FEP 7.01.120 Facet Arthroplasty

Effective Date: July 15, 2018

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

Facet Arthroplasty

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.

FDA REGULATORY STATUS

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration. The ACADIA™ Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) is currently being evaluated as part of an ongoing Food and Drug Administration-regulated investigational device exemption phase 3 trial. 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.)

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

POLICY STATEMENT

Total facet arthroplasty is considered **investigational**.

BENEFIT APPLICATION

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

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 a randomized controlled trial. 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 October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no

device has received U.S. Food and Drug Administration approval. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES

1. 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):e15-19. PMID 21703940
2. 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.

POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
September 2013	Update Policy	Policy updated with literature review. References updated. Policy statement unchanged.
September 2014	Update Policy	Policy updated with literature review, policy statement unchanged
September 2015	Update Policy	Policy updated with literature review, policy statement unchanged
June 2018	Update Policy	Policy updated with literature review through February 5, 2018; reference 2 updated. Policy statement unchanged