Fusion
Clinical Coverage Criteria

Overview

Spondylolisthesis is the displacement of one spinal vertebra compared to another. Spondylolisthesis may be defined as the forward or anterior displacement of a vertebra over the vertebra inferior to it (or the sacrum), or as displacement in any direction. Spondylolisthesis is graded based upon the degree of slippage of one vertebral body relative to the subsequent adjacent vertebral body. Spondylolisthesis is classified as one of the five major etiologies: degenerative, traumatic, dysplastic, isthmic, or pathologic. Spondylolisthesis most commonly occurs in the lumbar spine, but can also occur in the cervical spine and rarely, except for trauma, in the thoracic spine. Spondylolisthesis most commonly occurs at the L5-S1 level with anterior translation of the L5 vertebral body on the S1 vertebral body. The L4-5 level is the second most common location for spondylolisthesis. Spondylolisthesis is graded based on the degree of slippage of one vertebral body on the adjacent vertebral body. The ratio of amount of slippage to vertebral-body width is obtained as a percentage (Tenny and Gillis, 2019). Grade 1 is less than 25%, Grade 2 is 25% to 50%, Grade 3 is 50% to 75%, Grade 4 is 75% to 100%, and Spondyloptosis is > 100% (Burton and Mesfin, 2020).

Children normally develop the type of fracture called isthmic spondylolisthesis between the ages of 5 – 7. However, symptoms are not usually noticed until adulthood, when the facet joints continue to degenerate and spondylolisthesis results. The adult incidence is between 3.7% and 8% (Kreiner et al., 2016). Degenerative spondylolisthesis is a fairly common consequence of osteoarthritis.

A total of 3,529 participants of the Framingham Heart Study aged 40-80 years underwent multi-detector CT imaging to assess aortic calcification, all participants undergoing multi-detector CT scan were asked to complete the modified Nordic Low Back Questionnaire. A total of 188 of these participants were consecutively enrolled in cross-sectional study to assess radiographic features potentially associated with low back pain. Thirty-eight (38) of 188 subjects (20.2%) reported significant low back pain. Based on CT imaging, the prevalence of lumbar spondylolysis in an unselected community-based population was 11.3% (21 subjects demonstrated spondylolysis on CT imaging). The male-to-female ratio was approximately 3:1. This study did not reveal a significant association between the observation of spondylolysis (5 of 38, 13.5%), isthmic spondylolisthesis (4 of 38, 10.8%) or degenerative spondylolisthesis (6 of 38, 16.2%) on CT and the occurrence of low back pain. This suggests that the condition does not appear to represent a major cause of low back pain in the general population. The major finding of this study is a much higher prevalence of lumbar spondylolysis in the general population than previously reported. A likely explanation for the significantly higher prevalence is the use of CT (Kalichman et al., 2009).

The majority of patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits will do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery. Progression of slip correlates with jobs that require repetitive anterior flexion of the spine. Slip progression is less likely to occur when the disc has lost over 80% of its native height and intervertebral osteophytes have formed. Progression of clinical symptoms does not correlate with progression of the slip (Kreiner et al., 2016). The lateral radiograph is the most appropriate, noninvasive test for detecting degenerative lumbar

spondylolisthesis. The most appropriate, noninvasive test for imaging stenosis accompanying degenerative lumbar spondylolisthesis is MRI. Surgical decompression with fusion is suggested for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone. For symptomatic single level degenerative spondylolisthesis that is low-grade (<20%) and without lateral foraminal stenosis, decompression alone with preservation of midline structures provides equivalent outcomes when compared to surgical decompression with fusion. There is insufficient evidence to make a recommendation for or against the cost effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. A randomized trial of non-operative care showed only 54% underwent surgery after 4 years (Kreiner et al., 2016).

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☐ PACE

Prior authorization is required for fusion (arthrodesis).

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have a National Coverage Determination (NCD) for lumbar spinal fusion. Medicare does not have a NCD for cervical spinal fusion. National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) in our jurisdiction, does not have an LCD or LCA for lumbar spinal fusion. National Government Services, Inc. does not have an LCD or LCA for cervical spinal fusion. National Government Services, Inc. has an LCD for Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint L36406, and an LCA Billing and Coding: Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint A57431 (MCD search 03/21/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. Unless otherwise noted, in the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Unless otherwise noted, Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth ACO covered services for MassHealth members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Fallon Health Clinical Coverage Criteria
Spinal fusion

These criteria address lumbar spinal fusion for instability. For fusion performed with decompression, please refer to Decompression with or without Fusion Clinical Coverage Criteria. Prior authorization is required for fusion (arthrodesis).

