Introduction

Back pain is a common symptom and disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons, and structures of the spine, it is still very difficult to identify a specific source of back pain for many people. A part of the spine felt to cause pain for some people are the facet joints. Facet joints connect the bones of the spine (vertebrae) to stabilize your back and help your spine move. Arthritis or bone changes can develop in these small joints. It is felt that nerves can be compressed by the arthritic changes and lead to pain. Studies have shown that for a small number of people, back pain can be improved by destruction of these nerves (denervation). The nerves are destroyed using a form of electrical waves known as non-pulsed radiofrequency waves. Often the denervation must be repeated every 6 to 12 months because the nerves grow back. Because only a small number of people respond to this treatment, it is important to undergo temporary nerve blocks to identify who will get relief from the radiofrequency treatment. This service must be pre-approved by the plan before it is covered. Records that show at least two successful temporary nerve blocks are needed. Studies have shown that other methods of destroying these nerves (such as pulsed radiofrequency, heat, laser, chemical or freezing) do not work.

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>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Cervical/Lumbar Radiofrequency denervation | Non-pulsed radiofrequency denervation of cervical facet joints (C2-3 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:  
  - There is no prior spinal fusion surgery in the vertebral level being treated  
  AND  
  - Patient has experienced disabling low back (lumbosacral) or neck (cervical) pain for greater than three (3) months, suggestive of facet joint origin and other causes of cervical or lumbar pain such as disc herniation or narrowing of the vertebral canal have been excluded as documented in the medical record and radiographic imaging  
  AND  
  - Pain has failed to respond to three (3) months of conservative management, which may consist of therapies such as oral analgesics (nonsteroidal anti-inflammatory medications, acetaminophen), manipulation or physical therapy, and a home exercise program  
  AND  
  - There has been a successful trial of two controlled medial branch blocks (MBBs) with at least 80% pain relief for the duration of the anesthetic prior to performing the second MBB (see Related Information)  
  AND  
  - If there has been a prior successful radiofrequency denervation, a minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine)  
    - There should be a progress note supporting response to prior RF treatment |
### Procedure | Medical Necessity
--- | ---
**Additional diagnostic medial branch blocks** | If there has been a prior successful radiofrequency denervation, additional diagnostic medial branch blocks for the same level of the spine are not medically necessary.

### Procedure | Investigational
--- | ---
**Thoracic Radiofrequency denervation** | Radiofrequency denervation is considered investigational for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above including but not limited to treatment of thoracic facet joint pain.

**Therapeutic medial branch blocks** | Therapeutic medial branch blocks are considered investigational.

**All other methods of facet denervation** | All other methods of denervation are considered investigational for the treatment of chronic spinal/back pain, including, but not limited to
- Pulsed radiofrequency denervation
- Laser denervation
- Chemodenervation
  - alcohol, phenol, or high-concentration local anesthetics
- Cryodenervation
- Cooled radiofrequency ablation for facet denervation

### Documentation Requirements

**For requests for non-pulsed radiofrequency denervation of cervical facet joints (C2-3 and below) and lumbar facet joints, please provide the following current clinical notes:**
- The level and side (right or left) you are planning to treat
- Documentation that no prior spinal fusion surgery was done in the vertebral level (the specific area) being treated
- Detailed history and physical with notes detailing how long the patient has experienced disabling low back or neck pain
- Evidence that suggests the pain is is arising from the facet joint and documentation that other causes of the pain have been ruled out (eg, copy of imaging showing absence of disc herniation or narrowing of the vertebral canal)
- Conservative treatment tried/failed for at least 3 months (conservative treatment may consist of therapies such as oral analgesics [nonsteroidal anti-inflammatory medications, acetaminophen], manipulation or physical therapy, and a home exercise program)
Documentation Requirements

- Documentation of successful trial of controlled diagnostic medial branch blocks.
  Documentation shows at least 80% pain relief for the duration of anesthetic from the first medical branch block before the second medical branch block is performed:
  - Medial branch blocks should consist of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs)
  - Medial branch blocks should involve the vertebral levels being considered for radiofrequency treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure)

- If there has been a prior successful radiofrequency denervation:
  - There should be documentation that a minimum of six (6) months has passed since prior radiofrequency treatment (per side, per vertebral level of the spine)
  - Clinical note showing response to prior radiofrequency treatment

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
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<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (CT or fluoroscopy); cervical or thoracic, single facet joint</td>
</tr>
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<td>64634</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)</td>
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<tr>
<td>64635</td>
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<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 (List separately in addition to code for primary procedure)</td>
</tr>
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</table>

Related Information
Definition of Terms

**Diagnosis of facet-mediated pain:** This requires the establishment of pain relief following dual medial branch blocks (MBBs) performed at different sessions. Neither physical exam nor imaging has adequate diagnostic power to confidently distinguish the facet joint as the pain source.

