Facet Arthroplasty

Number 7.01.120
Effective Date April 1, 2017
Revision Date(s) 03/14/17; 05/10/16; 09/08/15; 09/08/14; 09/09/13; 09/11/12, 09/13/11; 09/14/10
Replaces N/A

Policy

Total facet arthroplasty is considered investigational.

Related Policies

7.01.555 Facet Joint Denervation

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0202T</td>
<td>Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine</td>
</tr>
</tbody>
</table>

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.
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 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 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.

Scope
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application
N/A

Rationale
This policy was originally created in July 2009 and has been updated periodically with searches of the MEDLINE database. The most recent search, performed through November 7, 2016, identified a report indicating that the U.S. Food and Drug Administration–regulated multicenter investigational device exemption trial (NCT00418197).
of the Total Facet Arthroplasty System (TFAS) was discontinued due to financial reasons. (1) Two of 10 TFAS procedures performed at the authors’ institution had stem fracture after total facet replacement.

We identified a 2014 conference proceeding of interim 2- and 4-year results in 243 patients from a phase 3 multicenter randomized trial of the ACADIA Facet Replacement System (NCT00401518; see Table 1). (2) The study began in 2006, is expected to enroll 390 subjects with lumbar spinal stenosis, and compares facet arthroplasty with the ACADIA system to spinal fusion. Completion of the study with submission of data to the U.S. Food and Drug Administration is expected in 2017.

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></td>
<td></td>
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<tr>
<td>NCT01933607*</td>
<td>A Study to Evaluate the Safety and Efficacy of the TOPS System (Post Market Study)</td>
<td>10</td>
<td>Dec 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT02234154*</td>
<td>A Study to Evaluate the Safety and Efficacy of the TOPS System (Post Market Study)</td>
<td>10</td>
<td>May 2017</td>
</tr>
<tr>
<td>NCT00401518*</td>
<td>The Investigational Plan for the Evaluation of the ACADIA® Facet Replacement System (Pivotal Study)*</td>
<td>390</td>
<td>Aug 2017</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00405691*</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 (completed)</td>
</tr>
<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 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
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.

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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
References


Appendix

N/A

History

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<tr>
<th>Date</th>
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<tbody>
<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>
</tr>
<tr>
<td>09/15/11</td>
<td>Replace Policy – Policy updated with literature review through May 2011; policy statement unchanged.</td>
</tr>
<tr>
<td>02/27/12</td>
<td>Related Policies updated; 7.01.130 added.</td>
</tr>
<tr>
<td>09/11/12</td>
<td>Replace policy. Policy updated with literature review through May 2012; reference numbers 1 and 2 added; policy statement unchanged.</td>
</tr>
<tr>
<td>09/27/12</td>
<td>Update Related Policies- 7.01.130 added.</td>
</tr>
<tr>
<td>09/27/13</td>
<td>Replace policy. Policy title updated, the word “Total” is deleted. A literature review through June, 2013 did not prompt additions to references. Policy statement unchanged.</td>
</tr>
<tr>
<td>03/11/14</td>
<td>Coding Update. Codes 84.84 and 84.85 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.</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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<tr>
<td>09/08/15</td>
<td>Annual Review. Policy updated with literature review through June 9, 2015; policy statement unchanged</td>
</tr>
<tr>
<td>05/10/16</td>
<td>Annual Review. 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>
</tr>
<tr>
<td>03/14/17</td>
<td>Annual review. Policy updated with literature review through November 7, 2016; reference 2 updated. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.
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  - Information written in other languages

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5992. 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 S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice contains important information. If you need帮助, please call 800-722-1471 (TTY: 800-842-5357)

Oromo (Cushite):

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Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsèn apikasyon w lan oswa konsèn konvètri asirans lan atravé Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kente konvèli asirans sante w la oswa pou yo ka ede w avèk desans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

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Daytoy a Pakdaar ket naglao iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglao iti napateg nga impormasion maipanggpin iti aipikasyonno wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelsa iti daytoy a pakdaar. Mabalini nga adda rumbeg nga aramideni nga adda sakkay dagiti particular nga naltingad nga alawd tapno mapagatalianiyo iti coverage ti salan-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasasa nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

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