MEDICAL POLICY – 6.01.524

Diagnosis and Treatment of Sacroiliac Joint Pain

BCBSA Ref. Policy: 6.01.23

Effective Date: March 1, 2018
Last Revised: Feb. 13, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
2.01.26 Prolotherapy
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy
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

The sacroiliac (SI) joints are between the lower spine and the pelvic bones. There is one on each side of the body. These joints transfer weight and the forces of the upper body to the hips and legs. Pain can develop in one or both of these joints and may be felt in the lower back, buttocks, or legs. One way to test if pain is coming from an SI joint is to inject a numbing solution. Imaging is used to guide and position the needle for the injection. If the numbing agent reduces pain, it is an indication that an SI joint is the cause. To relieve pain, steroids can be injected into the joint using the same type of imaging guidance. This policy describes when injections to diagnose and treat SI joint pain may be considered medically necessary. This policy also discusses investigational (unproven) techniques for diagnosing or treating SI pain. These include diagnosis by using a special dye and imaging (arthrography), and attempted treatments that call for destroying part of a nerve or fusing or stabilizing the sacroiliac joints.

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>Medical Necessity</th>
</tr>
</thead>
</table>
| **Diagnosis of sacroiliac joint pain**     | *Injection of anesthetic for the purpose of diagnosing sacroiliac joint pain may be considered medically necessary when the following criteria have been met:*  
   - Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program  
   **AND**  
   - Dual (controlled) diagnostic blocks with 2 anesthetic agents with differing duration of action are used  
   **AND**  
   - The injections are performed under imaging guidance |
| **Treatment of sacroiliac joint pain**     | *Injection of corticosteroid may be considered medically necessary for the treatment of sacroiliac joint pain when the following criteria have been met:*  
   - Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program  
   **AND**  
   - The injection is performed under imaging guidance  
   **AND**  
   - No more than 3 injections are given in one year |
| **Open Sacroiliac Joint Fusion**           | *Open sacroiliac joint fusion procedures may be considered medically necessary for any of the following indications:*  
   - As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum  
   **OR**  
   - As an adjunct to the medical treatment of sacroiliac joint infection/sepsis  
   **OR**  
   - As a treatment for severe traumatic injuries associated with pelvic ring fracture |
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Sacroiliac joint fusion performed by an open procedure for any other indication is considered not medically necessary.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Minimally invasive SIJ fusion/percutaneous SIJ fusion procedures</td>
<td>Percutaneous and minimally invasive SIJ fusion/stabilization procedures are considered investigational.</td>
</tr>
<tr>
<td></td>
<td>• iFuse® Implant System (SI Bone)</td>
</tr>
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<td></td>
<td>• Rialto™ SI Joint Fusion System (Medtronic)</td>
</tr>
<tr>
<td></td>
<td>• SJ-Fuse (Spine Frontier)</td>
</tr>
<tr>
<td></td>
<td>• SImmetry® Sacroiliac Joint Fusion System (Zyga Technologies)</td>
</tr>
<tr>
<td></td>
<td>• Silex™ Sacroiliac Joint Fusion System (XTANT Medical)</td>
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<tr>
<td></td>
<td>• SambaScrew® (Orthofix)</td>
</tr>
<tr>
<td></td>
<td>• SI-LOK® Sacroiliac Joint Fixation System (Globus Medical)</td>
</tr>
<tr>
<td>Arthrography</td>
<td>Arthrography of the sacroiliac joint is considered investigational.</td>
</tr>
<tr>
<td>Radiofrequency denervation</td>
<td>Radiofrequency denervation of the sacroiliac joint is considered investigational.</td>
</tr>
</tbody>
</table>

### Conservative Therapy and Controlled Diagnostic Lateral Branch Blocks

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
  - Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers (eg, gabapentin) or muscle relaxants

**AND**

- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy

**AND**

- Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues

**AND**

- Documentation of patient compliance with the preceding criteria

A successful trial of controlled diagnostic lateral branch blocks consists of 2 separate positive
Conservative Therapy and Controlled Diagnostic Lateral Branch Blocks

blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in a reduction in pain for the duration of the local anesthetic used (eg, 3 hours longer with bupivacaine than lidocaine). There is not a consensus on whether a minimum of 50% or 75% reduction in pain would be required to be considered a successful diagnostic block, although evidence supports a criterion standard of 75% to 100% reduction in pain with dual blocks. No therapeutic intra-articular injections (ie, steroids, saline, other substances) should be administered for a period of at least 4 weeks before the diagnostic lateral branch block. The diagnostic blocks should not be conducted under intravenous sedation unless specifically indicated (eg, the patient is unable to cooperate with the procedure).