**Facet joints (also referred to as zygapophyseal or Z-joints):** These enable the spine to bend and twist. Each vertebra has a set of facet joints at the top and bottom. Two medial branch (MB) nerves innervate the zygapophyseal joints.

**Region:** All injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.

**Session:** All injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RF ablations.

**Diagnostic Medial Branch Block Criteria**

- A successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive 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 at least an 80% reduction in pain for the duration of the local anesthetic used (eg, 3 hours longer with bupivacaine than lidocaine).
- No therapeutic intra-articular injections (ie, steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block.
- The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (eg, the patient is unable to cooperate with the procedure).
- These diagnostic blocks should be targeted to the likely pain generator. Single-level blocks lead to more precise diagnostic information, but multiple single-level blocks require several visits and additional exposure to radiation.
Description

Percutaneous radiofrequency (RF) facet denervation is used to treat neck and back pain originating in facet joints with degenerative changes. Diagnosis of facet joint pain is confirmed by response to nerve blocks. The goal of facet denervation is long-term pain relief. However, the nerves regenerate and, therefore, repeat procedures may be required.

Background

Facet joint denervation is performed under local anesthesia with fluoroscopic guidance. A needle or probe is directed to the median branch of the dorsal ganglion innervating the facet joint, where multiple thermal lesions are produced, typically by a, RF generator. A variety of terms may be used to describe RF denervation (eg, rhizotomy, rhizolysis). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

Alternative methods of denervation include pulsed RF, laser, chemodenervation and cryoablation. Pulsed RF consists of short bursts of electric current of high voltage in the RF range but without heating the tissue enough to cause coagulation. It is suggested to possibly be a safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip versus temperatures in the 60°C reached in thermal RF denervation, and tissues may cool between pulses. It is postulated that transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large myelinated fibers are not affected. With chemical denervation, injections with a diluted phenol solution, a chemical ablating agent, are injected into the facet joint nerve.

Summary of Evidence

For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes a systematic review of 17 diagnostic accuracy studies, a small randomized trial, and several large case series. Relevant outcomes are test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported the use of single or double blocks and at least 50% or 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have pain relief for
several months following RF denervation. Other large series have reported prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for diagnosis of facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive RFA, the evidence includes a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few randomized controlled trials with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint appears to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and durations of pain relief. Thus, the data indicate that, in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can improve outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation the evidence includes uncontrolled case series and randomized trials without a sham control. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Pulsed RF does not appear to be as effective as conventional RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (eg, alcohol, laser, cryodenervation) for facet joint pain or the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

McCormick et al (2014) stated that while cooled radiofrequency ablation (C-RFA) appeared to be a promising technology for joint denervation, outcomes of this technique for the treatment of lumbar facet syndrome have not been described. The authors concluded that the findings in this case series study suggested that C-RFA may improve function and to a lesser degree pain at long-term follow-up. However, a randomized, controlled trial is needed.
Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that might influence this review 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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<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT02073292</td>
<td>A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency</td>
<td>61</td>
<td>Dec 2018</td>
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<td></td>
<td>Ablation Techniques of Thoracic Facets’ Medial Branches to Manage Thoracic</td>
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<td></td>
<td>Pain</td>
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<tr>
<td>NCT03066960</td>
<td>Long Term Efficacy of Radiofrequency Neurotomy for Chronic Zygopophysial</td>
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<td>Jun 2019</td>
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<td></td>
<td>(Facet) Joint Related Neck Pain</td>
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<tr>
<td>NCT02148003</td>
<td>Effect of the Temperature Used in Thermal Radiofrequency Ablation on</td>
<td>237</td>
<td>Feb 2020</td>
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<tr>
<td></td>
<td>Outcomes of Lumbar Facets Medial Branches Denervation Procedures: A</td>
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<td></td>
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<td></td>
<td>Randomized Double-Blinded Trial</td>
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<tr>
<td>NCT02179476</td>
<td>A Multi-Site Study of the Zyga GlyDer Facet Restoration Device in Subjects</td>
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<td>May 2018</td>
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<tr>
<td></td>
<td>with Lumbar Facet Pain Syndrome (DUET)</td>
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<td></td>
<td><strong>Unpublished</strong></td>
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<td>NCT02478437</td>
<td>A Prospective Trial of Cooled Radiofrequency Ablation of Medial Branch</td>
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<td>Aug 2018</td>
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<td></td>
<td>Nerves for the Treatment of Lumbar Facet Syndrome</td>
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<td>(completed)</td>
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<td>NCT02002429</td>
<td>Medial Branch Blocks vs. Intra-articular Injections: Randomized, Controlled</td>
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<td>Study Comparing Lumbar Facet Radiofrequency Denervation Using Diagnostic</td>
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<td></td>
<td>Injections</td>
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</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Clinical Input Received through 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 4 physician specialty societies and 5 academic medical centers (6 responses) while this policy was under review in 2010. Input supported the use of radiofrequency denervation for facet joint pain. Those providing input supported use of 2 diagnostic blocks achieving a 50% reduction in pain.

