10 scale) after kyphoplasty. The improvement appeared to be durable out past 1 year, but all studies suffered from losses to follow-up.

Analysis and interpretation are difficult in a nonrandomized setting, as it is difficult to separate out effects of the intervention from differences between the treatment and control groups. These studies enrolled different patients with respect to age of fracture; one study enrolled patients with fractures older than 1 year, while another enrolled patients with acute fractures meeting specific radiologic criteria for instability. The brief format of the acute fracture study does not allow an assessment of the similarity of the kyphoplasty and control groups. Contrary to a nonrandomized 2003 study of vertebroplasty, the control groups in this study did not improve appreciably over a period of weeks to months.

To date, there are currently 3 trials underway comparing vertebroplasty and kyphoplasty. The KAVIAR study is a randomized, open label trial. The primary outcome of this study is the proportion of patients with subsequent fractures at 12 and 24 months. The trial is currently recruiting participants. OSTEO+6 and OSTEO-6 are 2 randomized, open-label, uncontrolled trials based in France, comparing vertebroplasty to kyphoplasty (and conventional treatment in OSTEO-6) with the primary aim being change in the kyphotic angle of the vertebra measured at 1 year. OSTEO+6 and OSTEO-6 are currently enrolling participants with fractures more than and less than 6 weeks old, respectively.

Unfortunately, the limitation of these trials is that they aim not to show the efficacy of kyphoplasty but to set kyphoplasty apart from vertebroplasty by showing additional benefits of one procedure over the other in terms of restoration of vertebral height, or by offering a lower number of subsequent fractures. These trials presuppose the efficacy of these procedures. There are no randomized trials comparing kyphoplasty to sham or medical management.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

CPT CODES

Vertebroplasty

22510 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic

22511 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; lumbar

22512 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Kyphoplasty

22513 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic

22514 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); lumbar

22515 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

HCPCS CODES

No specific codes identified

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Select Health

MEDICAL POLICY

RADIOFREQUENCY ABLATION (RFA) FOR ILIOTIBIAL BAND RELEASE

Policy # 460

Implementation Date:8/16/10

Review Dates: 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/18/23, 2/20/24, 12/19/24

Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The iliotibial band consists of connective tissue that runs from the ilium (top back part of hip) to the fibula (outside bone of lower leg). The band functions in coordination with several of the thigh muscles to provide stability to the outside of the knee joint. This band can get inflamed and trigger a condition termed Iliotibial Band Syndrome (ITBS). The irritation usually occurs over the outside of the knee joint, at the lateral epicondyle, the end of the femur (thigh) bone. It can also get irritated in the hip area at the point which it crosses, the greater trochanter.

The typical treatment of ITBS is conservative therapy, including rest, ice, physical therapy, and sometimes cortisone injections. A small percentage of patients are refractory to conservative treatment and may require surgical release of the iliotibial band. The most common approach is to perform open surgery and release the posterior 2 cm of the iliotibial band where it passes over the lateral epicondyle of the femur. The operation may involve: (1) releasing the posterior portion of the ITB, (2) performing an osteotomy of the lateral femoral epicondyle, or (3) performing a bursectomy.

Alternatively, radiofrequency is now being employed as part of an arthroscopic procedure. Unlike some other applications of radiofrequency energy, in this circumstance, a probe emits radiofrequency (RF) radiation in the 460 kHz range which heats the tissue, thereby creating an incision. A probe, connected to an electric generator, is placed inside the tissue, such that an electric current flows through the body and heats the tissue near the probe up to temperatures of more than 60 °C (140 °F). At such temperatures, the proteins of the heated tissue coagulate, and its cells die. If the tip is too hot, the vaporization and "charring" may cause decreased energy absorption and less-treated tissue volume; this lyses the iliotibial band.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers radiofrequency ablation for iliotibial band release. Clinical evidence shows it to be effective as a technique used to cut the tendon, primarily with arthroscopic hip procedures.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

A Medical Technology Assessment performed in July 2010 identified multiple studies that have been published demonstrating radiofrequency (RF) to be effective as an incisive tool in multiple clinical situations. Additionally, all studies related to lysis of the iliotibial band only reference RF use as a regular part of the arthroscopic treatment of iliotibial band release, not as a standalone therapy itself.

Only one study by Kashkouli et al. compared the effectiveness of RF vs. a scalpel to incise tissue. This was done in a cosmetic blepharoplasty study. Their conclusion is there was no significant difference between radiofrequency and scalpel incision in upper blepharoplasty with regards to sensation recovery and scar formation. Histologic zone and depth of tissue damage were greater, however, in the radiofrequency group. Other studies appear to corroborate the findings of Kashhouli et al. It remains unclear as to whether these findings can be translated into other clinical circumstances. Farr et al. used RF to incise the iliotibial band in bursitis patients with positive results.

In summary, though current evidence is limited in volume, multiple studies support radiofrequency energy to be effective and safe when used to incise soft tissue.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

20999 Unlisted procedure, musculoskeletal system, general

HCPCS CODES

No specific codes identified

Key References

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please

Select Health

Radiofrequency Ablation (RFA) for Iliotbial Band Release, continued

refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

SACROILIAC JOINT FUSIONS

Policy # 595

Implementation Date:10/20/16
Review Dates: 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 9/26/23, 8/13/24
Revision Dates: 7/19/17, 11/20/19, 4/24/20, 5/19/21, 4/19/24, 5/15/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The sacroiliac joint (SIJ) was considered the primary source of low back pain in the early 20th century. It became overshadowed by the herniated nucleus pulposus after the hallmark 1934 article by Mixter and Barr. Mounting evidence on computed tomography (CT), magnetic resonance imaging (MRI), and scintigraphy demonstrating destructive, inflammatory, and degenerative pathology, suggests that the joint should again be considered a potential source of low back pain. Provocative and palliative intraarticular injections have validated the SIJ as the pain generator in a subset of patients. Nevertheless, information pertaining to the SIJ is sparse within medical textbooks and courses.

Conventional wisdom has held fast to the notion that the SIJ is immobile. However, studies have demonstrated a screw-axis motion of simultaneous sagittal plane rotation and translation. However, there is gross incongruity among various reports pertaining to the position of the instantaneous axes of rotation, the extent of movement, and the existence of motion in other dimensional planes.

Several mechanisms of injury may be linked to the development of SIJ pain, including a direct fall on the buttocks, a rear-end motor vehicle accident (with the ipsilateral foot on the brake at the moment of impact), a broadside-type motor vehicle accident (via a blow to the lateral aspect of the pelvic ring), a step into an unexpected hole, or a fall from a miscalculated height. Additionally, the past medical history and review of systems should be noted for such conditions including polyarthritis, lumbar fusion surgery, and gravida/para. All patients with suspect presentations of SIJ pain should have the necessary laboratory and radiologic work-up for spondyloarthropathic, metabolic, or infectious etiologies.

Conservative treatment for SIJ pain usually involves cold application, anti-inflammatory medication, and relative rest in the acute stages. Once the acute pain has subsided, further efforts are often employed to restore normal mechanics, including manual medicine techniques; pelvic stabilization exercises to allow dynamic postural control, and muscle balancing of the trunk and lower extremities.

Muscle balancing efforts concentrate on the powerful two-joint muscles around the SIJ (e.g., gluteus maximus and biceps femoris) as they exert shear and torsion loads proportional to the strength of their contraction. Impact loading exercises such as plyometrics, or the use of a Heiden board, which is implemented in the final stages of the rehabilitation process. The patient must have demonstrated proper pelvic control during less demanding activities or exacerbation will likely result.

If conservative treatment fails, SIJ intra-articular injections are often performed not only as a therapeutic intervention but also to confirm the diagnosis. Reproduction of symptoms upon distension of the joint capsule and/or mitigation of symptoms by analgesic block is the most reliable and reproducible means by which a pain-generator can be identified. Selection is usually reserved for those patients who have not responded to aggressive, conservative treatment or who have reached an unsatisfactory plateau. In these cases, SIJ injection may affirm the diagnosis, avoid unnecessary surgery, reduce pain, and facilitate rehabilitation.

Cryotherapy is another potential treatment for SIJ dysfunction. The lateral branches of the SIJ are exposed to liquid or gas nitrogen, resulting in necrosis analogous to RF lesioning. It can also be used to cause an inflammatory response within the capsular ligaments as a means of prolotherapy. No controlled studies have been performed as a treatment remedy for SIJ mediated pain; limitations are similar to that of RF.

As a last resort, open sacral fusion surgery is infrequently considered. This surgery has significant morbidity and has significant risk for complications and suboptimal outcomes. More recently, several minimally invasive implant systems have been developed for SIJ infusion. The most prominent is the iFuse Implant system (SI-Bone, Inc., San Jose, CA); also, notable is the SImmetry SIJ Fusion system (Zyga Technology, Minnetonka, MN).

With regards to the iFuse Implant system, this minimally invasive surgical procedure is typically performed under general anesthesia with the patient in the prone position. A small incision is made in the lateral buttock through which the procedure is performed. The procedure is a typical orthopedic pin-based technique (pin, drill, broach, and implant). The entire procedure takes approximately 1-hour and instrument/implant position is confirmed with intraoperative fluoroscopy.

Related to the iFuse Implant system, the manufacturer of the iFuse implant describes it as follows: "The iFuse Implant System is comprised of a titanium implant coated with a porous, titanium plasma spray (TPS) and an instrument system. Typically, 3 implants are placed across the SIJ using a lateral transarticular approach during a minimally invasive surgical (MIS) procedure. The implant's unique triangular shape, large surface area, and interference fit are designed to minimize micromotion and rotation to provide immediate joint stability and to allow for biological fixation to support long-term fusion.

The SImmetry Sacroiliac Joint Fusion System is a MIS procedure for patients with SIJ dysfunction who have not gained relief from conservative care. The SImmetry System utilizes the proprietary SImmetry Decorticator, allowing surgeons to prepare the articular region of the SIJ and insert bone graft into the joint to help facilitate a true SIJ fusion. The muscles and ligaments surrounding the SIJ are maintained. The SImmetry System is cleared by the FDA for commercial distribution.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

1. Minimally Invasive Fusion of the Sacroiliac Joint

Select Health covers minimally invasive fusion of the sacroiliac joint *only* using the iFuse Implant System (transfixating approach) as a proven technology.

A. Criteria for Coverage (ALL must be met):

Minimally invasive fusion of the SI joint, utilizing the iFuse Implant System, is considered to be medically necessary for the treatment of SI joint syndrome and SI joint mediated mechanical low back pain when ALL the following criteria are met:

1. Patients with confirmed diagnosis of Sacroiliac (SI) Joint mediated pain based on history and physical exam;
2. Physical examination documentation reflects SIJ pain confirmed with:
    a) At least 3 of the 5 provocative maneuvers that stress the SI joint (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver), causing the patient's typical pain.
3. History documentation includes:
    a) Onset, location, character, duration, and modifiers of pain;
    b) Prior treatments and results;

c) Medication use; and

d) Prior surgical and non-surgical procedures and results.

4. Advanced imaging studies of the joint such as CT, MRI, or alternating standing films to exclude other diagnoses (e.g., L5/S1 compression, hip osteoarthritis, etc.);
5. Persistent SIJ pain of moderate-to-severe despite conservative therapy (baseline score of 30 or greater on the Oswestry Disability Index (ODI) and/or numeric pain score in the last week of 5 or higher on a 10-point VAS scale);
6. Failure to adequately respond* to at least 6 months of non-surgical treatment (if not contraindicated), including ALL the following:
   a) Non-steroidal anti-inflammatory drugs and/or opioids;
   b) Course of physical therapy;
   c) Activity modification; and
   d) CT or Fluoroscopic guided SIJ steroid injection.
7. Complete or near complete (> 79%) relief of typical pain on CT or fluoroscopic confirmed injection;

*Failure to respond is defined as continued pain interfering in activities of daily living or resulting in functional disability.

B. Exclusions

Minimally invasive SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of back pain;
- Inability to confirm pain arises from the SI joint;
- Failure to pursue conservative treatment of the SI joint (unless contraindicated);
- Pain not confirmed with a diagnostic SI joint block;
- SI joint pain due to chronic SIJ inflammatory disorders;
- Referred pain from other sources;
- Recent major trauma to the pelvis;
- Metabolic bone disease;
- Existence of other pathology that could explain the patient's pain;
- Patients involved in litigation, on disability leave, or receiving worker's compensation.

Select Health does NOT cover the use of minimally invasive fusion products (posterior approach) other than the iFuse Implant System for sacroiliac joint fusion, as current evidence related to alternative systems are inadequate to determine efficacy and safety of these products. Use of these technologies is considered experimental/investigational or unproven.

2. Open Sacroiliac Joint Fusions

A. Open sacroiliac joint fusion is considered medically necessary for:

i) Sacroiliac joint infection, or

ii) Tumor involving the sacrum, or

iii) Sacroiliac pain due to severe traumatic injury where a trial of an external fixator is successful in providing pain relief, or

iv) When performed as part of multi-segmental spinal constructs for the correction of spinal deformity

Sacroiliac joint fusions are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above have not been established.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Two systematic reviews and 27 primary studies were identified which met inclusion criteria for this review. The primary literature included outcomes from 7,589 patients who underwent SIJ fusion. With the exclusion of the Miller et al. paper, an analysis of post-market complaints, outcomes from 2,231 unique SIJ fusion patients have been reported.

The 2 systematic reviews included 34 studies: 18 reported on outcomes from MIS and 16 compared open to MIS surgeries. Pertaining to improvements in length of stay (LoS), blood loss, surgical time, and patient-reported pain improvements and revision surgeries at follow-up, MIS surgery outperformed open procedures. Of the 27 primary studies, all used only the iFuse implant. No studies were identified for the SImmetry Implant system. Most of the articles were cohort studies with only 3 of the 26 (12%) primary literature articles comparing minimally invasive SIJ fusion to open surgery.

