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.

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 policy 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 U.S. Food and Drug Administration (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™; Implant, Israel), is currently available in Europe. Premia Spine acquired Implant in 2011.

Related Policies

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

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Total facet arthroplasty is considered investigational.

**Rationale**

Search of the MEDLINE database, most recently performed identified a report indicating that FDA-regulated multicenter investigational device exemption (IDE) trial (NCT00418197) of the Total Facet Arthroplasty System® (TFAS®) was discontinued due to financial reasons. (1) (Facet Solutions acquired Archus Orthopedics and all of their assets in November 2009). Two out of 10 TFAS procedures performed at the authors’ institution had stem fracture after total facet replacement.

Identified from the EMBASE database was a conference proceeding of interim results in 100 patients from a phase 3 U.S. multicenter randomized trial of the ACADIA™ Facet Replacement System (NCT00401518, see Table 1). (2) The study began in 2006, is expected to enroll around 450 subjects with lumbar spinal stenosis, and compares facet arthroplasty with the ACADIA™ system to posterior spinal fusion.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>The Investigational Plan for the Evaluation of the ACADIA® Facet Replacement System (Pivotal Study)</td>
<td>450</td>
<td>Oct 2015</td>
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<tr>
<td>NCT01933607</td>
<td>A Study to Evaluate the Safety and Effectiveness of TOPS™ System in the Lumbar Spine</td>
<td>10</td>
<td>Dec 2016</td>
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<tr>
<td>Unpublished</td>
<td>A Prospective, Multi-Center Clinical Study to Assess the Safety and Effectiveness of the Implant TOPS System</td>
<td>450</td>
<td>May 2011</td>
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<tr>
<td>NCT00418197</td>
<td>A Prospective and Randomized Controlled Trial to Evaluate the Safety and Effectiveness of Total Facet Arthroplasty in the Treatment of Degenerative Spinal Stenosis (TFAS®)</td>
<td>450</td>
<td>Feb 2009</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial

**Summary**

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.
Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventative Services Task Force Recommendations

Not applicable

Medicare National Coverage
There is no national coverage determination.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td></td>
</tr>
<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review, policy statement unchanged</td>
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Keywords

Total facet arthroplasty
TFAS

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 18, 2015 and is effective October 15, 2015.

Signature on file
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