Facet Arthroplasty

Policy Number: 7.01.120  Last Review: 9/2019

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: ▪ With lumbar spinal stenosis</td>
<td>Interventions of interest are: ▪ Lumbar spinal decompression with facet arthroplasty</td>
<td>Comparators of interest are: ▪ Lumbar spinal decompression with spinal fusion</td>
<td>Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life ▪ 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 protheses 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**
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), 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 technology, two domains are examined: the relevance, and 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.

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, 2019.

**Clinical Context and Therapy Purpose**
The purpose of facet arthroplasty in patients who have lumbar spinal stenosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does facet arthroplasty improve the net health outcome in patients with lumbar spinal stenosis?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals with lumbar spinal stenosis.

**Intervention**
The therapy being considered is facet arthroplasty. 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.

**Comparators**
The following therapies/tools/rules/practices are currently being used to make decisions about facet arthroplasty.

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. Facet arthropathy may also be treated with nerve ablation techniques.
Outcomes
The general outcomes of interest are pain, function, QOL, and adverse events related to the surgical procedure.

Timing
Pain, function, and QOL outcomes should be measured over the long-term.

Setting
Facet replacement is a surgical procedure requiring inpatient hospitalization. A report by Palmer et al (2011) indicated 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. Two of ten Total Facet Arthroplasty System implants performed at the authors’ institution experienced stem fracture after total facet replacement.

A phase 3 multicenter randomized trial of the ACADIA Facet Replacement System (NCT00401518) was completed in October 2017 but results have not yet been fully published. The trial enrolled 390 subjects with lumbar spinal stenosis, and compared facet arthroplasty with the ACADIA system to spinal fusion. An abstract reported by Myer et al (2014) in conference proceedings provided interim 2- and 4-year results for 243 patients. According to a 2018 case report, 2 of 5 patients at 1 institution who received the ACADIA Facet Replacement System as part of the trial experienced a return of neurological symptoms, local tissue reaction, and development of cobalt allergy.

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, QOL, 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 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>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01933607&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>Dec 2016</td>
</tr>
<tr>
<td>NCT02234154&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>May 2017</td>
</tr>
<tr>
<td>NCT00401518&lt;sup&gt;a&lt;/sup&gt;</td>
<td>A Pivotal Study of a Facet Replacement System (ACADIA) to Treat Spinal Stenosis</td>
<td>390 (actual)</td>
<td>Oct 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
<sup>a</sup> 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.
9/1/13  No policy statement changes.
3/1/14  No policy statement changes.
3/1/15  No policy statement changes.
9/1/15  No policy statement changes.
3/1/16  No policy statement changes.
9/1/16  No policy statement changes.
3/1/17  No policy statement changes.
9/1/17  No policy statement changes.
3/1/18  No policy statement changes.
9/1/18  No policy statement changes.
3/1/19  No policy statement changes.
9/1/19  No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.