Notably, none of the long-term studies were comparative to open SIJ fusion. However, both papers that followed patients past 48 months (Cher et al. and Rudolf et al.) illustrated comparatively low Oswestry disability Index (ODI) scores at follow-up, a meaningful primary endpoint. Of note, is the lack of a sham control in any of the studies. This would have been a useful comparator given the relative immobility of the SIJ. That said, Polly et al. and Sturesson et al. both compared MIS SIJ fusion to conservative therapy, and both illustrated substantial improvements of the former to the latter.

In conclusion, the literature regarding MIS SIJ fusion illustrates clinically relevant patient improvements compared to conservative therapies or open SIJ fusion. There is substantial evidence from both short-term and long-term, cohort and randomized controlled studies, to know the effects of iFuse on patient outcomes. Studies also demonstrate minimally invasive implant surgery using the iFuse system appears to have lower morbidity and complication issues than open SI joint fusion.

Billing/Coding Information

Covered for the indications listed above when criteria are met

CPT CODES

27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed
01160	Anesthesia for closed procedures involving symphysis pubis or sacroiliac joint

HCPCS CODES

L8699	Prosthetic implant, not otherwise specified
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)
C1776	Joint device (implantable)

Not covered for the indications listed above

CPT CODES

0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intraarticular implant(s), including allograft or synthetic device(s) [Effective July 1, 2023]

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Revision History

Revision Date	Summary of Changes
4/19/24	For Commercial Plan Policy, added language to section #1 to clarify that Select Health only covers transfixating approach but not posterior approach; and removed age requirement in section #1 of 21 to 70 years of age in criterion #A-1.
5/7/24	For Commercial Plan Policy, added criterion #A-iv as a consideration of coverage to section #2 (Open Sacroiliac Joint Fusions): "When performed as part of multi-segmental spinal constructs for the correction of spinal deformity."

Select Health

Sacroiliac Joint Fusions, continued

Select Health

Select Health

MEDICAL POLICY

SHOULDER RESURFACING

Policy # 505
Implementation Date:4/12/12
Review Dates: 6/20/13, 4/17/14, 4/14/16, 4/27/17, 9/18/18, 4/17/19, 4/15/20, 4/15/21, 3/18/22, 4/20/23, 4/19/24, 4/17/25
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Shoulder pain may have several etiologies. Arthritic conditions can affect this joint, resulting in degeneration of the joint surface. These conditions include osteoarthritis and rheumatoid arthritis. Osteoarthritis (degenerative joint disease) is the most common form of arthritis found in the shoulder. Avascular necrosis is another cause of joint degeneration, it involves the death of bone tissue due to a lack of blood supply.

Shoulder pain is treated using several modalities, including physical therapy, medications, and surgery. Surgery may include arthroscopic debridement or go so far as to require total shoulder replacement. Recently, less invasive surgeries have been promoted as an alternative to total shoulder replacement. One technique is termed shoulder resurfacing, and there are a number of technologies already on the market approved for shoulder resurfacing. These include the Copeland EAS Humeral Resurfacing Head (Biomet, Inc., Warsaw, IN), the GLOBAL CAP (DePuy Orthopaedics, Inc., Warsaw IN), the Axiom Shoulder Resurfacing System, (Axiom Orthopaedics, Inc., Jersey City, NJ), the HemiCAP Resurfacing System (Arthrosurface, Franklin, MA), and the Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing Prosthesis (STD Manufacturing Inc., Stoughton, MA).

Resurfacing can be either done with biological material or with resurfacing prostheses. Biological glenoid resurfacing with prosthetic humeral head replacement has been suggested as a means to avoid the potential complications of polyethylene use in younger patients with glenohumeral arthritis.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover shoulder resurfacing. Current evidence suggests shoulder resurfacing has a greater number of complications and a higher revision rate than total shoulder arthroplasty for the same indications.

Select Health covers partial shoulder replacement and hemiarthroplasty. Current evidence supports partial shoulder replacement and hemiarthroplasty as an alternative to total shoulder replacement.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Three systematic reviews and 17 peer-reviewed journal articles were found concerning shoulder resurfacing. Perhaps the most significant of the systematic reviews is the Cochrane review by Singh et al. published in 2010. This study concluded: "Total shoulder arthroplasty seems to offer an advantage in terms of shoulder function, with no other clinical benefits over hemiarthroplasty. More studies are needed to compare clinical outcomes of surgery using different components and techniques in patients with osteoarthritis of the shoulder. There is a need for studies comparing shoulder surgery to sham, placebo and other non-surgical treatment options."

As it relates to revision surgery, the studies show significant variability. Bailie et al. noted the lowest revision rate of 3%. On the other hand, Elhassan et al. found a 77% revision rate for soft-tissue resurfacing of the glenoid in the treatment of glenohumeral arthritis. The latter study best demonstrates not only the revision rates but also comorbidities found at the time of the revision surgery. For example, during the revision surgery, the group found the biologic, soft-tissue, allograft to be absent and thick scar tissue was found around the glenoid. Furthermore, 2 of the 3 patients that did not require revision had complications related to infection. Long-term decreases in glenohumeral joint space are a concern with shoulder resurfacing.

Few studies looked at the comparative outcomes of patients undergoing total arthroplasty vs. resurfacing. Buchner et al., Elhassan et al., and Levy et al. performed trials comparing shoulder resurfacing to total shoulder arthroplasty (TSA) and concluded TSA to be superior to hemiarthroplasty using biologics. Constant score* was always higher in total shoulder groups when compared to soft-tissue resurfacing. **Table 1** summarizes the various revision and complication rates from the studies included in this report.

Table 1. Revision and Complication Rates

Paper	N Shoulders	Mean Age (Years)	Mean Follow (Months)	Pre-op CMS*	Post-op CMS	Complication Rate	Revision Rate	Prosthesis Type
Baile et al.	36 patients	42.3	38.1			14%	3%	Cementless
Buchner et al.	22	61.4	12	33.1	56.6		9%	Cementless
de Beer et al.	32	57.5	33.5	40.0	64.5	23%	23%	Biologics
Elhassan et al.	13 patients	34	40	24.0	43.0	46%	77%	Biologics
Fink et al.	45	62.7	45.1	46.9	62.6	0%	2%	Cementless
Fuerst et al.	42	61.4	73.1	20.8	64.3		7%	Cementless
Jerosch et al.	25	69	26	14.0	53.2	0%		Cementless
Lee et al.	18	54.8	57.6		71.4		10%	Biologics
Levy et al.	285		81.6	15.4	52.4	3%	12%	Cementless
Levy et al.	42	73.4	24	20.0	61.9	9%	4%	Cementless
Levy et al.	75		78	11.8	47.9		5%	Cementless
Mullett et al.	213	84.3	54	11.5	62.1	0%	0.5%	Cementless
Pritchett et al.	74	58	336	20.0	61.0		11%	Cemented
Raiss et al.	17	48	36	31.0	62.0	14%	0%	Cementless
Savoie et al.	80		54	26.0	79.0		22%	Biologics
Shrivastava et al.	6	63	17					Cementless
Wirth et al.	27	43	36			10%	7%	Biologics
Mean/Sum	**1003**	**58.1**	**61.3**	**24.2**	**60.1**	**12%**	**13%**	

Select Health

*The Constant-Murley score (CMS) has both self-report and performance-based components. Self-reported items assess the domains of pain and activities of daily living, and active range of motion and shoulder strength are measured from patient performance.

In summary, it appears from the literature that clinical outcomes from shoulder resurfacing are inferior to TSA. Revision rates average nearly 20% and rise if biological tissue is used rather than cement-less surface replacements. Additionally, current evidence is insufficient to draw conclusions as to the safety and efficacy of resurfacing as it compares to TSA.

Billing/Coding Information

CPT CODES

Not covered: Investigational/Experimental/Unproven for this indication

Shoulder Resurfacing

23470 Arthroplasty, glenohumeral joint; hemiarthroplasty

23929 Unlisted procedure, shoulder

Covered: For the conditions outlined above

Partial Shoulder Replacement/Hemiarthroplasty

23470 Arthroplasty, glenohumeral joint; hemiarthroplasty

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

SPINAL IMPLANT SYSTEMS FOR THE TREATMENT OF THORACIC INSUFFICIENCY SYNDROME (TIS)

Policy # 290
Implementation Date: 1/13/06
Review Dates: 1/26/07, 2/21/08, 4/23/09, 2/18/10, 4/12/12, 6/20/13, 4/17/14, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/28/21, 9/15/22, 10/13/23, 9/27/24
Revision Dates: 2/24/11, 12/9/14, 7/28/15

Description

Thoracic insufficiency syndrome is a congenital condition where severe deformities of the chest, spine, and ribs prevent normal breathing and lung growth and development. The rare condition of fused ribs and congenital scoliosis may result in a three-dimensional thoracic deformity with adverse effects on thoracic growth and function with development of thoracic insufficiency syndrome.

The vertical expandable prosthetic titanium rib (VEPTR/VEPTR II) is a surgically implanted device used to treat thoracic insufficiency syndrome (TIS) in pediatric patients. The VEPTR device is a curved metal rod that is attached to ribs near the spine using hooks located at both ends of the device. The VEPTR II is a modification of the VEPTR device in which additional implants have been added to the VEPTR. These additional implants provide the surgeon more surgical options to address the child's chest wall/or spine defects. The VEPTR/VEPTR II device helps straighten the spine and separate ribs so that the lungs can grow and fill with enough air to breathe. The length of the device can be adjusted as the patient grows.

During surgery, the VEPTR/VEPTR II device is adjusted to fit the patient and attached vertically on the patient's ribs near the spine. Lengthening the device enlarges the rib cage and increases the amount of lung space in the patient's chest. The VEPTR/VEPTR II device will be lengthened or replaced at specific times to allow for the patient's growth and to further correct spinal or chest wall deformity. Adjustments to the length of the VEPTR/VEPTR II device are made during surgery through a small cut (incision) in the patient's back.

An update to the VEPTR technology is the development of magnetically adjustable spinal implants. The MAGEC Spinal Bracing and Distraction System (Ellipse Technologies, Incorporated, Irvine, CA) received 510(k) clearance on January 24, 2014. Its FDA approved indication for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) is associated with those at-risk of Thoracic Insufficiency Syndrome (TIS). It is secured using standard commercially available fixation components, such as laminar hooks and/or pedicle screws. Both VEPTR/VEPTR II and the MAGEC rods are available in 4.5 mm and 5.5 mm diameters.

The MAGEC system differs from the VETPR, in that, adjustments can be made using magnetic distraction in the office without the need for the patient going to surgery; anesthesia is also not necessary. Routine x-ray or ultrasound is used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of the patient by the treating surgeon. Published studies have shown distractions to typically occur every 1 to 3 months after implantation.

Select Health

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers adjustable spinal implantation systems including the vertically expanding titanium rib (VEPTR/VEPTR II) and the MAGnetic Expansion Control System (MAGEC) systems for the treatment of thoracic insufficiency syndrome (TIS) in skeletally immature patients in situations that meet the FDA indications.

Conditions for which Adjustable Spinal Implantation Systems are covered, include:

1. Flail chest syndrome
2. Rib fusion and scoliosis
3. Hypoplastic thorax syndrome, including:
    a. Jeune's syndrome
    b. Achondroplasia
    c. Jarcho-Levin syndrome
    d. Ellis-van Creveld syndrome
4. Progressive scoliosis of congenital or neurogenic origin without rib anomaly

Contraindications:
The VEPTR/ VEPTR II and the MAGEC implant systems should NOT be used under the following conditions:

1. Inadequate strength of the bone (ribs/spine) for attachment of the titanium support rod
2. Absence of proximal ribs for attachment of the spinal implant supports
3. Absent diaphragmatic function
4. Inadequate soft tissue for coverage of the spinal implant
5. Age beyond skeletal maturity
6. Age below 6 months
7. Known allergy to any of the device materials
8. Infection at the operative site

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

VEPTR/VEPTR II A vertical expandable prosthetic titanium rib received initial FDA approval under a humanitarian device exemption (HDE) in 2004. On December 8, 2014, the FDA provided 510(k) clearance for the VEPTR and VEPTR II Vertical Expandable Prosthetic Titanium Rib Devices to treat children with thoracic insufficiency syndrome (TIS). The data submitted to the FDA as part of the approval process consisted of a case series of 147 children, ranging from ages 6 months to 15 years. The children had various serious defects affecting their ribs or chest wall and ability to breathe, including severe scoliosis. The study showed that the device was safe and showed probable benefit by enabling some of the patients to breathe unassisted, or to be less dependent on ventilators. There were 12 deaths that clinical researchers considered not related to a problem with the device. The labeled indications state that the device is not intended to correct conditions other than chest wall instability. It should not be used in children younger than 6 months or those older than about age 14 for girls and age 16 for boys (beyond the age of skeletal maturity). In 2007, the company submitted an amendment for clarification to add "progressive scoliosis of congenital or neurogenic origin without rib anomaly" as part of the indications for use.

A literature review performed in February 2011 identified 3 new studies using the HDE indications. Hasler et al. performed a retrospective review on 23 children treated with vertical expandable prosthetic titanium rib for correction of non-congenital early onset spine deformities. The device was lengthened at 6-month intervals and the average follow-up time was 3.6 years. Diagnosis included 1 early onset idiopathic scoliosis, 11 neuromuscular, 2 post-thoracotomy scoliosis, 1 Sprengel deformity, 2 hyperkyphosis, 1 myopathy and 5 syndromic. Of the 187 surgeries, 149 were device expansions, and 15 unplanned surgeries. 23 complications (0.13 per surgery) included 10 skin sloughs, 5 implant dislocations, 2 rod breakages, and 6 infections. Their conclusion identified the VEPTR as an alternative to dual growing rods for non-congenital early onset spine deformities. The complication rate was lower, the control of the sagittal plane and the pelvic obliquity was as good, but the correction of the coronal plane deformity was less than growing rods. However, VEPTR's spine-sparing approach might provoke less spontaneous spinal fusion and ease the final correction at maturity.

