Facet Arthroplasty

Policy Number: 7.01.120  Last Review: 3/2019

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for total facet arthroplasty. This is considered investigational.

When Policy Topic is covered
Total facet arthroplasty is considered investigational.

When Policy Topic is not covered
Not Applicable

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>▪ With lumbar spinal stenosis</td>
<td>▪ Lumbar spinal decompression with facet arthroplasty</td>
<td>▪ Lumbar spinal decompression with spinal fusion</td>
<td>▪ Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Quality of life</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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.

For individuals who have lumbar spinal stenosis who receive 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.
**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 the U.S. Food and Drug Administration (FDA). The ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA, acquired by Globus Medical in 2011) is currently being evaluated as part of an ongoing FDA-regulated investigational device exemption phase 3 trial. A 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™; Premia Spine), is currently available in Europe.

**Rationale**

This evidence review was created in July 2009 and has been updated regularly with searches of the MEDLINE database. The most recent update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more
intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Facet Arthroplasty
A report by Palmer et al (2011) indicated that the U.S. Food and Drug Administration–regulated multicenter investigational device exemption trial (NCT00418197) of the Total Facet Arthroplasty System was discontinued due to financial reasons.¹ Two of 10 Total Facet Arthroplasty System implants performed at the authors’ institution experienced stem fracture after total facet replacement.

An abstract reported by Myer et al (2014) in conference proceedings provided interim 2- and 4-year results for 243 patients from a phase 3 multicenter randomized trial of the ACADIA Facet Replacement System (NCT00401518; see Table 1).² The study, which was completed in late 2017, enrolled 390 subjects with lumbar spinal stenosis, and compared facet arthroplasty with the ACADIA system to spinal fusion. Submission of trial data to the U.S. Food and Drug Administration is expected.

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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this policy are listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01933607a</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>Dec 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT02234154a</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>May 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT00401518a</td>
<td>A Pivotal Study of a Facet Replacement System to Treat Spinal Stenosis²</td>
<td>390</td>
<td>Oct 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**References**

**Billing Coding/Physician Documentation Information**
**0202T** Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine

**Additional Policy Key Words**
N/A

**Policy Implementation/Update Information**
9/1/09 New policy; considered investigational.
3/1/10 No policy statement changes.
9/1/10 No policy statement changes.
1/1/11 Coding updated.
3/1/11 No policy statement changes.
9/1/11 No policy statement changes.
3/1/12 No policy statement changes.
9/1/12 No policy statement changes.
3/13/13 No policy statement changes.
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