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>27279</td>
<td>Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device</td>
</tr>
<tr>
<td>27280</td>
<td>Arthrodesis, sacroiliac joint (including obtaining graft)</td>
</tr>
<tr>
<td>64635</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint</td>
</tr>
<tr>
<td>64636</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint</td>
</tr>
<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
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</tbody>
</table>

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Related Information

. N/A
Evidence Review

Description

Sacroiliac joint (SIJ) arthrography using fluoroscopic guidance with injection of an anesthetic has been explored as a diagnostic test for SIJ pain. Duplication of the patient’s pain pattern with the injection of contrast medium suggests a sacroiliac etiology, as does relief of chronic back pain with injection of local anesthetic. Treatment of SIJ pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive SIJ fusion has also been explored.

Background

Sacroiliac Joint Pain

Similar to other structures in the spine, it is assumed that the sacroiliac joint (SIJ) may be a source of low back pain. In fact, before 1928, the sacroiliac joint was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the sacroiliac joint received less research attention.

Diagnosis

Research into sacroiliac joint pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, sacroiliac joint pain is typically without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for sacroiliac joint pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding study of the sacroiliac joint is that multiple structures, such as posterior facet joints and lumbar discs, may refer pain to the area surrounding the sacroiliac joint.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the sacroiliac joint for the diagnosis of sacroiliac joint pain. Treatments being investigated for sacroiliac joint pain include prolotherapy (see Related Policies), corticosteroid injection, radiofrequency ablation,
stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation (this is because there is little to no bridging bone on radiographs). Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (Rialto, Simmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote fusion of the SIJ.

**Summary of Evidence**

For individuals who have sacroiliac joint (SIJ) pain who receive therapeutic corticosteroid injections, the evidence includes small randomized controlled trials (RCTs) and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from 2 small RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, preferably using sham injections, are needed to determine the degree of benefit of corticosteroid injections over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive RFA, the evidence includes 4 small RCTs using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. For RFA with a cooled probe, the 2 small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. The RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled RCT showed no benefit of RFA. Further high-quality controlled trials are needed that compare this procedure in defined populations with sham control and with alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a triangular implant, the evidence includes 2 nonblinded RCTs of minimally invasive fusion and a number of cohort studies and two case series with more than 85% follow-up at 2 to 3 years. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be independent, blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer-term follow-up from these RCTs suggest has indicated that the results obtained at 6 months persist to 2 years. An additional cohort study/and case series, with sample sizes ranging from 45 to 149 patients and low dropout rates.
(<15%), have also shown reductions in pain and disability at 2 years. One small case series showed outcomes that persisted to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months and cumulative revision rate at 4 years of 3.54%. Several case series have reported follow-up out to five years with good outcomes, however, they are limited by study design and lack of a comparator group. Uncertainty remains due to a lack of longer-term follow-up measuring objective outcomes and evaluating long-term safety and effectiveness of SIJ fusion. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a cylindrical threaded implant, the evidence includes a prospective cohort. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for 2 years following implantation of slotted screws filled with autologous bone. Results at 1 year are consistent with findings from the studies using a triangular implant. However, longer follow-up and controlled trials are needed to evaluate this type of implant. 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>
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<tr>
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<tr>
<td>NCT01861899</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
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<td>Aug 2018</td>
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<tr>
<td>NCT02270203</td>
<td>LOIS: Long-Term Follow-Up in INSITE/SIFI</td>
<td>103</td>
<td>Dec 2019</td>
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<tr>
<td>NCT02074761</td>
<td>Evolusion Study Using the Zyga Simmetry Sacroiliac Joint Fusion System</td>
<td>250</td>
<td>Dec 2019</td>
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<tr>
<td>NCT03230279</td>
<td>Randomized Controlled Trial Of Minimally Invasive Sacroiliac Joint Fusion Compared To Radiofrequency Ablation For Sacroiliac Joint Dysfunction</td>
<td>84</td>
<td>Sep 2023</td>
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</tbody>
</table>
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.

