BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.120 Facet Arthroplasty

Effective Policy Date: July 1, 2023

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 patients with lumbar spinal stenosis.

POLICY STATEMENT

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

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA). 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.[3,] A phase 3 trial of the Total Facet Arthroplasty System (TFAS; Archus Orthopedics) was discontinued.

Another implant design, the Total Posterior-element System (TOPS™; Premia Spine), is currently available in Europe.

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who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of an otherwise unpublished randomized controlled trial (RCT), a planned interim analysis of an ongoing RCT, and a few case series studies.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-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 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. No device has received U.S. Food and Drug Administration approval. 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.

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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3. ClinicalTrials.gov. A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis (NCT00401518). Updated September 10, 2020. Accessed February 22, 2023.
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

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.