MEDICAL POLICY – 7.01.107
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

BCBSA Ref. Policy: 7.01.107

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<tr>
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Introduction

Back pain is a common symptom and can cause disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons and structures of the spine, it can still be very difficult to identify a specific cause of pain for many people. Scientists and physicians have felt that one cause may be pressure put on the nerves by the vertebrae (bones in the spine). Devices known as spacers have been designed to be positioned between the vertebrae. Spacers are intended to reduce pain. Generally speaking, a surgeon places the device and then expands it. This expansion lifts the part of the bone that’s pressing on the nerve. Some devices are used after surgery to take pressure off of nerves and some devices are used as a stand-alone treatment. These devices are considered unproven for all uses. Published scientific studies show high failure and complications rates.

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

Note: This policy applies only to the following FDA-approved devices:

- X-STOP® Interspinous Process Decompression (IPD®) System
- Coflex® Interlaminar Technology implant (formerly known as Interspinous U)
- Superion® Interspinous Spacer (ISS, VertiFlex)

This policy does not address other implanted interspinous/interlaminar spacer devices (see Regulatory Status and Related Policies).

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
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<tr>
<td>Interspinous or interlaminar distraction device</td>
<td>Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as a treatment of spinal stenosis.</td>
</tr>
<tr>
<td>Interlaminar stabilization device</td>
<td>Use of an interlaminar stabilization device following decompressive surgery is considered investigational.</td>
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Coding

<table>
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<th>Description</th>
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<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>22868</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)</td>
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<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
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<td>22870</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)</td>
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</table>
Related Information

N/A

Evidence Review

Description

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompressive surgery or as an alternative to decompressive surgery.

Background

Spinal stenosis, which can involve a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, is a common cause of back pain and disability, particularly as individuals get older. It can result from a number of pathologic processes, but in adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis (LSS) is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Conservative treatments for spinal stenosis include physical therapy, pharmacotherapy, and epidural steroid injections. If conservative treatments fail, surgical approaches for spinal stenosis may be used. They include decompression surgery with or without spinal fusion.
Spinal fusion is associated with complications and is generally reserved for patients with spinal instability or moderate grade spondylolisthesis, when a vertebral body slips forward relative to an adjacent vertebral body. The health benefit of fusion in patients with no or low grade spondylolisthesis who are undergoing decompression surgery for spinal stenosis has been questioned.\textsuperscript{1,2} Two studies published in 2016 reached different conclusions concerning the health benefit of spinal fusion in patients undergoing spinal decompression.\textsuperscript{1,2} The Swedish Spinal Stenosis Study (SSSS) included patients with spinal stenosis, with or without degenerative spondylolisthesis.\textsuperscript{1} Comparison of patients undergoing decompression surgery plus fusion to patients undergoing decompression surgery alone showed no benefit of fusion. In contrast, the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial included patients with spinal stenosis and grade I spondylolisthesis, and found that some outcomes were improved with the addition of spinal fusion to decompression surgery, albeit at higher cost and an increase in complications.\textsuperscript{2}

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication. Other types of dynamic posterior
stabilization devices are pedicle screw/rod-based devices and total facet replacement systems. However, they are not covered in this medical policy.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Active Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT03041896</td>
<td>Retrospective Evaluation of the Clinical and Radiographic Performance of Coflex® Interlaminer Technology Versus Decompression With or Without Fusion</td>
<td>5000</td>
<td>Oct 2017</td>
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<tr>
<td>NCT01316211</td>
<td>Comparative Evaluation of Clinical Outcome in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex™ Interlaminar Technology</td>
<td>245</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT02555280</td>
<td>A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex® Interlaminar Technology for FDA Real Conditions of Use Study (Post-Approval ‘Real Conditions of Use’ Study)</td>
<td>345</td>
<td>Jun 2022</td>
</tr>
<tr>
<td>NCT02457468</td>
<td>The Coflex®COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology</td>
<td>500</td>
<td>Jun 2023</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

Summary of Evidence

For individuals who have spinal stenosis and up to grade I spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes
randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression show a high failure and complication rates. Two devices are considered: the Superion® Interspinous Spacer (ISS) and the coflex® interlaminar implant. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superion® ISS to the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion® ISS on some outcome measures. For example, the percentage of patients experiencing improvement was reported as over 80%. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex® interlaminar implant (also called the interspinous U) was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain were similar in the 2 groups at 1-year follow-up, but reoperation rates due to absence of recovery were substantially higher with the coflex® implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex® and 6% for bony decompression. At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex® group and in 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal stenosis and up to grade I spondylolisthesis who receive an interlaminar spacer with spinal decompression surgery, the evidence for includes RCTs and non-randomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations, as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a population with grade 1 or lower spondylolisthesis, showed that stabilization of decompression with the coflex® implant was noninferior to decompression with spinal fusion. However, evidence of a health benefit for fusion in this population is inconclusive, calling into question the validity of the noninferiority trial. Because of this uncertainty, a key question is whether decompression plus a coflex® device improves health outcomes compared to decompression alone in this population. Non-randomized comparative studies have reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. Greater certainty about the net health outcome of this device might be obtained when results of an RCT on decompression with and without the coflex® implant are published. The evidence is insufficient to determine the effects of the technology on health outcomes.
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.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in March 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes (including durability). Two reviewers did not consider this investigational, stating the technology has a role in the treatment of selected patients with neurogenic intermittent claudication.

Practice Guidelines and Position Statements

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations and coverage criteria for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a level I study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade I instability. Recommended indications and limitations were presented. The document did not address interspinous and interlaminar distraction devices without decompression.

North American Spine Society

In 2014, the North American Spine Society (NASS) published specific coverage policy recommendations on lumbar interspinous device without fusion. NASS recommended that interspinous distraction devices may be indicated for degenerative lumbar stenosis with the following criteria: (a) associated with neurogenic claudication that is relieved by lumbar flexion,
(b) patients older than 50 years old, (c) failure of nonoperative treatment, (d) no more than 25° of degenerative scoliosis, (e) no more than a grade I degenerative spondylolistheses, and (f) open surgery (eg, laminectomy) is not a medically safe treatment option because of comorbidities. NASS states that interspinous distraction devices are not indicated in cases that do not fall within these parameters.

**American Pain Society**

The 2009 guidelines from the American Pain Society indicated that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends that clinicians consider offering the intervention). The net benefit was considered moderate through 2 years, with insufficient evidence to estimate the net benefit for long-term outcomes.

**National Institute for Health and Care Excellence**

The United Kingdom’s National Institute for Health and Care Excellence published guidance in 2010 that indicated “Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed.” The evidence reviewed consisted mainly of reports on X-STOP.

**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.

**Regulatory Status**

In 2015 the Superion® Interspinous Spacer (ISS, VertiFlex), was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The Superion® ISS is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging (MRI) and/or have computed tomography (CT) evidence of thickened ligamentum flavum, narrowed
lateral recess, and/or central canal or foraminal narrowing. The Superion® ISS is intended for patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment. The Superion® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated and at no more than 2 levels, from L1 to L5.

Continued FDA approval of the Superion® device is contingent on reports from 2 post-approval studies, the Superion® Post-Approval Clinical Evaluation and Review (SPACER), a 60-month study comparing the Superion® device with the X-STOP, and the Superion® New Enrollment Study, a new study comparing the Superion® with decompression alone in at least 358 subjects.

In 2012, the coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA through the premarket approval process (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex® (previously called the Interspinous U) is indicated for use in 1- or 2-level lumbar stenosis from the L1 to L5 vertebrae in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The coflex® “is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).”

FDA lists the following contraindications to use of the coflex®:

- “Prior fusion or decompressive laminectomy at any index lumbar level
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (eg, compression fracture)
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis
- Isthmic spondylolisthesis or spondylolysis (pars fracture)
- Degenerative lumbar scoliosis (Cobb angle greater than 25°)
- Osteoporosis
- Back or leg pain of unknown etiology
- Axial back pain only, with no leg, buttock, or groin pain
• Morbid obesity defined as a body mass index > 40
• Active or chronic infection- systemic or local
• Known allergy to titanium alloys or magnetic resonance(MR) contrast agents
• Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.”

The FDA labeling also contains multiple precautions and the following warning:

• “Data has demonstrated that spinous process fractures can occur with Coflex® implantation”.

Continued FDA approval of the coflex® is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study provides 5-year follow-up of the cohort of the cohort in the pivotal investigational device exemption trial. The second is a multi-center trial with 230 patients, followed for 5 years, that compares decompression alone with decompression plus coflex®. FDA product code: NQO.

The Wallis® System (originally Abbott Spine; currently Zimmer Spine) was introduced in Europe in 1986. The first-generation Wallis implant was a titanium block; the second-generation device is a plastic-like polymer inserted between adjacent processes and held in place with a flat cord wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an FDA-regulated clinical trial.

Also in an FDA-regulated clinical trial is the DIAM™ Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM™ system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes) and FLEXUS™ (Globus Medical) devices; the comparator in these trials is the X-STOP device, which has been withdrawn from the market.

The NL-Prow™ (Non-Linear Technologies), Aperius® (Medtronic Spine), and Falena® (Mikai) devices are in trials in Europe.

References


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<td>03/13/07</td>
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<td>08/23/07</td>
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<td>11/11/08</td>
<td>Codes updated; 84.58 removed from policy.</td>
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<td>07/14/09</td>
<td>Replace policy – Policy updated with literature search; no change to the policy statement. References added.</td>
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<td>09/14/10</td>
<td>Related Policies updated.</td>
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<td>06/13/11</td>
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<td>02/27/12</td>
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<td>08/22/12</td>
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<td>07/24/13</td>
<td>Replace policy. Interlaminar stabilization added to title. New policy statement added “Use of an interlaminar stabilization device following decompressive surgery is considered investigational”. New, approved device, added to regulatory status section. Rationale updated with literature review through April 4, 2013; references 7, 19, 20 added; others renumbered/removed. Policy statement changed as noted.</td>
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<td>01/21/14</td>
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<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>
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<td>Annual Review. In the Regulatory Status section under Coflex® contraindications for degenerative lumbar scoliosis, the Cobb angle was corrected to greater than 25°. Clinical trials reformatted into a table. Policy updated with literature review through March 11, 2015; references 1-2, 7, 9-12, 27 added. HCPCS code C1821 removed from policy as not used for adjudication. Policy statements unchanged.</td>
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<td>Annual Review, approved June 14, 2016. Policy updated with literature review through February 22, 2016; references 21, 26-27, and 29 added. Rationale section revised; policy statements unchanged.</td>
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<td>10/11/16</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<td>Coding update, added new CPT codes 22867-22870 effective 1/1/17.</td>
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<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Removed CPT code 22899. Policy statements edited for clarification; the intent of the policy is unchanged.</td>
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<td>01/01/18</td>
<td>Coding update; removed CPT codes 0171T and 0172T as they terminated 1/1/17.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
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Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonno wenn coverag baben a Piti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidendo nga addang sabbay dagiti partikular a naituding nga aldaw tapno mapatalignedyo ti coverage ti salun-ayto wenn tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukdoyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga oswa 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross (TTY: 800-842-5357).

Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de saúde ou de ajuda de saúde ou de ajuda de saúde.

liğini (Korean):

권리가 허용된 경우에만 중대한 비용을 지급할 수 있습니다. 원래의 보험을 유지한 경우에만 중대한 비용을 지급할 수 있습니다. 원래의 보험을 유지한 경우에만 중대한 비용을 지급할 수 있습니다.

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. Es posible que haya fechas clave en este aviso, por lo que es importante que consulte la fecha de las mismas.

Язык (Ukrainian):

Це повідомлення містить важливу інформацію. Це 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 імовірність того, що Вам треба буде здійснити певні кроки у конкретному разі 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).

Tiếng Việt (Vietnamese):