Ramirez et al. performed a retrospective study on 17 patients with early onset scoliosis. The patient population consisted of 17 primary VEPTR implantations and 33 expansion surgeries with a mean follow-up of 25 months. Results show that there was an improvement in the coronal plane deformity. The thoracic kyphosis was maintained at anatomically normal values and preserved the space available for the lung. The complication rate was 13%, which includes infection, device migration, and rib fracture. The analysis of the data shows that the natural history of the progressive spinal deformity was improved in all patients.

White et al. identified 57 patients with thoracic insufficiency syndrome. Fourteen of these 50 patients had placement of a spine-to-spine construct using a VEPTR implant in combination with standard spinal implants. Five had prior rib-based VEPTR or growing implants with an average of 2 failures before this surgery. Radiographic variables, preceding treatment, complications, and changes in ambulatory status, were recorded. The minimum follow-up was 2 years (mean, 35 months; range, 2−4 years). After an average of 5 expansions in these 14 patients, positive changes were recorded for space available for the lung. Complications included 2 rod fractures, 2 superficial infections, and 1 deep infection with rod removal. The study suggests growing constructs using VEPTR can be used with relatively few complications and extends the potential uses of this instrumentation system.

Lieber et al. (2012) noted that various surgical techniques have been described for repair of chest wall defects in Poland syndrome. These investigators described the case of a 16-year old boy who underwent autologous rib transposition after sternal osteotomy. Chest wall stabilization was achieved using a combination of K-wires and VEPTR. Reconstruction of the soft tissue defect was accomplished by combined latissimus dorsi muscle flap and Permacol patch. This approach might be considered an effective 1-stage treatment option of this condition in post-pubescent boys. It was noted the findings of this case study need to be validated by well-designed studies.

In a different retrospective analysis of prospectively collected data of a case series, Abol Oyoun et al. (2013) reported the preliminary results of the use of VEPTR in an Eiffel Tower construct in children with neuromuscular scoliosis in regard to coronal and sagittal profiles, space available for the lungs (SAL), and spinal growth. The report listed the complications we faced during the follow-up of 1.33 years after the index procedure. A total of 20 non-ambulatory children (mean age of 8.9 years) with neuromuscular

scoliosis were included in this analysis. Their primary diagnoses were myelomeningocele (n = 7), cerebral palsy (n = 3), spinal muscular atrophy (n = 2), myopathies (n = 3), arthrogryposis (n = 1), and syndromic scoliosis (n = 4). All 20 patients received percutaneous rib-to-pelvis VEPTR implantation. Mean operative time was 2 hours, and mean hospital stay was 12 days. None of them needed blood transfusion. They underwent 20 primary implantations and 39 lengthenings. Patients were assessed based on physiologic measures, that is, the radiographic improvement of their scoliosis, SAL, pelvic tilt, spinal height, and sagittal and coronal decompensation. At the latest follow-up, thoracolumbar curvature improved significantly (65.7° ± 20.5° to 49.9° ± 15.7°), as did lumbar curvature (61.6° ± 19.5° to 35° ± 21.2°), thoracic (17.2 ± 2.3 to 20 ± 2.3 cm) and lumbar spinal height (9.9 ± 1.7 to 11.9 ± 1.8 cm), SAL (86.5 ± 8.9 to 97 ± 10), pelvic obliquity (12.5° ± 8° to 5.2° ± 5.2°), and the ilio-lumbar angle (15° ± 8° to 10.06° ± 7.1°). Nine patients suffered complications in the form of proximal cradle migration (n = 5), implant breakage (n = 5), deep wound infection (n = 3), and dislodged iliac hooks (n = 2). The authors concluded that early results of VEPTR for neuromuscular scoliosis are encouraging; follow-up till skeletal maturity will best determine future indications.

In a review on "Surgical aspects of spinal growth modulation in scoliosis correction," Jain and colleagues (2014) state that: "In patients with early onset scoliosis, a hybrid construct with vertebral stapling and growing rods or a vertical expandable prosthetic titanium rib has been suggested. A failure of the spinal growth modulation procedure does not preclude spinal fusion. None of the devices for spine growth modulation have been approved by the FDA for human use and are still investigational. Early results are promising, and continued clinical studies are necessary."

Dede and associates (2014) state: "The experience with growing rods has been increasing, along with expanding indications. Several self-lengthening instrumentation systems have been introduced aiming for guided spinal growth. There has been considerable progress in the clinical and laboratory studies using magnetically controlled growing rod constructs. Growing rods and vertical expandable prosthetic titanium rib (VEPTR) systems provide deformity control while allowing for spinal growth along with a risk of spontaneous vertebral fusions. VEPTR may cause rib fusions as the implants overlie the thoracic cage, and therefore, the use in pure spinal deformities is controversial. There have been exciting recent advances concerning the treatment of spinal deformities in young children. Despite these advances, the surgical treatment of early-onset scoliosis remains far from optimal and more development is on the way."

MAGEC System: In a review on MAGnetic Expansion Control (MAGEC) systems, two systematic reviews and 8 primary studies were identified which met inclusion criteria for review. The articles are dated from 2012 to 2014 and involved outcomes on 64 patients. Patients' ages ranged from between 3.6 and 12.6 years old. The studies provide outcomes out to 24 months follow-up. The studies included outcomes on both single and double rod placement.

For comparative complications to the standard titanium rod implants, Bess et al. demonstrated 5 to 13.6% of patients needed an additional surgery because of complications with conventional growing rod surgery. Watanabe et al. illustrated that 57% of patients undergoing growing rod surgery had a complication (i.e., implant failures, infections, and neurological impairments). These numbers appear to be commensurate with complications in general and complications which would necessitate a reoperation.

No comparative, head-to-head trials have been completed comparing MAGEC to VEPTR or any other standard surgical therapy. However, based on assessment of VETPR studies and MAGEC studies, it would appear the MAGEC rods have lower complications specifically related to surgery such as post-surgical infections due to the need for fewer surgeries but similar complications such as fractured rods requiring replacement, etc. Efficacy of both rod systems also appears similar.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

20999	Unlisted procedure, musculoskeletal system, general
21899	Unlisted procedure, neck or thorax
22899	Unlisted procedure, spine

HCPCS CODES

No specific codes identified

Key References

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Spinal Implant Systems for the Treatment of Thoracic Insufficiency Syndrome (TIS), continued

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MEDICAL POLICY

STEM CELL THERAPY FOR ORTHOPEDIC APPLICATIONS

Policy # 593

Implementation Date: 8/29/16

Review Dates: 8/17/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 9/1/24

Revision Dates:

Description

Multipotential stem cell (MSCs) are cells that possess the ability to differentiate into various tissues including organs, trabecular bone, tendon, articular cartilage, ligaments, muscle, and fat. MSCs are associated with the blood vessels within bone marrow, synovium, fat, and muscle, where they can be mobilized for endogenous repair as occurs with healing of bone fractures. Bone-marrow aspirate is considered to be the most accessible source, and thus, the most common place to isolate MSCs for treatment of musculoskeletal disease. However, harvesting MSCs from bone marrow requires an additional procedure that may result in donor-site morbidity. In addition, the number of MSCs in bone marrow is low, and the number and differentiation capacity of bone marrow-derived MSCs decreases with age, limiting their efficiency when isolated from older patients.

Tissues such as muscle, cartilage, tendon, ligaments, and vertebral discs show limited capacity for endogenous repair. Thus, when injuries occur to these structures it is hypothesized the use of MSCs may speed or enable healing of these tissues. Therefore, tissue engineering techniques are being developed to improve the efficiency of repair or regeneration of damaged musculoskeletal tissues. Tissue engineering focuses on the integration of biomaterials with MSCs and/or bioactive molecules such as growth factors. In vivo, the fate of stem cells is regulated by signals in the local 3-dimensional microenvironment from the extracellular matrix and neighboring cells. It is believed that the success of tissue engineering with MSCs will also require an appropriate 3-dimensional scaffold or matrix, culture conditions for tissue-specific induction, and implantation techniques that provide appropriate biomechanical forces and mechanical stimulation. The ability to induce cell division and differentiation without adverse effects, such as the formation of neoplasms, remains a significant concern. Given that each tissue type requires different culture conditions, induction factors (signaling proteins, cytokines, growth factors), and implantation techniques, each preparation must be individually examined.

MSCs have increasingly been employed by orthopedists and other specialists and alternative medicine providers as a means to heal musculoskeletal injuries, cartilage defects, and fractures, as either a standalone or augmenting therapy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover mesenchymal stem cell therapy for orthopedic applications as it is considered investigational for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue.

Select Health does NOT cover allograft bone products containing viable stem cells, including but not limited to, demineralized bone matrix (DBM) with stem cells, as this is considered investigational for all orthopedic applications due to a lack of evidence supporting safety and efficacy.

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

The use of mesenchymal stem cells (MSCs) for orthopedic conditions is an active area of research. Despite continued research into the methods of harvesting and delivering treatment, there are uncertainties regarding the optimal source of cells and the delivery method. Current available evidence on procedures using autologous bone marrow-derived MSCs for orthopedic indications in humans consists of a few small randomized and nonrandomized comparative trials with insufficient data to evaluate health outcomes. In addition, expanded MSCs for orthopedic applications are not Food and Drug Administration (FDA) approved (concentrated autologous MSCs do not require FDA approval). Due to the lack of evidence that clinical outcomes are improved, and the lack of regulatory approval, use of stem cells for orthopedic applications is considered investigational.

The evidence base on MSCs for cartilage repair is increasing, although nearly all studies to date have been performed in Asia with a variety of methods of MSC preparation; only 2 small randomized studies have been identified. Both these studies reported an improvement in histological and morphologic outcomes. One of these studies also reported an improvement in functional outcomes. The method of preparation used in this positive study was to obtain MSCs from bone marrow at the time of microfracture, and then culture (expand) over a period of 3 weeks and inject in the knee in a carrier of hyaluronic acid (HA). The second randomized trial, using MSCs from peripheral blood, found improvement in histological and morphologic outcomes, but not functional outcomes, following stimulation with recombinant human granulocyte colony-stimulating factor. Other nonrandomized comparative studies reported no benefit compared with ACI but have reported a benefit compared with microfracture alone.

Two small studies from Asia have compared core decompression alone versus core decompression with MSCs in patients with osteonecrosis of the femoral head. Both studies reported improvement in the Harris Hip Score in patients treated with MSCs, although it was not reported whether the patients or investigators were blinded to the treatment group. Hip survival was significantly improved following treatment with either expanded or concentrated MSCs. The effect appears to be larger with expanded MSCs compared with concentrated MSCs. Additional studies with a larger number of patients are needed to permit greater certainty regarding the effect of this treatment on health outcomes.

The American Association of Orthopaedic Surgeons states that stem-cell procedures in orthopedics are still at an experimental stage; most musculoskeletal treatments using stem cells are performed at research centers as part of controlled, clinical trials, and results of studies in animal models provide proof-of-concept that in the future, similar methods could be used to treat osteoarthritis, nonunion of fractures, and bone defects in humans.

The U.S. Food and Drug Administration (FDA) has stated: “A major challenge posed by SC [stem-cell] therapy is the need to ensure their efficacy and safety. Cells manufactured in large quantities outside their natural environment in the human body can become ineffective or dangerous and produce significant adverse effects, such as tumors, severe immune reactions, or growth of unwanted tissue.”

Stem Cell Therapy for Orthopedic Applications, continued

Billing/Coding Information

CPT CODES

20999	Unlisted procedure, musculoskeletal system, general
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

HCPCS CODES

S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post-transplant care in the global definition

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13. Sen RK, Tripathy SK, Aggarwal S et al. Early results of core decompression and autologous bone marrow mononuclear cells instillation in femoral head osteonecrosis: a randomized control study. J Arthroplasty 2012; 27(5):679-86.
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21. Zhao D, Cui D, Wang B et al. Treatment of early stage osteonecrosis of the femoral head with autologous implantation of bone marrow-derived and cultured mesenchymal stem cells. Bone 2012; 50(1):325-30.

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MEDICAL POLICY

SYNTHETIC CARTILAGE IMPLANT (CARTIVA) FOR HALLUX RIGIDUS/LIMITUS

Policy # 614

Implementation Date: 6/1/17
Review Dates: 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/13/22, 8/17/23, 9/1/24
Revision Dates:

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Osteoarthritis of the great toe can be a painful and limiting condition. Hallux rigidus (HR) describes a first metatarsophalangeal (MTP) joint that shows unusual stiffness resulting in limited great toe extension. The term, "hallux rigidus," is typically used only when the cause of the reduced range of motion (ROM) is osteoarthritis of the first MTP. "Hallux limitus," refers to a great toe that lacks normal motion but does not demonstrate degenerative changes at the MTP joint. Hallux limitus can arise from inflammation, thickening of the joint capsule, or from an idiopathic cause possibly representing a complex regional pain syndrome.

The treatment of hallux rigidus/limitus usually involves an initial trial of over-the-counter or custom orthotics and modifications of shoes to allow adequate room in the toe box. Orthotics are the primary intervention used for most patients treated conservatively. Some patients, particularly those with obvious swelling of the first MTP joint, gain significant pain relief from glucocorticoid injection.

