FEP Medical Policy Manual

FEP 7.01.120 Facet Arthroplasty

Annual Effective Policy Date: July 1, 2024

Original Policy Date: December 2011

Related Policies:

7.01.107 - Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.87 - Artificial Intervertebral Disc: Lumbar Spine

Facet Arthroplasty

Description

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 patients with facet arthrosis, spinal stenosis, and spondylolisthesis.

OBJECTIVE

The objective of this evidence review is to determine whether facet arthroplasty as an adjunct to neural decompression improves the net health outcome in individuals with lumbar spinal stenosis.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In June 2023, the Total Posterior Spine (TOPS™; Premia Spine) System was approved by the U.S. Food and Drug Administration (FDA) via the premarket approval (PMA) process (PMA: P220002).[3,] Per the approval order statement, "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. The TOPS System is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade 1, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or of the scarring facet joint capsule at one level from L3 to L5."

TOPS System was previously granted breakthrough device status through the FDA in October 2020. The TOPS System has been marketed outside of the U.S. since 2012, and is commercially available in several European Union countries, in Australia, and in several Asian countries. FDA Product Code: QWK.

Other products are currently under review. The ACADIA Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in a FDA regulated investigational device exemption phase 3 trial, which was completed in October 2017; results without statistical analysis were posted on ClinicalTrials.gov but have not been published in the peer-reviewed literature.[4,]ACADIA Facet Replacement System is currently only available outside of the U.S.

RATIONALE

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 (RCT), 2 planned interim analyses of an ongoing RCT, and a few case series studies. 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 completed in October 2017, have been identified to date. Interim results from a pivotal randomized trial of the Total Posterior Spine (TOPS) System indicated substantial improvement compared to baseline at 1 year and over transforaminal lumbar interbody fusion (TLIF) in multiple patient-reported outcomes related to functional status and symptoms up to 2 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. Based on 24 month results, the TOPS System received U.S. Food and Drug Administration approval in June 2023; the final trial results have not yet been published. While the interim results are promising, clarity is needed on the final results of the trial to determine if adjustments for increased risk of type 1 error were made and to evaluate other strengths and limitations of the trial. Additionally, continued follow-up of the TOPS trial is ongoing, which will shed light on longer-term safety profiles of TOPS versus TILF with lumbar spinal decompression. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" 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 as of March 2024.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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4. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020. Accessed March 5, 2024.
5. 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
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8. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED): TOPS System. June 15, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf22/P220002B.pdf. Accessed March 4, 2024.
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11. 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

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
September 2013	Replace policy	Policy updated with literature review. References updated. Policy statement unchanged.
September 2014	Replace policy	Policy updated with literature review, policy statement unchanged
September 2015	Replace policy	Policy updated with literature review, policy statement unchanged
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; reference 2 updated. Policy statement unchanged
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; reference 3 added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 28, 2020; references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 11, 2021; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through February 21, 2023; references added. Policy statement unchanged.
June 2024	Replace policy	Policy updated with literature review through March 5, 2024; references added. Minor editorial refinements to policy statements; intent unchanged.