Fallon Health considers lumbar spinal fusion medically necessary when:

- The member has sensory changes, muscle weakness or cauda equina syndrome.
- The disc has lost < 80% of its native height.[1]
- For isthmic spondylolisthesis
  - Standing plain radiographs, or if negative, then MRI to document the condition.
  - Posterolateral fusion and 360° fusion surgeries are recommended to improve the clinical outcomes in adult patients with low grade isthmic spondylolisthesis (Nass, 2014). There is insufficient evidence to recommend one surgical fusion technique over another to improve long term outcomes in adult patients undergoing surgical treatment for isthmic spondylolisthesis (Nass, 2014).
- For degenerative lumbar spondylolisthesis
  - When the radicular symptoms of stenosis predominate, a multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections AND at least 4 weeks of physical therapy.
  - For symptomatic single level degenerative spondylolisthesis that is low-grade (<20%) and without lateral foraminal stenosis, decompression alone with preservation of midline structures provides equivalent outcomes when compared to surgical decompression with fusion (Nass, 2014a). For 20% or more, then surgical decompression with fusion is the appropriate procedure. There is insufficient evidence to make a recommendation for or against efficacy of surgical decompression with fusion, with or without instrumentation, for treatment of multi-level degenerative lumbar spondylolisthesis compared to medical/interventional treatment alone (Nass, 2014a).
  - The addition of instrumentation is suggested to improve fusion rates in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis (Nass, 2014a).

Sacroiliac joint fusion

Sacroiliac joint fusion (arthrodesis) is a surgical technique that is intended to achieve bony fusion of the sacroiliac joint and stabilize it, thus reducing pain and disability. Sacroiliac joint fusion may be performed as an open surgical procedure or as a minimally invasive (percutaneous) procedure. Prior authorization is required for sacroiliac joint fusion.

Open sacroiliac joint fusion

Fallon Health considers open sacroiliac joint fusion (CPT 27280) medically necessary when all of the following criteria are met:

- Recent (within 6 months) plain radiographs and/or cross-sectional imaging (CT or MRI) demonstrate localized sacroiliac joint pathology
- Documentation of nicotine-free status with EITHER of the following:
  - Patient is a never-smoker
  - Patient has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidenced by nicotine lab results of ≤ 10 ng/mL
- ANY of the following:
  - Post-traumatic injury of the sacroiliac joint (e.g., following pelvic ring fracture)
  - As an adjunctive treatment for sacroiliac joint infection

[1] Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery. Slip progression is less likely to occur when the disc has lost over 80% of its native height and intervertebral osteophytes have formed. Progression of clinical symptoms does not correlate with progression of the slip (NASS, 2014a).

- Management of sacral tumor (e.g., partial sacrectomy)
- When performed as part of a multisegmental long fusion constructs for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

Minimally invasive sacroiliac joint fusion
Fallon Health follows coverage criteria for minimally invasive sacroiliac joint fusion found in the National Government Services, Inc. LCD for Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint L36406 for all plan members.

Links:
LCD: **Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint L36406**
LCA: **Billing And Coding: Minimally-Invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint A57431**

Minimally-invasive surgical (MIS) fusion of the sacroiliac (SI) joint (CPT 27279)* is considered medically necessary when ALL of the following criteria are met:

- Have moderate to severe pain with functional impairment and pain persists despite a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program
- Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain
- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist
- Positive response to a cluster of 3 provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test).
- Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
- Diagnostic imaging studies that include ALL of the following:
  - Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
  - Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
  - Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
- At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection.
- A trial of at least one therapeutic intra-articular SIJ injection (i.e. corticosteroid injection)

* The lateral MIS SI joint fusion procedure should be coded with CPT code 27279. The posterior (dorsal) MIS SI joint fusion procedure is significantly distinct from the lateral procedure and is, as of yet, unproven (Lorio et al., 2020).

The procedure typically involves the insertion of three small titanium implants across the sacroiliac joint, and is designed to stabilize and fuse the sacroiliac joint. There are numerous devices available that have received FDA 510(k) clearance for use in MIS or percutaneous lateral SI joint fusion stabilization.

Exclusions

- Interspinous fixation (fusion) devices, are considered experimental and not covered for any indication, including but not limited to use:
  - In combination with interbody fusion
  - Alone for decompression in patients with spinal stenosis

  There are no specific CPT codes for these devices.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

CPT	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
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

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans