MEDICAL POLICY – 7.01.120
Facet Arthroplasty

BCBSA Ref. Policy: 7.01.120
Effective Date: July 1, 2021
Last Revised: June 1, 2021
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.555  Facet Joint Denervation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞  Clicking this icon returns you to the hyperlinks menu above.

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.

Policy Coverage Criteria
Total facet arthroplasty is considered investigational.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0202T</td>
<td>Posterior vertebral joint(s) arthroplasty (eg, 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>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### 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 and a few case series studies. 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 in 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 (FDA) approval. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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>
<td></td>
</tr>
<tr>
<td>NCT03012776a</td>
<td>A Clinical Study to Assess the Safety and Effectiveness of the Premia Spine TOPS™ System</td>
<td>266</td>
<td>Sept 2023</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01933607a</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>Dec 2016 (unknown)</td>
</tr>
<tr>
<td>NCT02234154a</td>
<td>Post-market Study of the TOPS™ System (TOPS)</td>
<td>10</td>
<td>May 2017 (unknown)</td>
</tr>
<tr>
<td>NCT00401518a</td>
<td>A Pivotal Study of a Facet Replacement System (ACADIA) to Treat Spinal Stenosis²</td>
<td>390 (actual)</td>
<td>Oct 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 FDA. The ACADIA™ Facet Replacement System (Facet Solutions, acquired by Globus Medical in 2011) was being evaluated in a FDA–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>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</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>9/27/12</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>
</tr>
<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>
</tr>
<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>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>
</tr>
<tr>
<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</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.
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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can also 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.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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 has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Ayi sila a gen Enfòmasyon Enpòtan Iadann. Ayi sila a kapab genyen enfòmasyon enpòtan konpòsan aplikaasyon w lan oswa konpòsan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan ayi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asisants nan lang ou paile a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmooob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaara ket naglaon iti Napateg nga Impomarsyon. Daytoy a pakdaara mabalbin nga adda ket naglaon iti napateg nga impomarsyon maipanggep iti aplikaasyon woy yoy yoy coverage babaen Premera Blue Cross. Daytoy ket mabalbin dagni importante a pelta iti daytoy a pakdaara. Mabalbin nga adda rumbeng nga aramidemy nga adda sabbay dagiti partikular a naituding nga alaw tapo mapagnalidemyo ti coverage ti salun-atyo woy yoy yoy yoy coverage nga kava. Adda karbenganyo a mangala iti daytoy nga impomarsyon ken tulog iti bukodyo a pagasaso nga awan ti bayadanoy. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保單的重要訊息。本通知可能有關於重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

عربي (Arabic):
تحذير هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة لمصلحة طلبي أو منتجك. العملية التي عبرت عنها في هذا الإشعار ملخصة على أنها تأكيد إجراء. قد تحتاج لإدراج إجراء في توثيق مادة للمساعد على تعرفك على الصحة والاستعداد في ذلك الكشف ومثل هذه المعلومات والمساعدات ينطبق دون تكييد أي خاصية. اتصل 800-722-1471 (TTY: 800-842-5357).
Japanese (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれています。この通知には、記載されている可能性がある重要な日付をご確認ください。健康保険や失業サポートを維持するには、特定の期間までに行動を取る必要があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

Korean (Korean):
본 통지서에는 중요한 정보가 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통해 커버리지에 관한 정보를 포함하고 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하가 이러한 정보와 조치를 귀하의 안전과 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화해보십시오.

Polish (Polish):

Farsi (Persian):
این اطلاعات به افرادی که می‌خواهند بازپرداخت مالیات در مورد پوشش یا کمک‌های مالی در حال صدور باشند یا ممکن است به افرادی که به مدت محدودیتی پوشش یا کمک مالی می‌پذیرند، کاربردی است. اطلاعات مهمی در این اعلامیه وجود دارد که ممکن است قبل از ورود به سفارش‌هایی که در تاریخ‌ها و تغییراتی که در این اعلامیه ذکر شده است مربوط باشند. در صورت نیاز به کمک‌های مالی، شما می‌توانید با Premera Blue Cross تماس بگیرید. 800-722-1471 (TTY: 800-842-5357) برای تماس نمایید.

Tagalog (Tagalog):