2017 Input

In response to requests, clinical input focused on sacroiliac joint (SIJ) fusion was received from 10 respondents, including 5 specialty society-level responses from 7 specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy was under review in 2017. Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of fusion/stabilization of the SIJ using percutaneous and minimally invasive techniques for carefully selected patients as outlined in statements from the North American Spine Society.

2015 Input

In response to requests, focused input on SIJ fusion was received from 5 physician specialty societies and 3 academic medical centers while this policy was under review in 2015. A majority of reviewers considered sacroiliac joint fusion to be investigational.
2014 Input

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers (5 responses) while this policy was under review in 2014. Input was mixed concerning the use of arthrography, RFA, and fusion of the sacroiliac joint. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (NASS) published coverage recommendations for percutaneous SIJ fusion in 2015. NASS indicated that there was relatively moderate evidence. In the absence of high-level data, policies reflect the multidisciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States. NASS recommended coverage when ALL of the following criteria are met:

1. “[Patients] have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.

2. Patient’s report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.

3. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.

4. Positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.
5. Absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia).

6. Diagnostic imaging studies that include ALL of the following:
   a. Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion.
   b. Imaging of the pelvis (AP [anteroposterior] plain radiograph) to rule out concomitant hip pathology.
   c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.
   d. Imaging of the SI joint that indicates evidence of injury and/or degeneration.

7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.

8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection).”

**American Society of Interventional Pain Physicians**

American Society of Interventional Pain Physicians guidelines were updated in 2013. The updated guidelines recommend the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain. A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic SIJ injections.

**American Society of Anesthesiologists et al**

In 2010, the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine Practice updated their guidelines for chronic pain management. The guidelines recommend that “Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain.” Based on
opinions of consultants and society members, the guidelines recommend that “Water-cooled RFA may be used for chronic sacroiliac joint pain.”

**American Pain Society**

The 2009 practice guidelines from the American Pain Society (APS) were based on a systematic review commissioned by the Society.²³ The guidelines stated that there is insufficient evidence to evaluate validity or utility of diagnostic SIJ block as a diagnostic procedure for low back pain with or without radiculopathy; the guidelines further stated that there is insufficient evidence to adequately evaluate benefits of SIJ steroid injection for nonradicular low back pain.

**International Society for the Advancement of Spine Surgery**

The International Society for the Advancement of Spine Surgery (ISASS) first published a policy statement on minimally invasive SIJ fusion in 2014.³⁸ These recommendations were updated in a 2016 statement.³⁹ Society recommendations indicated that patients who have all of the following criteria may be eligible for minimally invasive sacroiliac joint fusion:

1. “Significant SI joint pain or significantly limitations in activities of daily living because of pain from the SI joint(s).

2. “SI joint pain confirmed with at least 3 positive physical provocation examination maneuvers that stress the SI joint.

3. “Confirmation of the SI joint as a pain generator with ≥ 75% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic.

4. “Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or one or more of the following: physical therapy; Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability;

5. “Additional or alternative diagnoses that could be responsible for the patient’s ongoing pain or disability have been considered, investigated and ruled out.”
National Institute for Health and Care Excellence

National Institute for Health and Care Excellence guidance was published in 2017 on minimally invasive SIJ fusion surgery for chronic sacroiliac pain. The recommendations included:

- **1.1** “Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

- **1.2** Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

- **1.3** This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.”

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

A number of radiofrequency generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product code: GXD.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510 (k) process. They include the , the iFuse® Implant System (SI Bone), the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the Simmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew® (Orthofix) and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical).
FDA Product Code: OUR.

References


33. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System(R)). Med Devices (Auckl). Dec 2015;8:485-492. PMID 26648762


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/18</td>
<td>New policy, approved February 13, 2018. This policy replaces the previous policy 6.01.23. Diagnosis and treatment of sacroiliac joint pain are considered medically necessary when criteria are met. Arthrography and radiofrequency denervation of the sacroiliac joint are considered investigational. Open SIJ Fusion is medically necessary when criteria are met. Percutaneous and minimally invasive SIJ fusion/stabilization procedures are considered investigational.</td>
</tr>
</tbody>
</table>

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Email AppealsDepartmentInquiries@Premera.com

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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:


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