

(701120)

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

***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
Patients/individuals with: <ul style="list-style-type: none"> <li>Facet arthrosis</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Facet arthroplasty</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Conservative therapy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Quality of life</li> <li>Functional outcomes</li> <li>Treatment-related morbidity</li> <li>Symptoms</li> </ul>
Patients/individuals with: <ul style="list-style-type: none"> <li>Spinal stenosis</li> <li>Spondylolisthesis</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Facet arthroplasty</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Conservative therapy</li> <li>Decompression with/without spinal fusion</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Quality of life</li> <li>Functional outcomes</li> <li>Treatment-related morbidity</li> <li>Symptoms</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

Evidence to date includes a preliminary report of a pivotal trial on the ACADIA® Facet Replacement System. Completion of this trial is expected October 2015. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received U.S. Food and Drug Administration approval.

### Policy

Total facet arthroplasty is considered **investigational**.

### Background

Spinal fusion is a common surgical treatment for degenerative disc disease 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 Protocol 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 FDA at this time. The ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA) is currently being evaluated as part of an ongoing FDA-regulated investigational device exemption phase 3 trial. The phase 3 trial of the Total Facet Arthroplasty System® (TFAS®; Archus Orthopedics) has been discontinued. (Facet Solutions acquired Archus Orthopedics and all of its assets in 2009. In 2011, Globus Medical acquired substantially all assets of Facet Solutions.) Another implant design, the Total Posterior-element System (TOPS™; Impliant, Israel), is currently available in Europe. Premia Spine acquired Impliant in 2011.

### Related Protocols

Artificial Intervertebral Disc: Lumbar Spine

Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)

---

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. Dryer RF, Regan JJ, Hartjen CA, et al. Prospective US IDE trial: Interim results for the treatment of symptomatic lumbar spinal stenosis with facet replacement in 100 patients enrolled at 15 centers. *Spine J.* 2010; 10(9 Supp. 1):90S.
3. National Government Services, Inc. Local Coverage Determination (LCD): Category III CPT® Codes (L33392), Revision Effective Date for services performed on or after 02/08/2016.