If conservative therapy fails, surgical intervention is sometimes undertaken. Common surgical procedures performed for hallux rigidus/limitus include chielectomy where the bony osteophytes are surgically trimmed away, restoring more normal motion to the joint, joint replacement surgery, or arthrodesis (joint fusion). The latter two procedures involve significant morbidity and healing time limiting many patients' activities for as long as 6 months. While arthrodesis has been demonstrated to have excellent outcomes, total joint replacement demonstrates lesser outcomes and higher complication rates.

The Cartiva Synthetic Cartilage Implant (SCI) device is a polymer-based biomaterial implant for treatment of first metatarsophalangeal joint osteoarthritis approved by the FDA (Food and Drug Administration) in 2016. The Cartiva SCI does not regrow or replace cartilage but acts as a synthetic cushion in the joint. The device is implanted during a short and minimally invasive implantation procedure that allows for faster recovery, preservation of joint function compared to the standard of care treatment options, and preserves the option for future surgical treatment in the event of complications. The Cartiva SCI is intended as an alternative to fusion procedures which result in a total loss of joint movement.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers the Cartiva Synthetic Cartilage Implants for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

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Select Health does NOT cover Cartiva Synthetic Cartilage Implants for any other indication as it is considered experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

In a 2017 evidence review, a search of the literature identified no systematic reviews and only 3 primary studies related to Cartiva. Despite the small number of trials, the evidence quality is high in part based on the Baumhauer et al. study from 2015 which provides a comparative randomized prospective control multicentered trial, comparing Cartiva implant to first metatarsal arthrodesis. This prospective, randomized (2:1), controlled, noninferiority clinical trial was performed to compare the safety and efficacy of a small synthetic cartilage bone implant to first MTP arthrodesis in patients with advanced-stage hallux rigidus. This study showed equivalent pain relief and functional outcomes. The synthetic implant was an excellent alternative to arthrodesis in patients who wished to maintain first MTP motion. The percentage of secondary surgical procedures was similar between groups. Less than 10% of the implant group required revision to arthrodesis at 2 years.

Adding to the Baumhauer study, studies by Daniels et al. in 2017 has shown postoperative active MTP natural joint dorsiflexion and peak MTP dorsiflexion were mean 18.2 (range, 10.0–30.0) and 29.7 (range, 10.0–45.0) degrees, respectively. Pain VAS, SF-36 PCS, FAAM ADL, and FAAM Sports scores demonstrated clinically and statistically significant improvements. Radiographically, no patient demonstrated changes in implant position, implant loosening or subsidence, or implant wear. One implant was removed because of persistent pain and converted to fusion 2 years postoperation. This study provided outcomes to 5 years from implantation.

The Miniaci-Coxhead et al. study in 2016 reported the mid-term results of the Cartiva implant for the management of hallux rigidus. Overall, patients were very satisfied with the procedure. At an average of five years, patients are functioning very well, with limited pain, and maintained motion of the 1st MTP joint. These results are promising as a viable alternative to fusion of the 1st MTP joint for management of moderate-to-severe hallux rigidus. This study provides evidence out to 5 years demonstrating high functionality and good pain relief, though, the quality of the study's design is not as robust as the Baumhauer study.

Though the volume of studies is limited, current evidence supports satisfactory efficacy, safety, and durability of the Cartiva implant for patients experiencing pain and dysfunction due to osteoarthritic changes of the first metatarsophalangeal joint.

Billing/Coding Information

CPT CODES

28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28899	Unlisted procedure, foot or toes

Synthetic Cartilage Implant (Cartiva®) for Hallux Rigidus/Limitus, continued

HCPCS CODES

C1776	Joint device (implantable)
L8641	Metatarsal joint implant
L8642	Hallux implant
L8658	Interphalangeal joint spacer, silicone or equal, each

Key References

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MEDICAL POLICY

TENDON COBLATION (TOPAZ) FOR TENDINOPATHIES AND OTHER ORTHOPEDIC CONDITIONS

Policy # 380

Implementation Date:8/16/07

Review Dates: Review Dates: 8/21/08, 8/13/09, 8/19/10, 9/15/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/18/23, 2/20/24, 12/19/24

Revision Dates:

Disclaimer:
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Description

Tendon injuries after physical overloading or overuse are very common in athletes, as well as those involved in recreational sports or repetitive motion activities. Injuries most commonly involve the lateral and medial epicondyles of the elbow, as well as rotator cuff, Achilles, and patellar tendons. The term tendinitis implies the presence of inflammatory cells and is technically a histopathologic, not a clinical, diagnosis. Intrinsic tendon degeneration (tendinosis) is histologically devoid of inflammatory cells and is a pathophysiologic process, distinct from tendinitis. The clinical picture of pain, swelling, and physical limitation related to tendons is more correctly referred to as tendinopathy. The result is progressive loss of functional tendon fibers, which increases the load on the remaining tendon, thus increasing its susceptibility to progressive failure.

Standard treatments for tendinosis include activity modification, non-steroidal anti-inflammatories (NSAIDs), corticosteroid injections, bracing, physical therapy, and surgical debridement. Extracorporeal shock wave therapy (ESWT) has also been promoted as a mechanism to treat some tendinopathies. However, long-term outcomes from ESWT are lacking currently.

Recently, a novel bipolar radiofrequency technique for arthroscopic debridement has been developed. In conventional radiofrequency treatment, tissue is denatured, desiccated, and vaporized through heat-generated mechanisms. Coblation technology is fundamentally different from traditional radiofrequency and thermal devices. Coblation uses radiofrequency energy to excite the electrolytes in a conductive medium (e.g., synovial fluid in joints) creating a precisely focused plasma. The plasma's energized particles have sufficient energy to break molecular bond within tissue, causing tissue to dissolve at relatively low temperatures (typically 40°C–70°C). The result is volumetric removal of target tissue with minimal damage surrounding tissue. This type of radiofrequency ablation is referred to as cold or controlled ablation.

TOPAZ MicroDebrider (ArthroCare Corporation, Sunnyvale, CA) is a minimally invasive coblation procedure for the debridement of soft tissue, such as tendons in the knee, shoulder, elbow, and ankle. The TOPAZ system consists of 2 primary components. The TOPAZ MicroDebrider is a bipolar, single-use, high-frequency electrosurgical device designed for use in specific arthroscopic and orthopedic procedures. This wand-like device has a narrow shaft diameter (0.8 mm) that allows for creating small shallow impressions. The ArthroCare Timer regulates the length of radiofrequency bursts at half-second intervals.

Through a small incision about an inch long the TOPAZ MicroDebrider is applied on and around the affected tendon for 1/2 second duration treatments a quarter inch apart until a grid-like pattern is formed. With every fourth application, the device is inserted deeper into the tendon, approximately 1/4 inch in depth. Small amounts of tissue are removed as a light dose of radiofrequency energy is directed into the

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tissue. The entire TOPAZ procedure typically takes less than 20 minutes, and the patient is ready to leave the clinic once recovered from light anesthesia.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover tendon coblation therapy (TOPAZ) in the treatment of tendinopathies and other orthopedic conditions. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Currently, there are no randomized controlled trials in the medical literature demonstrating the efficacy of Coblation technology and related devices for treatment of joint or musculoskeletal soft tissue conditions. The available studies are nonrandomized small case series reporting short-term outcomes (Tasto, 2005). In a small study by Weil and colleagues (2008), the effectiveness of a minimally invasive technique using bipolar radiofrequency was performed on ten individuals with recalcitrant plantar fasciosis that failed conservative care. A percutaneous microtenotomy was performed unilaterally with the TOPAZ MicroDebrider. Outcome measures included visual analog scale (VAS), American Orthopaedic Foot & Ankle Society (AOFAS) Hindfoot and Midfoot Scale, and participant satisfaction assessment. According to the investigators, the participants had a statistically significant improvement in baseline VAS and AOFAS midfoot scores when compared with the one-year scores ($p < .0001$); however, a significant improvement was not noted in VAS scores at six months compared with one-year follow-up. The investigators stated that participants continued to improve at one year but may have reached maximal improvement at six months or before. Limitations of this study include the small sample size and short-term follow-up. The investigators concluded that a large, prospective, double blind randomized controlled study is needed to determine the true beneficial effects of this procedure. A phase IV study was identified in the clinicaltrials.gov database comparing pain relief (primary outcome measure) utilizing the TOPAZ MicroDebrider with Coblation during percutaneous fasciotomy (no incision) to standard surgical fasciotomy in the treatment of plantar fasciosis. To date, the results of this study are pending publication in peer-reviewed literature.

In summary, published prospective, randomized studies with large sample sizes reporting long-term outcomes are needed to demonstrate the safety and efficacy of Coblation technology compared to established methods of management of musculoskeletal conditions.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

20999	Unlisted procedure, musculoskeletal system, general
24999	Unlisted procedure, humorous or elbow

Tendon Coblation (TOPAZ®) for Tendinopathies and Other Orthopedic Conditions, continued

29999 Unlisted procedure, arthroscopy

HCPCS CODES

No specific codes identified

Key References

1. Arthrocare Inc. 2002. Available: http://www.topazinfo.com/. Date Accessed: June 11, 2007.
2. Arthrocare Inc. Coblation® In Brief. 2006. Available: http://www.arthrocare.com/our_technology/ot_coblation_explained.htm. Date Accessed: 2007, June 14.
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MEDICAL POLICY

THERMAL CAPSULORRHAPHY OF JOINT CAPSULES AND OTHER LIGAMENTOUS STRUCTURES

Policy # 259
Implementation Date: 1/3/05
Review Dates: 2/28/06, 5/17/07, 4/24/08, 4/23/09, 8/16/11, 8/16/12, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/18/18, 8/8/19, 8/20/20, 8/19/21, 7/20/22, 8/17/23
Revision Dates: 4/22/10

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Description

Initial treatment of shoulder, knee, elbow, and ankle instability is conservative in nature followed by range of motion and strengthening exercises. However, if instability persists, either activity modifications or surgical treatment may be considered. Activity modification may be appropriate for those patients who can identify a single motion that aggravates instability, such as overhead throwing motions with shoulder instability. Surgical treatment may be considered in those who are unwilling to give up specific activities (i.e., related to sports) or when instability occurs frequently or during daily activities. The shoulder surgery consists of inspection of the shoulder joint with repair; the repair can reattach or tighten the labrum, ligaments, or capsule. This is accomplished either with sutures alone or attached to absorbable tacks or anchors.

Arthroscopic approaches have been investigated over the past decade. Their success has been controversial due to a higher rate of recurrent instability compared with open techniques. This recurrence is thought to be related, in part, to the lack of restoration of capsular tension. Thermal capsulorrhaphy has been proposed as a technically simpler arthroscopic technique for tightening the capsule and ligaments. The technique is based on the observation that the use of non-ablative levels of radiofrequency electrothermal energy can alter the collagen in the glenohumeral ligaments and/or capsule, resulting in their shrinkage and a decrease in capsular volume, both thought to restore capsular tension. Thermal capsulorrhaphy was initially investigated using laser energy; now the uses of radiofrequency probes are more commonly used.

While interest in thermal capsulorrhaphy has focused on the shoulder joint, its use in the knee, elbow, and ankle has been anecdotally reported as treatment for instability resulting from ligamentous laxity.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover thermal capsulorrhaphy of *any* joint capsule. This therapy meets the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Thermal capsulorrhaphy may be used in conjunction with arthroscopic repair of torn ligaments or other structures (i.e., repair of Bankart or SLAP [superior labrum anterior and posterior] lesion). Additionally, thermal capsulorrhaphy has also been investigated as an arthroscopic treatment of glenohumeral laxity, a common injury among overhead athletes, such as baseball players, resulting in internal impingement of the posterior rotator cuff against the glenoid labrum. Thermal capsulorrhaphy has also been proposed as a sole arthroscopic treatment. For example, the technique may be considered in patients with chronic shoulder pain without recognized instability, based on the theory that the pain may be related to occult or microinstability. This diagnosis may be considered when a diagnostic arthroscopy reveals only lax ligaments and is commonly seen among baseball players. Finally, thermal capsulorrhaphy has been investigated for treatment of patients with congenital ligamentous laxity, such as Ehlers-Danlos or Marfan's syndrome.

Shoulder

There is minimal data published in the peer-reviewed literature regarding the use of thermal capsulorrhaphy, either as a sole arthroscopic procedure, or as an adjunct to other arthroscopic repair of shoulder lesions. The available literature consists of uncontrolled case series of patients. Unresolved issues regarding the technique include the following:

1. Identifying and quantifying joint laxity
2. Optimal temperature and length of exposure to heat
3. Variable response of collagen to heat, based on patient age and other factors
4. Control of tissue shrinkage (both at the time of surgery and during follow-up as the acute thermal damage heals)
5. Effect of potential temperature damage on proprioceptive and position sensitive nerve endings within the capsule
6. Risk of capsular ablation
7. Risk of neurologic complications
8. Appropriate rehabilitation (i.e., length of immobilization during healing phase, followed by exercise)

Knee, Elbow, and Ankle

A literature review did not identify any peer-reviewed published studies describing the use of non-ablative radiofrequency electrothermal energy to treat ligamentous laxity of the knee, elbow, and ankle.

A literature review performed in April 2010 identified an article from Zheng et al. They concluded there was no immediate difference in the joint after thermal shrinkage in the knee; open surgery later improved the lateral stiffness. For the shoulder, Sullivan et al. indicated that joint position sense was similar in the repaired shoulders and uninjured shoulders of each group of capsulorrhaphy patients. The mechanism responsible for heightened position sense in open and thermal capsulorrhaphy patients is unknown but may result from capsular retensioning and muscular scarring. The long-term implications of this outcome deserve further attention.

