Introduction

Facet joints connect the bones of the spine (vertebrae) to both stabilize your back and help your spine bend and twist. Damage to the facet joints due to aging, arthritis, or injury can result in pain. There are a number of proven treatments that can address facet joint pain. A newer treatment calls for a small device to replace the facet joint or the back part of the spine bone. The goal of this surgery is to implant a small device to try to stabilize the spine while allowing normal twisting and bending. This type of surgery is investigational (unproven). No final results have been published about whether or how well this technique works. In addition, the Food and Drug Administration has not approved any device to be used in this type of surgery.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Total facet arthroplasty is considered investigational.

**Related Information**

**Definition of Terms**

**Facet arthroplasty:** The implantation of a spinal prosthesis to restore posterior element structure and function, as an adjunct to neural decompression

**Facet arthrosis:** Chronic degenerative disease affecting the joints in the spine

**Spinal stenosis:** Narrowing of the spinal column, resulting in pressure on the spinal cord

**Spondylolisthesis:** A vertebra in the lower part of the spine slips out of the proper position onto the bone below it

**Evidence Review**
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 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 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.

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.
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>
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<tr>
<td>Unpublished</td>
<td></td>
<td></td>
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<tr>
<td>NCT01933607</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>Dec 2016</td>
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<tr>
<td>NCT02234154</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>May 2017</td>
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<tr>
<td>NCT00401518</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>
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</table>

NCT: national clinical trial

* Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination.

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 a 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.

References


History

<table>
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<tr>
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<th>Comments</th>
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<tr>
<td>09/15/09</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>09/14/10</td>
<td>Replace Policy - Policy updated with literature search through May 2010; the policy statement remains unchanged.</td>
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<td>09/15/11</td>
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<tr>
<td>02/27/12</td>
<td>Related Policies updated; 7.01.130 added.</td>
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<td>9/27/12</td>
<td>Update Related Policies - 7.01.130 added.</td>
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<tr>
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<td>03/11/14</td>
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<tr>
<td>05/20/14</td>
<td>Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555.</td>
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<td>Date</td>
<td>Comments</td>
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<td>09/08/15</td>
<td>Annual Review. Policy updated with literature review through June 9, 2015; policy statement unchanged.</td>
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<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy updated with literature review through April 21, 2016; reference added. No change to the policy statement. Related policies updated; 7.01.87,7.01.107 and 7.01.130 removed.</td>
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<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</td>
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Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


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Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impomarsion maipangeep iti aplikasyono no coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaar. Mabalin nga adda rambng nga aramideno nga addang sabbay dagiti partikular a naituding nga aldaw tapno mapatalainedyyo no coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala ti daytoy nga impomarsion ken tulong iti bukodyo a pagsaaso nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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