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%.[1] 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

[1] Kreiner et al., 2016, 13.

symptoms does not correlate with progression of the slip.[2] 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.[3]

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

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. does not have an LCD or LCA for lumbar spinal fusion or cervical spinal fusion (MCD search 06-23-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows guidance from CMS for coverage determinations. 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 will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Prior authorization is required. These criteria address fusion for spinal instability, and do not cover fusion accompanying decompression surgery. For fusion performed with decompression, please refer to the Medical Policy for Decompression with or without Fusion.

Fallon Health considers 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.
- For isthmic spondylolisthesis
    - Standing plain radiographs, or if negative, then MRI to document the condition.

[2] Ibid., 31.

[3] Ibid., 37.

    - Posterolateral fusion and 360° fusion surgeries are recommended to improve the clinical outcomes in adult patients with low grade isthmic spondylolisthesis. 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.
- For degenerative 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. 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.
    - The addition of instrumentation is suggested to improve fusion rates in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

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.

References

1. Tenny S, Gillis CC. Spondylolisthesis. [Updated 2019 Nov 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430767/.
2. Burton MR, Mesfin FB. Isthmic Spondylolisthesis. [Updated 2020 Jan 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK441846/.
3. McCunniff PT, Yoo H, Dugarte A, Bajwa NS, Toy JO, Ahn UM, Ahn NU. Bilateral Pars Defects at the L4 Vertebra Result in Increased Degeneration When Compared with Those at L5: An Anatomic Study. *Clin. Orthop. Relat. Res*. 2016 Feb;474(2):571-7.
4. Kalichman L, Kim DH, Li L, Guermazi A, Berkin V, Hunter DJ. Spondylolysis and spondylolisthesis: prevalence and association with low back pain in the adult community-based population. *Spine (Phila Pa 1976)*. 2009;34(2):199-205.
5. Matz PG, Meagher RJ, Lamer T, et al. Guideline summary review: An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis. *Spine J.* 2016;16(3):439-448.
6. Kreiner DS, Baisden J, Mazanec DJ, et al. Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of adult isthmic spondylolisthesis. *Spine J*. 2016;16(12):1478-1485.
7. Lorio M, Kim C, Araghi A, Inzana J, Yue JJ. International Society for the Advancement of Spine Surgery Policy 2019-Surgical Treatment of Lumbar Disc Herniation with Radiculopathy. *Int J Spine Surg*. 2020;14(1):1-17.
8. Möller H, Hedlund R. Surgery versus conservative management in adult isthmic spondylolisthesis--a prospective randomized study: part 1. *Spine (Phila Pa 1976).* 2000;25(13):1711-1715.
9. Ekman P, Möller H, Hedlund R. The long-term effect of posterolateral fusion in adult isthmic spondylolisthesis: a randomized controlled study. *Spine J*. 2005;5(1):36-44.

Policy history

Origination date:	11/01/2013
Approval(s):	Technology Assessment Committee: 08/28/2013 (adopted Interqual criteria), 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review), 05/27/2020 (adopted Fallon Health criteria). *06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.*

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