Billing/Coding Information

CPT CODES

29999	Unlisted procedure, arthroscopy

Thermal Capsulorrhaphy of Joint Capsules and Other Ligamentous Structures, continued

HCPCS CODES

S2300 Arthroscopy, shoulder, surgical; with thermally-induced capsulorrhaphy

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Select Health

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MEDICAL POLICY

TOTAL ANKLE ARTHROPLASTY (TOTAL ANKLE REPLACEMENT)

Policy # 358

Implementation Date:7/11/07

Review Dates: 2/26/09, 2/18/10, 2/17/11, 7/18/13, 4/14/16, 4/27/17, 4/17/19, 4/14/20, 4/15/21, 3/16/22, 4/20/23, 4/19/24, 4/17/25

Revision Dates: 3/4/08, 1/17/12, 3/4/14, 4/29/20, 7/22/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Osteoarthritis of the ankle may occur as a result of chronic "wear and tear" or degeneration of the joint cartilage that comes with age. However, the most common cause of ankle arthritis is a result of trauma. In patients with ankle osteoarthritis, treatment is designed to relieve pain and/or improve function. Early during therapy, patients use anti-inflammatory medications, bracing, and modified shoe gear to reduce pain and improve functionality. However, as the joint degenerates, these measures often fail. In some instances, arthrodesis (joint fusion) is performed. Total ankle arthroplasty (replacement) is a surgical treatment used in patients with highly symptomatic ankle arthritis and involves removal of the dome of the talus (the main ankle bone) and part of the tibia and replacement with a motion-preserving artificial prosthesis.

The materials of the ankle implants are the same as knee and hip implants. The prosthesis generally consists of a metal talar component, with a highly polished, grooved, convex articulating surface, and a short fixation stem. The tibial component consists of a metal stem, and baseplate for fixation, and a concave articulating surface composed of ultra-high molecular weight polyethylene. The polyethylene component is locked to the tibial plate in currently marketed U.S. prostheses but is free-floating (mobile-bearing) in some newer designs.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers total ankle arthroplasty/replacement using an FDA approved device as medically necessary, when ALL the following criteria are met:

1. The patient is skeletally mature*;
2. Ankle joint damage is due to arthritis;
3. The patient has moderate-to-severe ankle pain that significantly limits daily activity;
4. The patient has failed at least 12 weeks of conservative treatment, including both of the following:
   a. Anti-inflammatory medications; AND

b. Splints or orthotic devices;

5. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to surgery;

6. The patient does not have one of the following contraindications:

a. Extensive avascular necrosis of the talar dome.

b. Poor bone quality that would result in inadequate bony fixation.

c. Severe malalignment (e.g., > 15 degrees) or severe deformity of involved or adjacent anatomic structures (hindfoot, forefoot, knee) not correctable by surgery.

d. Active ankle joint infection.

e. Peripheral vascular disease.

f. Charcot neuroarthropathy.

Select Health covers revisions of the artificial joint with clinical documentation.

All other uses for total ankle arthroplasty/replacement are considered experimental/ investigational, and therefore, not covered; because their safety and/or effectiveness cannot be established by review of the available, published peer-reviewed literature.

*Refers to a system of fused skeletal bones, which occurs when bone growth ceases after puberty; for females, this generally occurs around 16 years of age, and for males, around 18 years of age.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
In a previous review of total ankle replacement completed in December 2011, the literature summary noted numerous limitations in the quality of the literature, including level of surgeons' experience, patient selection, durability, failure rate, and others. The largest issue identified was the high failure rate vis-à-vis ankle fusion. Much of this centered on the lack of quality published literature with only 2 systematic reviews and nine primary studies meeting inclusion criteria for the report. Since then, a significant increased body of literature is available, which allows better conclusions regarding the efficacy, safety, and durability to total ankle replacement procedures.

Since 2011 five systematic reviews and thirty-five primary literature articles have been published which

met inclusion criteria for review. Regarding both the 2011 and 2014 data, different devices were studied, though all devices were FDA approved for patients with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic arthritis, or osteoarthritis of the ankle. Despite a lack of consensus on patient selection criteria, authors agree careful patient selection is essential to successful outcomes.

Of the current body of 35 papers, 14 (40%) discussed revision rates at different time intervals and with different brands of devices. Revision or reoperation rates varied widely as they did when the technology was reviewed in 2011. For example, of the primary literature articles, 16 articles noted the revision or reoperation rates which ranged from 4% at 33.6 months to 54.4% at 180 months. There is a notable cluster of 12 studies which demonstrated likely revision at approximately 3 to 5 years (range of 33.6 to 72 months and revision rates of 4% to18.4%) post-implantation. These data, however, include a large degree of heterogeneity of patient populations and inclusion criteria of the studies. Common causes for revision included aseptic loosening, talar migration, and infection or polyethylene insert fractures.

Unfortunately, little evidence exists regarding proper patient selection criteria, clinical comparison of arthroplasty to arthrodesis, and how different devices compare to one another. Zaidi et al. in their 2013 systematic review stated well that: "… the quality of evidence is weak and fraught with biases and high quality randomized controlled trials are required to compare TAR with other forms of treatment such as fusion." Patients who have undergone this procedure report an improvement in visual analogue scores and American Orthopaedic Foot and Ankle Society scores, and all studies that tracked patients out to ten years reported that > 70% of implants survived at ten years, though this statistic cannot be compared to any other intervention at the same interval.

Only 3 of the published studies directly compared total ankle replacement to arthrodesis. The studies by Daniels et al., Flavin et al., and Schuh et al., performed comparative analyses of the two techniques. All three groups stated that there is no significant difference in outcomes between arthrodesis and arthroplasty of the ankle at follow-up. Only Daniels et al. compared revision rates of the two techniques and noted that at a mean follow-up of 66 months revision rates were 7% for arthrodesis and 17% for arthroplasty. The group concluded that clinical outcomes for the two techniques were comparable in a diverse cohort of patients. In conclusion, the current evidence regarding total ankle replacements is weak when looking at aggregate data from a methodological perspective. Few head-to-head prospective trials compare total ankle replacement with other standards of care and fewer still aid in determining appropriate patient selection criteria.

Billing/Coding Information

CPT CODES

27700	Arthroplasty, ankle;
27702	Arthroplasty, ankle; with implant (total ankle)

HCPCS CODES

C1776	Joint device, implantable
L8699	Prosthetic implant, not otherwise specified

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Revision History

Revision Date	Summary of Changes
7/22/25	For Commercial Plan Policy, added requirements pertaining to smoking cessation (new criterion #5): "Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to surgery."

Select Health

Total Ankle Arthroplasty (Total Ankle Replacement), continued

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MEDICAL POLICY

TOTAL HIP ARTHROPLASTY

Policy # 599

Implementation Date:1/1/18

Review Dates: 2/18/19, 2/17/20, 2/18/21, 1/11/22, 2/16/23, 3/3/24, 2/12/25

Revision Dates: 1/12/18, 2/16/18, 12/13/18, 5/1/19, 6/8/21, 9/24/21, 10/8/21, 1/22/25, 7/21/25

Related Medical Policies:

#254 Total Hip Resurfacing

#277 Computer-Assisted Orthopedic Surgeries

#506 Joint Replacements Using Makoplasty

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Hip arthroplasty is most performed as a treatment for deterioration of the hip joint due to a variety of musculoskeletal conditions, such as osteoarthritis, osteonecrosis, or other types of inflammatory arthritis. The aims of hip arthroplasty are relief of pain and improvement in joint function. Total hip arthroplasty (THA), also called total hip replacement (THR), entails removing the affected hip joint and replacing it with an artificial joint, called a hip prosthesis or hip implant. This requires cutting into and/or detaching segments of hip bone and surrounding soft tissues. Surgical cement may be used to fill gaps between the stem and remaining bone to secure the implant. Hip implants consist of a socket component known as the acetabular cup, a socket liner, a ball component, and a femoral stem that connects the ball component to the femur. Hard-on-hard bearings were developed to address the issues associated with conventional metal-on polyethylene prosthesis failure associated with excessive wear particles and limited femoral head size.

This procedure is sometimes done in a minimally invasive fashion. Minimally invasive THA (MI THA) uses smaller incisions and/or less soft-tissue dissection to reduce blood loss and tissue damage, thus, shortening recovery and rehabilitation times.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers total hip arthroplasty as medically necessary when the following criteria are met:

Must meet either criteria 1 or 2.

1. Advanced joint disease, demonstrated by all the following:
    a. Radiographic supported evidence or when conventional radiography is not adequate, magnetic resonance imaging (MRI) and/or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed) supported evidence (subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, severe joint space narrowing); **and**
    b. Pain or functional disability from injury due to trauma or arthritis of the joint; **and**

c. Unsuccessful conservative therapy (non-surgical medical management) lasting at least 12 weeks that is clearly addressed in the pre-procedure medical record. Includes one or more of the following:

   i. Anti-inflammatory medications or analgesics, or

   ii. Flexibility and muscle strengthening exercises, or

   iii. Supervised physical therapy [activities of daily living (ADLs) diminished despite completing a plan of care], or

   iv. Weight reduction as appropriate, or

   v. Therapeutic injections into the hip as appropriate

   Note: Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (medial and/or lateral but not patello-femoral).

   If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.

d. BMI is less than 45.

e. Hemoglobin A1C (Hgb A1C) is less than 8 in diabetics.

f. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to hip arthroplasty.

2. The patient has severe deformity, pain, or significant disability with interference in ADLs, and the surgeon determines that nonsurgical medical management would be ineffective or counterproductive, due to:

   a. Malignancy of the joint involving the bones or soft tissues of the pelvis or proximal femur; or

   b. Avascular necrosis (osteonecrosis of femoral head); or

   c. Fracture of the femoral neck; or

   d. Acetabular fracture; or

   e. Non-union or failure of previous hip fracture surgery; or

   f. Malunion of acetabular or proximal femur fracture

Select Health will NOT cover total hip arthroplasty if any of the following contraindications or relative contraindications are present:

a. Active infection of the hip joint or active systemic bacteremia

b. Active urinary tract or dental infection

c. Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip.

d. Rapidly progressive neurological disease except in the clinical situation of a concomitant displaced femoral neck fracture

e. Absence or relative insufficiency of abductor musculature

f. Any process that is rapidly destroying bone

g. Neurotrophic arthritis

Select Health does NOT cover total hip arthroplasty for any other indication as it is considered experimental/investigational.

Select Health does NOT cover robotic-assisted total hip arthroplasty, such as makoplasty or RIOS, as there is a lack of evidence to demonstrate meaningful clinical differences in outcomes for patients undergoing THA using these technologies; use of these technologies is considered experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health Community Care will follow the Commercial Plan Policy (Effective May 1, 2019)

Summary of Medical Information
More than 497,000 total hip replacements (THRs), also called total hip arthroplasties (THAs), are performed each year in the United States. These are necessitated by deterioration in the hip joint due to a variety of musculoskeletal conditions. Candidates for THA are patients with radiographic evidence of hip joint damage and moderate-to-severe persistent pain or disability, or both, that is not substantially relieved by an extended course of nonsurgical management, including nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, walking aids, physical activity reduction, and additional disease-specific therapies.

Crawford and Murray, in 1997, characterized total hip replacement as one of the most successful and cost-effective interventions in medicine, offering reliable pain relief and significant functional improvement in patients. However, Söderman et al., in 2001, performed a clinical outcome analysis on patients from The Swedish National Total Hip Arthroplasty Register using the Harris Hip Score and a conventional radiographic examination as outcome measures. The authors found clinical failure rates of 13% and 20% for all implants after 10 years, using 60 points or revision as the definition of failure in the Harris Hip Score and WOMAC, respectively. They contrasted this with 7% failure rate according to the register, which used the revision rate as the endpoint for failure.

Total hip resurfacing arthroplasty (HRA) has been proposed as an alternative to conventional total hip arthroplasty (THA) for the treatment of active patients less than 55 years old who have radiographic evidence of joint damage and/or chronic pain or disability that interferes with daily activities, is refractory to conservative treatment, and who would be expected to outlive any conventional THA prosthesis. In some cases, total HRA may also be viewed as a time-buying procedure to delay the need for a THA. This can be especially helpful for young, active patients with osteonecrosis who face the possibility of multiple revision procedures during their lifetime.

With regards to risk factors found to predict complications post hip replacement surgery, SooHoo et al., in 2010, reviewed discharge data from 138,399 patients undergoing primary THA in California from 1995 to 2005. The rate of complications during the first 90 days postoperatively (mortality, infection, dislocation, revision, perioperative fracture, neurologic injury, and thromboembolic disease) was regressed against a variety of independent variables, including patient factors (age, gender, race/ethnicity, income, Charlson

comorbidity score) and provider variables (hospital volume, teaching status, rural location). Compared with patients treated at high-volume hospitals (above the 20th percentile), patients treated at low-volume hospitals (below the 60th percentile) had a higher aggregate risk of having short-term complications (odds ratio, 2.00). A variety of patient factors also had associations with an increased risk of complications: increased Charlson comorbidity score, diabetes, rheumatoid arthritis, advanced age, male gender, and black race. Hispanic and Asian patients had lower risks of complications.

Duchman, K.L. et al., in their 2015 review queried the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database to identify patients who had undergone primary total hip or total knee arthroplasty between 2006 and 2012. Patients were stratified by smoking status and pack-year history of smoking. Thirty-day rates of mortality, wound complications, and total complications were compared with use of univariate and multivariate analyses. They identified 78,191 patients who had undergone primary total hip or total knee arthroplasty. Of these, 81.8% (63,971) were nonsmokers, 7.9% (6158) were former smokers, and 10.3% (8062) were current smokers. Current smokers had a higher rate of wound complications (1.8%), compared with former smokers and nonsmokers (1.3% and 1.1%, respectively; $p < 0.001$). Former smokers had a higher rate of total complications (6.9%) compared with current smokers and nonsmokers (5.9% and 5.4%, respectively; $p < 0.001$). Multivariate analysis identified current smokers as being at increased risk of wound complications (odds ratio [OR], 1.47; 95% confidence interval [CI], 1.21 to 1.78), particularly deep wound infection, while both current smokers (OR, 1.18; 95% CI, 1.06 to 1.31) and former smokers (OR, 1.20; 95% CI, 1.08 to 1.34) were at increased total complication risk. Increasing pack-year history of smoking resulted in an increasing total complication risk. Based on these findings, the authors concluded that current smokers have an increased risk of wound complications and both current and former smokers have an increased total complication risk following total hip or total knee arthroplasty.

Similarly, Marchant et al., in 2009, published a review which demonstrated the extent uncontrolled diabetes has on complications in patients undergoing total hip arthroplasty. This retrospective study compared patients with uncontrolled diabetes mellitus (n = 3973), those with controlled diabetes mellitus (n = 105,485), and those without diabetes mellitus (n = 920,555) with regards to common surgical and systemic complications, mortality, and hospital course alterations. Additional stratification compared the effects of glucose control among patients with Type-I and Type-II diabetes. Glycemic control was determined by physician assessments based on the American Diabetes Association guidelines with use of a combination of patient self-monitoring of blood-glucose levels, the hemoglobin A1c level, and related comorbidities. Compared with patients with controlled diabetes mellitus, patients with uncontrolled diabetes mellitus had a significantly increased odds of stroke (adjusted odds ratio = 3.42; 95% confidence interval = 1.87 to 6.25; $p < 0.001$), urinary tract infection (adjusted odds ratio = 1.97; 95% confidence interval = 1.61 to 2.42; $p < 0.001$), ileus (adjusted odds ratio = 2.47; 95% confidence interval = 1.67 to 3.64; $p < 0.001$), postoperative hemorrhage (adjusted odds ratio = 1.99; 95% confidence interval = 1.38 to 2.87; $p < 0.001$), transfusion (adjusted odds ratio = 1.19; 95% confidence interval = 1.04 to 1.36; $p = 0.011$), wound infection (adjusted odds ratio = 2.28; 95% confidence interval = 1.36 to 3.81; $p = 0.002$), and death (adjusted odds ratio = 3.23; 95% confidence interval = 1.87 to 5.57; $p < 0.001$). Patients with uncontrolled diabetes mellitus had a significantly increased length of stay (almost a full day) as compared with patients with controlled diabetes ($p < 0.0001$). All patients with diabetes had significantly increased inflation-adjusted postoperative charges when compared with nondiabetic patients ($p < 0.0001$). This study identified, regardless of diabetes type, patients with uncontrolled diabetes mellitus exhibited significantly increased odds of surgical and systemic complications, higher mortality, and increased length of stay during the index hospitalization following lower extremity total joint arthroplasty.

A subsequent study by Jamsen et al., from 2012, confirmed these findings. This study revealed uncontrolled diabetic patients more than doubled the periprosthetic joint infection risk independent of obesity (adjusted OR, 2.3; 95% CI, 1.1 to 4.7). In patients without a diagnosis of diabetes at the time of the surgery, there was a trend toward a higher infection rate in association with a preoperative glucose level of ≥ 6.9 mmol/L (124 mg/dL) compared with < 6.9 mmol/L. The infection rate was 1.15% (95% CI, 0.56% to 2.35%) in the former group compared with 0.28% (95% CI, 0.15% to 0.53%) in the latter, and the adjusted OR was 3.3 (95% CI, 0.96 to 11.0). The type of diabetes medication was not associated with the infection rate.

Billing/Coding Information

CPT CODES

27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
1/22/25	For Commercial Plan Policy, added the following note concerning the conservative therapy requirement listed in criterion #1-c: "Note: Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (medial and/or lateral but not patello-femoral). If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable."
7/21/25	For Commercial Plan Policy, clarified smoking cessation requirement in criterion #1-f: "Tobacco

Select Health

	smoking, which includes cigarette usage, e-cigarette usage, or vaping; ***and vaping or inhalation of any other substances for a sustained period***, must be discontinued for at least four weeks prior to hip arthroplasty."

Select Health

Select Health

MEDICAL POLICY

TOTAL HIP RESURFACING

Policy # 254
Implementation Date:12/14/04
Review Dates: 12/12/06, 10/23/08, 12/17/09, 10/21/10, 10/13/11, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/18/19, 2/17/20, 2/18/21, 1/11/22, 2/16/23, 3/3/24, 4/17/25
Revision Dates: 5/15/06, 12/21/06, 10/03/07, 2/14/12, 1/16/25, 5/12/25

Related Medical Policies:
#599 Total Hip Arthroplasty

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Hip resurfacing can be categorized as partial hip resurfacing, in which a femoral shell is implanted over the femoral head, and total hip resurfacing, consisting of an acetabular and femoral shell. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head and preservation of the acetabulum. Total hip resurfacing, investigated in a broader range of patients including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis, may be considered an alternative to total hip arthroplasty, particularly in active young patients who would potentially outlive a total hip prosthesis. Therefore, total hip resurfacing could be viewed as a time-buying procedure to delay the need for a total hip arthroplasty. Proposed advantages of total hip resurfacing compared to total hip arthroplasty include preservation of the femoral neck and femoral canal, thus, facilitating revision or conversion to a total hip replacement, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing stability and decreasing the risk of dislocation compared to total hip arthroplasty.

Compared to a traditional total hip replacement system with a metal-on-plastic socket, the potential benefit of hip resurfacing is that its metal-on-metal socket shows less wear in laboratory testing. Reported additional benefits include improved ability to maintain 'usual' activities due to improved proprioception due to continued ability to sense spatial relationships as the joint's proprioceptors remain at least partially intact.

Because part of the head and all the femoral neck are preserved in hip resurfacing, the normal stress pattern is maintained in the femur, potentially leading to less thigh pain and less weakening of the femur. Another major advantage of surface replacement is that, if a future revision or full replacement becomes necessary (highly likely in young active patients), the revision procedure is as simple as a novel procedure, without the complications of typical joint replacement revisions. Finally, if post-operative infection occurs, with surface replacement it is easier to treat than a total replacement infection that may extend well down inside the femur.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers total hip resurfacing *in limited circumstances*. Medical literature has demonstrated favorable short- and mid-term outcomes for these prostheses when used in an appropriately selected population. For all other clinical circumstances, or for other uses of hip resurfacing technology, this is considered experimental/investigational.

Select Health

Criteria for coverage of hip resurfacing procedure (must meet all):

1. The patient has either severe osteoarthritis or osteonecrosis of the hip
2. Implanted device must be FDA approved for this indication
3. Patient age:
   a. Females ≤ 55 years of age
   b. Males ≤ 60 years of age
4. BMI ≤ 35.0
5. Normal proximal femoral bone geometry and bone quality is present
6. The physician performing the procedure has been formally trained in performing hip resurfacing procedures and is credentialed to perform them at a Select Health contracted facility

Contraindications:

1. Presence of an active infection of the body or blood
2. Immature skeletal structure
3. Blood vessel-related disease, muscle-related disease, or nerve-and-muscle related disease that will prevent the artificial hip joint system from remaining stable
4. Patients with a history of reactions to wearing metal jewelry (metal sensitivity)

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The Medical Technology review from March 2006 concluded that methodological weaknesses of the few published studies (6 studies) to that point limited conclusions regarding whether total hip resurfacing is as effective or durable as conventional total hip replacement. Since that review, the Birmingham Hip Resurfacing System received 510(k) approval from the FDA. The Cormet Hip Resurfacing System received premarket (PMA) approval in 2007.

In the safety and efficacy data presented to the FDA for the Birmingham Hip Resurfacing System (BHR), the manufacturer reported the following information:

- From July 1997 to May 2004, one investigator implanted the BHR system in 2,385 hips at a single hospital in the UK. The mean age of the cohort was 53.1 years (range = 13–86 years); 70.6% were men and 29.4% were women. In 75.0% of patients, osteoarthritis was the primary diagnosis followed by dysplasia (15.8%), avascular necrosis (4.1%), inflammatory arthritis (2.4%), and other diagnoses (2.7%).
- After 5 years, 27 (1.1%) implantation procedures required revision. Ten of these were a result of femoral neck fracture, 8 for infections, 6 for femoral head collapse, 2 for avascular necrosis, and 1 for dislocation. No deaths related to the implantation procedure were reported.
- After five years, the mean Oswestry-modified Harris Hip (OSHIP) score in 1,111 unilateral procedures improved from a baseline mean of 60.1 to 94.8. For the group of patients who had baseline OSHIP

Select Health

scores ≥ 80, the mean OSHIP scores improved from 84.5 to 99.3. For the group of patients who had baseline OSHIP scores < 80, the mean OSHIP scores improved from 59.4 to 95.6.

- At postoperative years 2, 3, 4, and 5, the percentage of 1,111 cases with good or excellent OSHIP scores was 96.9%, 95.8%, 95.2%, and 92.8%, respectively.
- At 5 years, 99.5% of 1,626 cases were pleased or very pleased with the operation.

Data from a second cohort of 3,374 BHR cases (mean age = 52.5 years) performed by 140 surgeons worldwide were also reported:

- After 5 years, 76 cases (2.2%) required revision. Of these, 34 were for a fracture, 26 for component loosening, 7 for infection, 5 for avascular necrosis, 5 for dislocation, 5 for miscellaneous device failures, 3 for pain, and 3 for unknown reasons.
- The 5-year survivorship was 96.3%.
- After 5 years, mean OSHIP scores improved from 56.95 at baseline to 89.77.

In 2007, the FDA gave a pre-market approval (PMA) for the Cormet Hip Resurfacing System. As part of the approval, the FDA also required Corin USA to provide the following data in a separate post approval study report. This included:

a. Two post-approval studies:
   i. The first is designed to evaluate the long-term safety and effectiveness of the Cormet Hip Resurfacing system among patients who participated in the pivotal investigational device exemption study. Patients will be followed and will undergo clinical and radiographic evaluation annually through the 5th year postoperatively, and subsequently at years 8 and 10. Patients will receive mailed questionnaires at years 6, 7, and 9. As part of this study, 350 patients will have serum cobalt and chromium ions and renal function data collected at 5 and 10 years postoperatively.
   ii. The second post-approval study is designed to examine the performance of the Cormet Hip Resurfacing System under actual conditions of use. This will include the recruitment of 4 new investigation sites and investigators with 40 study subjects at each site. Study subjects will be followed for 2 years and will undergo physician follow-up visits postoperatively at 6 weeks, 6 months, 12 months, and 24 months.

b. A mandatory Training Program with web-based e-simulation review followed by live surgery observation or review of a surgical video. This is to be followed by a hands-on experience at a training center with interactive eSimulation, a sawbone workshop, and tissue surgery practice. This must also be followed through the first surgery.

c. Unlimited access to the web-based interactive e-simulation training must also be provided for any newly trained surgeon.

d. Results of the post-approval studies must be reflected in the labeling (via a supplement) when the post-approval study is completed and/or at earlier time points, as needed.

A Hayes Directory published since FDA approval of the devices assigned a 'B' rating to metal-on-metal resurfacing arthroplasty in fit, active patients younger than age 55, with normal bone geometry and bone quality ('B' ratings reflect a device with some proven safety and efficacy in the published literature, though further research is required to fully clarify clinical indications, contraindications, treatment parameters, comparisons with other technologies, and/or impact on health outcomes). A 'D' was assigned to hip resurfacing in patients older than age 55 (A 'D' reflects a device with no proven benefit and/or that is not safe). The review concluded that short and midterm data suggest that metal-on-metal hip resurfacing can alleviate pain and improve hip joint function. However, comparative data is very limited and long-term data over 10 years are not available, which limits conclusions about relative safety, efficacy, and durability.

A September 2007 update identified 16 additional studies published since the review in March 2006. Of these, 5 were feasibility or biomechanical analyses and did not examine clinical outcomes. Girard et al. randomly assigned patients to hip resurfacing or conventional hip replacement and reported that femoral offset was significantly increased with hip replacement and restored to within ± 4 mm in 14 (25%) patients. Femoral offset was decreased with hip resurfacing and restored to within ± 4 mm in 29 (59%) patients. Leg length increased by a mean of 2.6 mm in the replacement group and shortened by a mean of 1.9 mm in the resurfacing group, compared with the contralateral side. Leg-length inequality was

restored to within ± 4 mm in 33 (60%) patients in the resurfacing group and in 42 (86%) patients in the resurfacing group. The authors concluded that, in the typical patient, restoration of normal proximal femoral anatomy is more precise with resurfacing and that the use of a large-diameter femoral head with resurfacing avoids over-lengthening of the limb.

One prospective, randomized controlled trial was published comparing revision rates, pain, and functioning with the Birmingham Hip and conventional total hip replacement. Vendittoli et al. compared total hip resurfacing and metal on metal total hip replacement in patients aged < 65 years. Of 105 total hip replacements, one required revision due to recurrent dislocation while 2 hips in the resurfacing group were revised for femoral head aseptic loosening. The mean surgical time was 101 minutes vs. 85 minutes, mean incision length was 17.2 cm vs. 14.5 cm, and the mean length of hospital stay was 5.0 days vs. 6.1 for the resurfacing and replacement groups respectively. At 1-year, physical functioning did not differ significantly between the groups, and 98% of patients in both groups were either satisfied or very satisfied. Resurfacing patients reported a significantly higher activity level and a greater percentage (72% vs. 39%) had returned to heavy or moderate activities, 1-year postoperatively compared with the replacement group. Complication rates were similar across the 2 procedures.

Findings in a comparative study of metal-on-metal hip resurfacing and total hip arthroplasty by Vail et al., they retrospectively compared the outcomes of 52 patients (57 hips) with resurfacing arthroplasty (mean age = 47 years, range = 22–64) to 84 patients (93 hips) (mean age = 57 years, range 17–92) with cement-less primary total hip replacement. The mean follow-up was 3 years. Pain and functioning scores were similar between the 2 groups, but the resurfacing group had higher activity scores and range of motion. The complication rates and re-operation rates were similar. Thus, while both hips produce similar improvements in pain and functioning with similar revision and complications rates, the Birmingham hip appears to improve activity levels and overall quality of life over conventional hip resurfacing. The impact of the Pollard et al. study observed biomechanical changes on the durability of each device will be determined with longer-term research. The remaining studies were primarily retrospective case series describing pre- and post-surgical outcomes in patients who underwent hip resurfacing. These studies largely support the findings from comparative studies identifying that hip resurfacing improves activity levels from baseline with a revision rate of 3%–6%. Mont et al. further demonstrated that revision rates and activity improvement were similar for patients with osteoarthritis or osteonecrosis.

Four studies presented data regarding the potential problem of high serum concentrations of metal ions. The largest of these, Witzleb et al., involved 111 patients implanted with a Birmingham hip, 74 patients implanted with a 28 mm metal-on-metal total hip, and 130 implant-free control subjects. The study measured serum ion levels over a 24-month period and found that patients with Birmingham hips had higher concentrations of serum chromium and cobalt than the patients receiving the total hip implant or controls. The remaining studies report similarly elevated levels compared to pre-implantation, although Daniel et al. found no difference in ion levels between resurfacing and replacement patients. The eventual health impact of these elevated metal ion serum levels is unknown and cannot be determined without longer-term follow-up.

The primary weakness of the literature continues to be a lack of long-term data about the durability of resurfacing implants and the health effects of elevated metal ions. The available literature suggests that resurfacing is as effective as conventional hip replacement at improving overall functioning. Resurfacing appears to permit a higher degree of activity than hip replacement, which would make it an appealing alternative to young, active patients at least in the short to mid-term. Long-term studies are needed to establish the life-expectancy of a typical resurfacing implant and to determine whether elevated serum metal ions have any deleterious health effects.

A January 2012 Medical Technology Assessment focused on the upper age limit for successful total hip resurfacing. 2 systematic reviews and 14 primary literature articles were identified. The articles date from 2006–2011, and except for the systematic reviews, examined the outcomes of total hip replacement on nearly 18,000 hips. Males were studied 2:1 over females and the average age of the patient undergoing total hip resurfacing was 52 years old.

The BCBS TEC systematic review concluded that a substantial body of evidence shows hip resurfacing to be associated with strong improvements up to 5 years. Since the publication of this systematic review, six studies have been published illustrating substantive improvements (e.g., low revision rates, high prosthesis survival, etc.) with follow-up times exceeding five years. BCBS TEC also found THR to be as

beneficial as total hip arthroplasty (THA) in patients who are likely to outlive the 10 years or more functional lifespan of traditional metal-on-metal prostheses.

Neither of the 2 systematic reviews addressed the issue of patient outcomes in patients older than 55 years of age. Though the average age of patients in the studies was 52 years old, the following studies examined patients of different pertinent age groups including those > 55 years old:

- Amstutz et al.; THR in patients over age 50 and under age 50
- Carrothers et al.; THR in patients ≥ 70 years of age
- Costa et al.; THR in patients between 21 and 84 years of age
- Jameson et al.; THR in patients between 28 and 74 years of age
- Kreuzer et al.; THR in patients between 31 and 63 years of age
- Li et al.; THR in patients between 37 and 64 years of age
- McBryde et al.; THR in patients between 14 and 65 years of age
- Papavasiliou et al.; THR in patients over age 60 and under age 60

Amstutz et al. noted that there was no difference in objective clinical outcomes in patients from the "young" group (mean age = 41.2 years old) vs. the "old" group (mean age = 57.4 years old). Importantly, Carrothers et al. who examined the oldest cohort of patients found there was a high mid-to-long term success rate after THR in patients ≥ 70 years old. Likewise, they concluded that though this group of patients scored two points lower on postoperative outcome measures than did the control group, it is likely this is of only minor clinical significance. Papavasiliou et al. published results of patients > 60 years of age who underwent THR and concluded that age alone should not influence a surgeon's decision to proceed with a THR.

Despite the conclusions from many of the studies suggesting outcomes related to hip resurfacing/partial hip replacement are comparable to total hip replacement, nearly all the studies except for those specifically focusing on an 'elderly' population (Amstutz and Carrothers mentioned above along with Papavasiliou et al.) suffer from a significant methodological limitation in that the outcomes for the populations over age 55 are not separated from the rest of the study population. In other instances, the duration of follow up was too short to conclude whether there would be a divergence of revision rates over time as most studies were of a duration < 5 years. This limits any conclusion as to the efficacy, complication, and revision rates as it relates to these populations.

A pertinent coincidental finding uncovered in the literature was the poor outcomes for women undergoing THR. Only one-third of the patients studied in the 14 primary literature articles were female. Carrothers et al. noted a significantly higher revision rate for women than in men (1.5% for men and 15.8% in women). Jameson et al. noted a 6% lower hip score improvement in women than in men. Likewise, men in the study had 2.2% and 1.3% revision rates and femoral head fractures respectively where women saw 7.4% and 3% in the same categories. Prosser et al. also found higher revision rates for females before adjusting for head size. Coincidentally, as an offshoot of this review, several articles have addressed the outcomes of women, and show higher revision rates, higher femoral head fracture rates, and lower hip score improvements in this population, especially over age 55. The exact reason for this is not identified.

Multiple studies have been published since the previous review on this topic in 2006 pertinent to the age limitation question. Eight studies specifically addressed outcomes of patients aged > 55. None of those studies concluded that patients older than 55 years of age performed statistically significantly worse than patients younger than 55 years of age at follow-up. However, the studies suffer methodological limitations which make it difficult to ascertain an optimal upper age limit for patients undergoing the procedure. Nevertheless, the articles suggest performance of this procedure beyond age 55 is similarly safe and effective.

Billing/Coding Information

CPT CODES

27125	Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty) **[this is the incorrect code to bill for hip resurfacing; the two codes listed below should be used when billing for this procedure]**

27299 Unlisted procedure, pelvis or hip joint

HCPCS CODES

S2118 Metal-on-metal total hip resurfacing, including acetabular and femoral components

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Revision History

Revision Date	Summary of Changes
1/16/25	For Commercial Plan Policy, removed previous criterion #6, which included a life-expectancy requirement.
5/12/25	For Commercial Plan Policy, removed previous contraindications #4 and #5: "4. Females of child-bearing age since it is unknown whether metal ions released by the device could harm an unborn child; 5. Patients with significantly impaired function of the kidneys."

Select Health

Select Health

MEDICAL POLICY

TOTAL KNEE ARTHROPLASTY

Policy # 598
Implementation Date:1/1/18
Review Dates: 2/18/19, 2/17/20, 2/18/21, 1/11/22, 2/16/23, 3/3/24, 2/15/25
Revision Dates: 1/12/18, 2/16/18, 12/5/18, 5/1/19, 6/8/21, 9/24/21, 10/8/21, 1/22/25, 7/21/25

Related Medical Policies:
#431 Partial Knee Replacement/Resurfacing (Unicompartmental and Bicompartmental)
#277 Computer-Assisted Orthopedic Surgeries
#506 Joint Replacements Using Makoplasty
#511 Custom Components for Total Knee Replacement (TKA)
#579 Ligament-Sparing Knee Replacement Surgery

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Total knee arthroplasty (TKA) is the medical term for total knee joint replacement (TKR). There are three compartments in the knee: the medial, the lateral, and the patellofemoral. The surfaces of these compartments are covered with articular cartilage and synovial fluid. Other common reasons for TKR include rheumatoid arthritis, traumatic arthritis, osteonecrosis, and malignancies.

Primary indications for TKA are severe pain with activity or at rest not responsive to conservative therapy, or loss of function and impairment in activities of daily living (ADL). Conservative measures typically employed include non-steroidal anti-inflammatory medications or using other conservative therapies such as steroid injections and physical therapy. The goal of total knee replacement surgery is to relieve pain and improve patient function.

To perform a TKA, a surgeon removes the damaged part of the joint and then reshapes the surface to hold a replacement joint that is either metal or plastic. Then the artificial joint is attached to the thigh bone, shin bone, and knee cap. Replacement joints have a limited life; factors such as a person's age, severity of the knee disease, obesity, and the type of knee replacement all affect the time frame that an artificial joint will last.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers total knee arthroplasty as medically necessary when the following criteria are met:

Must meet either criteria 1 or 2.

1. Advanced joint disease demonstrated by all the following:
    a. Radiographic supported evidence or when conventional radiography is not adequate, magnetic resonance imaging (MRI) and/or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed) supported evidence (subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis); **and**

b. Pain or functional disability from injury due to trauma or arthritis of the joint; **and**

c. Unsuccessful conservative therapy (non-surgical medical management) lasting at least 12 weeks that is clearly addressed in the pre-procedure medical record. Includes one or more of the following:

i. Anti-inflammatory medications or analgesics, or

ii. Flexibility and muscle strengthening exercises, or

iii. Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care], or

iv. Weight reduction as appropriate, or

v. Therapeutic injections into the knee as appropriate.

Note: Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (medial and/or lateral but not patello-femoral).

If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.

d. BMI is less than 45; **and**

e. Hemoglobin A1C (Hgb A1C) is less than 8 in diabetics; **and**

f. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to knee arthroplasty.

2. The patient has severe deformity, pain or significant disability with interference in activities of daily living, and the surgeon determines that nonsurgical medical management would be ineffective or counterproductive due to:

a. Failure of a previous osteotomy; or

b. Distal femur fracture; or

c. Malignancy of the distal femur, proximal tibia, knee joint or adjacent soft tissues; or

d. Failure of previous unicompartmental knee replacement; or

e. Avascular necrosis of the knee; or

f. Proximal tibia fracture

Select Health will NOT cover total knee arthroplasty if any of the following contraindications or relative contraindications are present:

a. Active infection of the knee joint or active systemic bacteremia

b. Active urinary tract or dental infection

c. Any skin infection which may cause an adverse event

d. Rapidly progressive neurological disease

e. Insufficiency of extensor mechanism/quadriceps

f. Any process that is rapidly destroying bone

g. Neurotrophic arthritis

Select Health does NOT cover total knee arthroplasty for any other indication as it is considered experimental/investigational.

Select Health does NOT cover robotic-assisted total knee arthroplasty such as makoplasty or RIOS, as there is a lack of evidence to demonstrate meaningful clinical differences in outcomes for patients undergoing TKA using these technologies; use of these technologies is considered experimental/investigational.

Select Health will NOT reimburse additionally for custom knee components (see medical policy #511) as current evidence has not demonstrated any meaningful clinical differences in outcomes for patients undergoing TKA compared to use of standard components. If the procedure otherwise meets criteria for TKA, the procedure will be covered, but the components will only be reimbursed at the standard component reimbursement level.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Select Health Community Care will follow the Commercial Plan Policy (Effective May 1, 2019)

Summary of Medical Information
Total knee arthroplasty is a well-established procedure that was first performed in the 1970s and has been further improved and refined over the subsequent years. Excellent long-term outcomes can be achieved with contemporary methods of ligament reconstruction and open reduction, and internal fixation for injuries around the knee; nevertheless, posttraumatic arthritis frequently develops. Reconstruction options for symptomatic posttraumatic knee arthritis include osteotomy, arthrodesis, and arthroplasty. Surgical challenges include the presence of extensive (often broken) hardware, scarring, stiffness, bony defects, compromised soft tissues, and malalignment. Patient age and activity, and the anatomic location and extent of damage to the articular surface, must be considered when determining the surgical treatment plan. For younger patients, osteotomy, allograft transplantation, or arthrodesis of the knee is considered, whereas older, low-demand patients are usually treated with arthroplasty. Attention to specific technical details and careful surgical technique are necessary to achieve a successful result. Functional improvement is usually seen following arthroplasty and, sometimes, arthrodesis. However, complications are common, and outcomes following arthroplasty are generally inferior to those reported for other diagnoses.

Knee-replacement surgery is frequently done and highly successful. It relieves pain and improves knee function in people with advanced arthritis of the joint. The most common indication for the procedure is osteoarthritis. A review completed by Health Quality Ontario in 2005 established patients who undergo TKR surgery for osteoarthritis have substantial improvements in terms of reduction of pain and improvement of function. A comparison of the mean effect score, and the percent change in 19 studies that reported preoperative and postoperative outcome scores for patients who had TKR, showed that the procedure is effective. The 19 studies included patients of various ages and used a variety of prostheses and techniques to implant the device. TKR was effective in all the studies. The revision rates ranged from

0% to 13% in the studies that reported at least 5 years of follow-up. As for the factors that predict TKR outcomes, a variety of factors have been evaluated, including obesity, age, gender, prosthesis design, and surgical techniques; however, none of these have been shown to predict outcomes (pain or function) consistently across studies. However, the regression analyses identified accounted for only 12% to 27% of the variance, indicating that over 70% of the variance in the outcomes of TKR is unexplained. In terms of the timing of TKR surgery, 2 studies found that the severity of osteoarthritis does not predict outcome, but 1 study was found that higher functioning patients had significantly less pain and better function up to 2 years after surgery compared with lower functioning patients. It is important to note that the patients in the low and high function groups were evenly matched on comorbid conditions.

