PREMERA HMO

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MEDICAL POLICY – 7.01.120

Facet Arthroplasty

BCBSA Ref. Policy:	7.01.120
Effective Date:	April 1, 2024
Last Revised:	Mar. 12, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

7.01.555 Facet Joint Denervation

7.01.589 Artificial Intervertebral Disc: Lumbar Spine

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Facet joints connect the bones of the spine (vertebrae) to both stabilize your back and help your spine bend and twist. Damage to the facet joints due to aging, arthritis, or injury can result in pain. There are a number of proven treatments that can address facet joint pain. A newer treatment calls for a small device to replace the facet joint or the back part of the spine bone. The goal of this surgery is to implant a small device to try to stabilize the spine while allowing normal twisting and bending. This type of surgery is investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Total facet arthroplasty	**Total facet arthroplasty in individuals with lumbar spinal stenosis undergoing spinal decompression is considered investigational.**

Coding

Code	Description
CPT	
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Facet arthroplasty: The implantation of a spinal prosthesis to restore posterior element structure and function, as an adjunct to neural decompression

Facet arthrosis: Chronic degenerative disease affecting the joints in the spine

Spinal stenosis: Narrowing of the spinal column, resulting in pressure on the spinal cord

Spondylolisthesis: A vertebra in the lower part of the spine slips out of the proper position onto the bone below it

Evidence Review

Description

Facet arthroplasty refers to the implantation of a spinal prosthesis to restore posterior element structure and function as an adjunct to neural decompression. This procedure is proposed as an alternative to posterior spinal fusion for individuals with facet arthrosis, spinal stenosis, and spondylolisthesis.

Background

Spinal fusion is a common surgical treatment following surgical decompression when conservative treatment fails.[1] However, spinal fusion alters the normal biomechanics of the back, which may potentially lead to premature disc degeneration at adjacent levels. A variety of implants have been investigated as alternatives to rigid interbody or posterolateral intertransverse spinal fusion. This policy addresses the implantation of prostheses intended to replace the facet joints and excised posterior elements, termed facet arthroplasty.

The objective of facet arthroplasty is to stabilize the spine while retaining normal intervertebral motion of the surgically removed segment following neural decompression.[2] It is proposed that facet arthroplasty should also maintain the normal biomechanics of the adjacent vertebrae. If normal motion patterns are achieved by artificial joints in the spine, the risk of adjacent-level degeneration thought to be associated with fusion may be mitigated.

Summary of Evidence

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of an otherwise unpublished randomized controlled trial, a planned interim analysis of an ongoing RCT, and a few case series studies. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Interim results from a pivotal trial of the ACADIA Facet Replacement System were reported in 2012. No additional publications from this trial, which was expected to be completed in October 2017, have been identified to date. Interim results from a pivotal randomized trial of the Total Posterior-element System (TOPS) indicated substantial improvement over transforaminal lumbar interbody fusion (TLIF) in multiple patient-reported outcomes related to functional status and symptoms up to two years post-operatively; the results further suggested relatively preserved range of motion at the treated vertebral level with

TOPS versus TLIF, without increased risk of adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03012776[a]	A Clinical Study to Assess the Safety and Effectiveness of the Premia Spine TOPS System	305	June 2026 (active, not recruiting)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In June 2023, the Total Posterior-element System (TOPS; Premia Spine) received premarketing approval from the FDA (P220002). "The TOPS System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS System is intended to stabilize the spine following a lumbar decompression without rigid fixation. It is indicated for individuals between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5."

FDA Product Code: QWK

The ACADIA Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in an FDA–regulated investigational device exemption phase 3 trial, which was completed in October 2017 but has not been published. A phase 3 trial of the Total Facet Arthroplasty System (TFAS; Archus Orthopedics) was discontinued. (Facet Solutions acquired Archus Orthopedics in 2009. In 2011, Globus Medical acquired Facet Solutions.)

References

1. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. Jan 04 2016; 352: h6234. PMID 26727925
2. Gu BJ, Blue R, Yoon J, et al. Posterior Lumbar Facet Replacement and Arthroplasty. Neurosurg Clin N Am. Oct 2021; 32(4): 521-526. PMID 34538478
3. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020. Accessed February 14, 2024
4. Palmer DK, Inceoglu S, Cheng WK. Stem fracture after total facet replacement in the lumbar spine: a report of two cases and review of the literature. Spine J. Jul 2011; 11(7): e15-9. PMID 21703940
5. Myer J, Youssef JA, Rahn KA, et al. ACADIA facet replacement system IDE clinical trial: Preliminary outcomes at two-and four-years postoperative [abstract]. Spine J. 2014;11(Suppl. 1):S160-161.
6. Goodwin ML, Spiker WR, Brodke DS, et al. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. J Neurosurg Spine. Jul 2018; 29(1): 81-84. PMID 29652237
7. Smorgick Y, Mirovsky Y, Floman Y, et al. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. J Neurosurg Spine. Oct 04 2019: 1-6. PMID 31585417
8. Coric D, Nassr A, Kim PK, et al. Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. J Neurosurg Spine. Jan 01 2023; 38(1): 115-125. PMID 36152329

History

Date	Comments
09/15/09	Add to Surgery Section - New Policy
09/14/10	Replace Policy - Policy updated with literature search through May 2010; the policy statement remains unchanged.
09/15/11	Replace Policy – Policy updated with literature review through May 2011; policy statement unchanged.
02/27/12	Related Policies updated; 7.01.130 added.
09/11/12	Replace policy. Policy updated with literature review through May 2012; reference numbers 1 and 2 added; policy statement unchanged.
9/27/12	Update Related Policies- 7.01.130 added.
07/25/13	Update Related Policies. Change title to 7.01.107.
09/27/13	Replace policy. Policy title updated, the word "Total" is deleted. A literature review through June 2013 did not prompt additions to references. Policy statement unchanged.
03/11/14	Coding Update. Codes 84.84 and 84.85 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.
05/20/14	Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555.
09/23/14	Annual Review. Added definition of terms to the policy guidelines section. A literature review through June 3, 2014 did not prompt the addition of new references. Policy statement unchanged.
09/08/15	Annual Review. Policy updated with literature review through June 9, 2015; policy statement unchanged
06/01/16	Annual Review, approved May 10, 2016. Policy updated with literature review through April 21, 2016; reference added. No change to the policy statement. Related policies updated; 7.01.87,7.01.107 and 7.01.130 removed.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 7, 2016; reference 2 updated. Policy statement unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
07/01/18	Annual Review, approved June 5, 2018. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; reference 3 added. Policy statement unchanged.

Date	Comments
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through January 11, 2021; no references added. Policy statement unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
10/01/22	Archive policy, approved September 13, 2022. Policy archived due to low utilization.
04/01/24	Policy reinstated from archived status, approved March 12, 2024. Policy updated with literature review through February 21, 2023; references added. Total facet arthroplasty in individuals with lumbar spinal stenosis undergoing spinal decompression is considered investigational.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

PREMERA HMO

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Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 844-722-4661 (TTY: 711).

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CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 844-722-4661 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 844-722-4661 (TTY: 711) 번으로 전화해 주십시오.

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