Axial Lumbosacral Interbody Fusion

Introduction

Fusing the bones at the lowest part of the back may be one choice to treat lower back (lumbar) pain. When this kind of fusion is needed, it’s usually done by making an opening (an incision) through the back muscles and other tissue. In axial lumbar interbody fusion, the incision is made in the buttock. A tube, long enough to reach the spine, is inserted upwards along a specific path. Special tools are then threaded through the tube to reach the disc that sits between the bones. The surgeon cuts way the damaged disk and removes it through the tube. The tube also guides the path for the bone graft material and a small implant. The bone graft material promotes bone growth, and over time the two bones grow together and are permanently joined. Because more studies are needed to determine the risks and benefits of this procedure compared to other methods of lumbar fusion, this service is considered unproven (investigational).

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

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial lumbosacral interbody fusion</td>
<td>Axial lumbosacral interbody fusion is considered investigational.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0195T</td>
<td>Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace (code terminated 1/1/19)</td>
</tr>
<tr>
<td>0196T</td>
<td>Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (List separately in addition to code for primary procedure) (code terminated 1/1/19)</td>
</tr>
<tr>
<td>22586</td>
<td>Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace.</td>
</tr>
<tr>
<td>22899</td>
<td>Unlisted procedure, 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

N/A

Evidence Review
Description

Axial lumbosacral interbody fusion (LIF; also called presacral, transsacral or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion, while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

Background

Interbody Fusion

Interbody fusion is a surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion

Axial lumbosacral interbody fusion (LIF; also called presacral, transsacral, or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

An advantage of axial LIF is that it preserves the annulus and all paraspinous soft tissue structures. However, there is an increased need for fluoroscopy and an inability to address intracanal pathology or visualize the discectomy procedure directly. Complications of the axial approach may include perforation of the bowel and injury to blood vessels and/or nerves.

Summary of Evidence

For individuals with degenerative spine disease at the L4- S1 disc spaces who receive axial LIF the evidence includes comparative systematic review of case series and a retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal LIF than following axial LIF, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were
limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies suggest that complication rates may also be increased with 2-level axial LIF. Controlled trials with clinical outcome measures are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

An unpublished trial that might influence this policy is listed in Table 1. A search of ClinicalTrials.gov in March 2019 did not identify any ongoing trials that would likely influence this policy.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01716182*</td>
<td>RAMP Study: A Prospective Randomized Study Comparing Two Lumbar Fusion Procedures</td>
<td>200</td>
<td>July 2014 (terminated) slow enrollment</td>
</tr>
</tbody>
</table>

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

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty medical societies and 3 academic medical centers while this policy was under review in 2011. The input considered axial lumbosacral interbody fusion to be investigational.
Practice Guidelines and Position Statements

North American Spine Society


National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbar spine in 2011. The guidance stated that current evidence on the efficacy of transaxial interbody lumbosacral fusion is “limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation.” The Institute encouraged “further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality-of-life measures, and the frequency of both early and late complications.”

In July 2018, the NICE guidance was updated and replaced by evidence-based recommendations on transaxialinterbodylumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, “Evidence on the safety of transaxialinterbodylumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor.”

Medicare National Coverage

There is no national coverage determination.
Regulatory Status

The U.S. Food and Drug Administration has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (see Table 2). The systems are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are not meant to be used in patients with vertebral compression fractures or any other condition in which the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 disc spaces in conjunction with legally marketed facet or pedicle screw systems. Food and Drug Administration product code: KWQ

Table 2. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by FDA

<table>
<thead>
<tr>
<th>Orthotic</th>
<th>Description</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>501(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TranS1® AxiaLIF™ System</td>
<td>For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L5-S1 in conjunction with legally marketed pedicle screws</td>
<td>TranS1</td>
<td>12/04</td>
<td>K040426</td>
</tr>
<tr>
<td>TranS1® AxiaLIF™ System</td>
<td>Indication modified to include facet screws</td>
<td>TranS1</td>
<td>06/05</td>
<td>K050965</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® II System</td>
<td>For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L4-S1 in conjunction with legally marketed facet and pedicle screws</td>
<td>TranS1</td>
<td>04/08</td>
<td>K073643</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® 2L System</td>
<td>Indication unchanged, marketed with branded bone morphogenetic protein</td>
<td>TranS1</td>
<td>01/10</td>
<td>K092124</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® Plus System</td>
<td>Intended to provide anterior stabilization of the L5-SI or L4-SI</td>
<td>TranS1</td>
<td>03/11</td>
<td>K102334</td>
</tr>
</tbody>
</table>
Orthotic Description | Manufacturer | Date Cleared | 501(k) No.
--- | --- | --- | ---
spinal segment(s) as an adjunct to spinal fusion
This device’s instruments are used for independently distracting the L5-S1 or L4-S1 vertebral bodies and inserting bone graft material (D3M, autograft or autologous blood) into the disc space.
Use limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF

Adapted from the Food and Drug Administration (2007, 2008)\(^1,2\)
FDA: Food and Drug Administration

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/27/12</td>
<td>Replace Policy – Policy Section on axial LIF moved from policy 7.01.542 (Minimally Invasive Lumbar Interbody Fusion) and updated with literature search through September 2011.</td>
</tr>
<tr>
<td>09/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature review through August 2012; references 7 and 8 added; one reference removed. Policy statement unchanged. CPT coding updated: CPT codes 22586 and 0309T, effective 1/1/13, added; descriptors changed for codes 0195T and 1096T.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.120.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Replace policy. Policy updated with literature review through September 30, 2013. Reference 5 added; others renumbered/removed. Policy statement unchanged. ICD-9 code 81.08 descriptor updated.</td>
</tr>
<tr>
<td>01/28/15</td>
<td>Annual Review. Policy updated with literature review through September 24, 2014; references 6, 13 added; policy statement unchanged.</td>
</tr>
<tr>
<td>06/01/15</td>
<td>Coding update. ICD-10 PCS codes added; these were inadvertently removed at last publication.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Removed CPT code 0309T from policy as it was terminated 1/1/18.</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). ©2019 Premera All Rights Reserved.

**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 any other 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 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:

200 Independence Avenue SW, Room 509F, 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).

Arabic (Arabic):
يجري هذا الإشعار عن خدمات مالية. قد يجري هذا الإشعار معلومات مهمة بخصوص طبلك أو طبيبك. قد تكون تلك الملاحظات عليا من خلال تحويله إلى الإصدار العربي. قد تتم إضافته إلى ترتيب محتوى للمساعدة على تطوير 서비스 الصحة أو الخدمات في دفع الكشف. يرجى تقديم المعلومات على هذه المعلومات والمساعدة باللغة العربية. اتصل

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

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保障或費用補貼。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).

Cushite (Oromo):

Lakkoofsa biibiliaa 800-722-1471 (TTY: 800-842-5357) ti biibiliaa.

Italiano (Italian):

德语 (German):

Iloko (Ilocano):
Daytoy a Pakdaar ket nagliao iti Napateg nga Impomarson. Daytoy a pakdaar mabalini nga adda ket nagliao iti napateg nga impomarsion maipanggep iti aplikasyono woy nggoyo coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pesta iti daytoy a pakdaar. Mabalini a nga adda rumbeng nga aramideny nga adda sabbay dagiti partikular a naituding nga aldaw tajaajila nyoog uas teev tseg rau hauv daim niaww no mas koj kajj juuy juuy tuai taux beeksist kun odeeffannoo barbaachisaa qaba. Guyyaaww daim niaww no mas koj kajj juuy juuy tuai taux beeksist kun odeffannoo barbaachisaa qaba.

Kreyòl ayisyen (Creole):

Spanish (Spanish):
Consentirte de mantener tu cobertura o ayuda con los costos. Tienes el derecho de obtener esta información y la ayuda en tu idioma a ningún costo. Llámanos al 800-722-1471 (TTY: 800-842-5357).
Premera Blue Cross. For important information about your application or coverage, please note that for the terms listed below, the following deadlines are applicable.

- August 31, 2017: You must request your coverage to be updated by this date to ensure continuous coverage.
- September 1, 2017: Your coverage will begin on this date.
- October 1, 2017: You must honor this deadline for any immediate needs.
- December 15, 2017: This is the last day that you can sign up for coverage under the regular open enrollment period, unless you qualify for a special enrollment period.

For more information, call 800-722-1471 (TTY: 800-842-5357).

---

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

---

Română (Romanian):

---

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

---

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de 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).

---

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang patak na dito sa paunawa. Maaaring maging lahat o hindi lahat ang mga impormasyon na may mahalagang impormasyon na sinasayang dito. Kaya'y halimbawa, 800-722-1471 (TTY: 800-842-5357).

---

ไทย (Thai):
ประกาศนี้มีข้อมูลที่เกี่ยวข้องกับการสมัครหรือการเปลี่ยนแปลงการสมัครของคุณผ่าน Premera Blue Cross และคุณมีสิทธิ์ในการรับข้อมูลที่เกี่ยวข้องกับการสมัครหรือการเปลี่ยนแปลง การสมัครของคุณผ่าน Premera Blue Cross. การสมัครหรือการเปลี่ยนแปลงการสมัครมีกำหนดระยะเวลาที่ชัดเจนที่คุณอาจจำเป็นต้องปฏิบัติเพื่อให้การสมัครหรือการเปลี่ยนแปลงการสมัครของคุณมีผลใช้ ต่อสิทธิ์ที่คุณได้รับ 800-722-1471 (TTY: 800-842-5357).

---

Українська (Ukrainian):
Це повідомлення містить важливу інформацію. Ця повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує можливість того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).