Further study has identified the impact of co-morbidities on outcomes from surgery which has shaped the consideration of patients deemed to be optimal candidates for surgery. Particularly prevalent in the literature is the impact of obesity and smoking on total joint replacement. McElroy et al. in 2013 completed a systematic review of the literature to identify all studies reporting outcomes of total knee arthroplasty in obese (30 ≤ BMI < 40 kg/m2) and morbidly obese patients (40 ≤ BMI < 50 kg/m2). Twenty-four studies were identified in our literature search. At a mean 5-year follow-up, morbidly obese patients (88%) had significantly lower implant survivorship than obese patients (95%) and nonobese patients (97%). Significantly, lower postoperative mean Knee Society objective and function scores (71 and 60 points) were observed for morbidly obese patients than for nonobese patients (75 and 90 points), but obese patients did not have significantly lower Knee Society objective and function scores than nonobese patients (78 and 84 points). Complication rates for nonobese, obese, and morbidly obese patients were 9%, 15%, and 22%, respectively; all of which were significantly different. However, no significant difference was observed in the incidence of radiolucent lines that were 12%, 19%, and 14%, respectively. The authors concluded a BMI greater than 40 kg/m2 may be used as a cutoff to help guide patient education and treatment options for primary total knee arthroplasty.

As for the impact of smoking on joint replacement outcomes, Singh et al. in 2011 completed a systematic review which looked at the impact of smoking tobacco on complications and outcomes from TKA. The review identified current smokers were significantly more likely to have any post-operative complication (risk ratio, 1.24 [95% confidence interval, 1.01 to 1.54]) and death (risk ratio, 1.63 [95% confidence interval, 1.06 to 2.51]), compared to non-smokers. Former smokers were significantly more likely to have any post-operative complication (risk ratio, 1.32 [95% confidence interval, 1.05 to 1.66]) and death (risk ratio, 1.69 [95% confidence interval, 1.08 to 2.64]). The author concluded studies examining long-term consequences of smoking on implant survival and complications are needed. He also noted smoking cessation may improve outcomes after THA or TKA. In a subsequent study by Singh et al. published in 2015, these findings were reinforced. They identified the tobacco use status for 7,926 patients (95%) and not available for 446 patients (5%); 565 (7%) were current tobacco users. Compared to non-users, current tobacco users were more likely to be male ($p < 0.001$), and less likely to be obese ($p \leq 0.008$), be older than 60 years, have a Charlson score > 0, or have undergone TKA rather than THA ($p < 0.001$ each). The hazard ratios for deep infection (2.37; 95% CI 1.19, 4.72; $p = 0.01$) and implant revision (1.78; 95% CI 1.01, 3.13; $p = 0.04$) were higher in current tobacco users than in non-users. No significant differences were noted for periprosthetic fractures or superficial infections.

Finally, uncontrolled diabetes mellitus has been identified as a significant factor contributing to worsened outcomes in joint replacement. Following a TKA, patients with diabetes have higher risks of pulmonary embolism, postoperative hemorrhage, infection, wound complications, ileus, and even death compared with patients without diabetes. In a retrospective study by Illingworth et al. in 2013 of 4241 TKAs, patients with diabetes had an infection rate of 3.43% (12 of 350 TKAs), while nondiabetic patients had an infection rate of .87% (34 of 3,891 TKAs).

Billing/Coding Information

CPT CODES

27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component

27487 Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

HCPCS CODES

No specific codes identified

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Revision History

Revision Date	Summary of Changes
1/22/25	For Commercial Plan Policy, added the following note concerning the conservative therapy requirement listed in criterion #1-c: "Note: Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (medial and/or lateral but not patello-femoral). If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable."
7/21/25	For Commercial Plan Policy, clarified smoking cessation requirement in criterion #1-f: "Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; ***and vaping or inhalation of any other substances for a sustained period***, must be discontinued for at least four weeks prior to knee arthroplasty."

Select Health

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MEDICAL POLICY

TOTAL SHOULDER REPLACEMENT

Policy # 629
Implementation Date:9/25/18
Review Dates: 10/15/19, 10/15/20, 11/18/21, 9/15/22, 1/27/24, 2/20/25
Revision Dates: 5/1/19, 5/20/21, 9/16/21, 9/30/22, 10/31/23, 2/2/24, 7/18/24, 7/22/25

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description
Severe shoulder arthritis can be quite painful and cause restriction of motion. While the symptoms of shoulder arthritis may be tolerated with some medications and lifestyle adjustments, there may come a time when surgical treatment is necessary. Shoulder replacement surgery, also called arthroplasty, involves the replacement of the damaged bone and cartilage with metal and plastic implants. Shoulder arthroplasty is a treatment option that can relieve pain and restore function.

A reverse total shoulder replacement surgery is recommended for people with torn rotator cuffs, severe arthritis with or without cuff tear arthropathy, or prior failed shoulder surgery. In a reverse total shoulder replacement surgery, the ball and the socket are switched. The metal ball is attached to the scapula, and the socket is attached to the end of the humerus. This allows the deltoid muscles, instead of the damaged rotator cuff muscles, to lift the arm above the shoulder.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers <u>total shoulder replacement surgery</u> when <u>all</u> the following criteria are met (1−4):

1. The patient has pain and loss of motion, and
2. Radiographs are consistent with advanced glenohumeral arthritis, and
3. Conservative therapy has failed, as defined by <u>both</u> of the following:
   a) NSAIDs or acetaminophen ≥ 3 weeks; and
   b) Activity modification ≥ 12 weeks; and
4. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to surgery.
5. <u>Contraindications:</u>
   a) Active joint infection
   b) Systemic infection
   c) Irreparable rotator cuff tear

Contraindication for surgery: No surgery should be done within 3 months of a steroid injection.

B. Criteria for Reverse Shoulder:

Select Health covers reverse shoulder arthroplasty when 1 and 2 are met:

1. One of the following conditions must be met (a−j):

    a) Rheumatoid arthritis
    b) Osteoarthritis with posterior glenohumeral subluxation
    c) Reconstruction post tumor resection
    d) Failed arthroplasty
    e) Fracture sequelae (malunion or fracture nonunion)
    f) Failed rotator cuff repair, deemed irreparable.
    g) Advanced glenohumeral arthritis
    h) Rotator cuff tear arthropathy
    i) Massive irreparable rotator cuff tear
    j) Acute Proximal Humerus fracture deemed irreparable by open reduction and internal fixation (ORIF)

    AND

2. Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to surgery.

Contraindication for surgery: No surgery should be done within 3 months of a steroid injection.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The first reported prosthetic arthroplasty of any type was a reverse total shoulder arthroplasty performed in approximately 1892. The modern era of shoulder arthroplasty began in the 1950s when Neer developed and reported on solid vitallium proximal humeral hemiarthroplasty implanted for fracture. Subsequent developments include modular components, total shoulder arthroplasty for degenerative arthrosis, and reverse total shoulder for rotator cuff arthropathy. Current trends have led to bone sparing humeral designs, including resurfacing, smaller stems, and stemless implants, as well as humeral components that can accommodate both a humeral head replacement and a socket for a reverse total shoulder arthroplasty.

The overall incidence of all types of shoulder arthroplasty has been increasing over the past twenty years. The incidence of reverse total shoulder arthroplasty has increased at a greater rate than any other type of arthroplasty. Anatomic total shoulder arthroplasty remains the standard of care for glenohumeral

osteoarthritis in the presence of an intact functional rotator cuff. Research efforts continue to be directed at both material and design, to increase prosthetic longevity. An increasing body of evidence is demonstrating effectiveness of reverse shoulder arthroplasty for an increasing breadth of surgical indications including glenohumeral osteoarthritis when rotator cuff dysfunction is of concern or glenoid bone deficiencies exist.

Billing/Coding Information

CPT CODES

23470 Arthroplasty, glenohumeral joint; hemiarthroplasty

23472 Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))

Key References

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3. Total Shoulder Replacement (n.d.). In *The Centers for Advanced Orthopaedics*. Retrieved August 31, 2018, from http://www.mdbonedocs.com/PatientEducation/tabid/2540/ctl/View/mid/6001/Default?ContentPubID=131

Revision History

Revision Date	Summary of Changes
10/31/23	For Commercial Plan Policy, updated overall coverage criteria to align with current clinical guidelines.
2/22/24	For Commercial Plan Policy, modified requirements in criterion #A-2: "Radiographs are consistent with ***advanced glenohumeral arthritis***." and removed previous criterion #A-3b: "PT or OT or home exercises ≥ 12 weeks"; and included the following contraindication in both criteria section A and B: "**Contraindication for surgery:** No surgery should be done within 3 months of a steroid injection."
7/18/24	For Commercial Plan Policy, removed previous criterion #2 in Section B for Reverse Shoulder: "Conservative therapy has failed, as defined by both of the following: a) NSAIDs or acetaminophen ≥ 3 weeks; and b) Activity modification ≥ 12 weeks."
7/22/25	For Commercial Plan Policy, added smoking cessation requirement in both new criterion #A-4 and new criterion #B-2: "Tobacco smoking, which includes cigarette usage, e-cigarette usage, or vaping; and vaping or inhalation of any other substances for a sustained period, must be discontinued for at least four weeks prior to surgery."

Select Health

Total Shoulder Replacement, continued

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MEDICAL POLICY

UNICONDYLAR INTERPOSITIONAL SPACER

Policy # 428
Implementation Date:11/12/09
Review Dates: 5/19/11, 6/21/12, 6/20/13, 4/17/14, 4/14/16, 4/27/17, 9/18/18, 4/17/19, 4/15/20, 4/15/21, 3/16/22, 4/20/23, 4/19/24, 4/17/25
Revision Dates: 2/9/10

Description

Osteoarthritis of the knee is common, affecting almost a tenth of the population over age 55. There are three compartments to the knee: the medial (inside) compartment, the lateral (outside) compartment, and the patellofemoral (kneecap) compartment. Osteoarthritis can affect one or more compartments of the knee joint.

Many different types of surgical procedures are used to treat OA of the knee, including knee debridement, high tibial osteotomy, and partial (unicompartmental) and total knee arthroplasty (replacement). Although often beneficial, such procedures can also be associated with long recovery periods, compromise of the joint to future interventions, and treatment failure after a short period of improvement. In addition, most procedures do not address mechanical alignment issues.

Several devices have been developed in an attempt to treat localized arthritic joint changes and minimize joint trauma and recovery time. The **UniSpacer** (Sulzer Orthopedics, Austin, TX) is a metallic interpositional spacer for arthritis, affecting primarily the medial compartment of the knee. The device is a U-shaped metallic shim, designed to be implanted in the knee joint following removal of any damaged cartilage. The UniSpacer has been used for the treatment of isolated, moderate degeneration of the medial compartment (Grade III-IV chondromalacia) with no more than minimal degeneration (Grade I-II chondromalacia, no loss of joint space) in the lateral condyle or patellofemoral compartment. The UniSpacer is intended to restore the stability and alignment of the knee and relieve pain, thereby delaying or avoiding the need for total knee replacement.

The **iForma** (ConforMIS, Burlington, VA) iForma implant is designed to treat moderate osteoarthritis isolated to the medial or lateral compartments. This device differs from other implants in that it uses MRI data to customize the implant for each patient. The implant is sized and shaped based on the surface measurements of the joint and degree of cartilage loss apparent on the femur and tibia. The undersurface of the iForma represents an imprint of the tibial surface to facilitate fixation. This personalized fit enables the implant to achieve 'functional fixation' without the need for invasive tissue removal, screws, pegs, or cement.

The **OrthoGlide** Medial Knee Implant (ABS Corp, Minnetonka, MN) is a disc-shaped device made from cobalt chrome alloy and intended for patients with primarily medial compartment osteoarthritis. The OrthoGlide has special design features that contour to the surface of the tibia; giving stability to the implant within the knee joint. The anterior surface of the OrthoGlide is polished and open, thus, providing for a smooth and unconstrained glide path for the femoral condyle. Insertion of the implant involves a minimally invasive surgical procedure that requires no bone cuts and only a small (2- to 3-inch) incision.

Select Health

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health NOT cover unicondylar interpositional spacers for the knee. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

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Summary of Medical Information

The only published systematic review of unicompartmental spacers was completed by the California Technology Assessment Forum (CTAF) in 2003. They reported no published studies available to assess the safety and efficacy of the UniSpacer device and recommended surgical placement of knee joint spacer devices be evaluated in controlled trials to determine safety and efficacy before widespread adoption can be recommended. Consequently, surgical placement of a knee joint spacer for the treatment of osteoarthritis did not meet the CTAF criteria. Since the CTAF review, 5 studies have been published. These studies present primarily alignment outcomes, some over the long term, and some offer data on revision rates or functional outcomes. Bailie et al., for example, examined reported 2-year revision rates in a prospective series of 18 patients (44%) required revision within 2 years, 6 of whom required a unicompartmental or total knee replacement. Mean pain ratings had dropped 30% since surgery. The authors concluded that the UniSpacer is associated with a high rate of revision and provides unpredictable pain relief.

Clarius et al. reported 5-year outcomes of the UniSpacer device. A mean valgus change of 4.7° +/- 1.9° was the only significant alignment change observed in 20 legs followed during a 5-year period. However, the revision rate was 21%, which they considered "unacceptably high" compared with alternative treatment options. Hallock et al. reported 2-year functional outcomes in 67 patients, finding improvements of 193% and 140% in the mean Knee Society function and Lysholm scores, respectively. Fifteen implants (21%) were revised. In contrast, Sisto et al. reported poor functional outcomes and a 32% revision rate in 37 implanted knees. Only 1 study examined the iForma device, a feasibility study by Koeck et al., which reported an average 3.8° correction and an average under-adjustment of 0.9° after implantation. No functional outcomes were reported. No studies examined the OrthoGlide system. Overall, the literature offers tepid support for unicondylar interpositional devices. There are no comparative trials and three of the five uncontrolled studies reported unacceptably high revision rates and equivocal functional outcomes, even in the short-term. Additionally, published literature is lacking for several of the devices possibly due to their FDA 510(k) approval rather than the more stringent premarket approval (PMA) process. Clearly, the literature does not support use of this procedure as an alternative to unicompartmental or total knee replacement.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

27599	Unlisted procedure, femur or knee

Select Health

HCPCS CODES

No specific codes identified

Key References

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