

(701120)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/12	<b>Next Review Date:</b> 09/20
<b>Preauthorization</b>	No	<b>Review Dates:</b> 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With lumbar spinal stenosis</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Lumbar spinal decompression with facet arthroplasty</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Lumbar spinal decompression with spinal fusion</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Treatment-related morbidity</li> </ul>

### 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.

### 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. 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 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.

### POLICY

Total facet arthroplasty is considered **investigational**.

### BACKGROUND

Spinal fusion is a common surgical treatment following surgical decompression when conservative treatment

fails. 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 evidence review 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. 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.

### 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) was being evaluated in an Food and Drug Administration-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.)

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

### RELATED PROTOCOL

Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

### REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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.

3. Goodwin, MM, Spiker, WW, Brodke, DD, Lawrence, BB. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. *J Neurosurg Spine*, 2018 Apr 14;29(1). PMID 29652237