Practice Guidelines and Position Statements

**Association of Neurological Surgeons and Congress of Neurological Surgeons**

The American Association of Neurological Surgeons and the Congress of Neurological Surgeons (2014) CNS updated their joint guidelines on the treatment of degenerative disease of the lumbar spine. The 2 groups provided grade B recommendations: (1) intra-articular injections of lumbar facet joints were not suggested for the treatment of facet-mediated chronic low back pain; (2) medial nerve blocks were suggested for the short-term relief of facet-mediated chronic low back pain; and (3) lumbar medial nerve ablation is suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower back pain without radiculopathy from degenerative disease of the lumbar spine.

**American Society of Interventional Pain Physicians**

Updated guidelines on interventional techniques in the management of chronic spinal pain from the American Society of Interventional Pain Physicians were published in 2013. Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumbar facet joint nerve blocks with 75% to 100% pain relief as criterion standard. For the treatment of facet joint pain, evidence was considered good for conventional radiofrequency (RF), limited for pulsed RF, fair-to-good for lumbar facet joint nerve blocks, and limited for intra-articular injections. Based on the evidence review, the Society recommended treatment with conventional RF neurotomy or therapeutic facet joint nerve blocks.
**American Society of Anesthesiologists et al**

Practice guidelines on chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine were published in 2010. The guidelines included the following recommendations:

- "Radiofrequency ablation: Conventional (eg, 80°C) or thermal (eg, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief."

- "Chemical denervation: Chemical denervation (eg, alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic noncancer pain."

**American Pain Society**

The American Pain Society (2009) practice guidelines on nonsurgical interventions for low back pain stated that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including facet denervation.11

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE; 2016) published guidance on the assessment and management of low back pain and sciatica in those over 16 years of age. NICE recommended that RF denervation can be considered for patients with chronic low back pain when “non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localized back pain.” RF denervation should only be performed “after a positive response to a diagnostic medial branch block.” NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A number of RF 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 Sienergy® (Kimberly Clark/Baylis), a water-cooled single-use probe, was cleared by the Food and Drug Administration, listing the Baylis Pain Management Probe as a predicate device. The intended use is with an RF generator to create RF lesions in nervous tissue. Food and Drug Administration product code: GXD

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/12/14</td>
<td>New PR policy replacing 7.01.116, same title. Policy coverage on non-pulsed RF now considered medically necessary for level C2-3 (is investigational at C2 in policy 7.01.116) when criteria are met including two controlled medial branch blocks (MBBs) with an indication of at least 80% relief for the duration of the anesthetic prior to performing the second MBB. Unlisted CPT code 64999 removed; there are CPT codes specific to this policy referenced within. ICD-9 and ICD-10 diagnosis and procedure codes removed; these to not facilitate adjudication, this is outpatient.</td>
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<tr>
<td>02/16/16</td>
<td>Coding update. Added 64999.</td>
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<tr>
<td>11/01/16</td>
<td>Annual Review, approved October 11, 2016. Literature search. No changes to policy statement. Policy moved into new format. Removed unlisted CPT code 64999 from</td>
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<td>Date</td>
<td>Comments</td>
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<tr>
<td>03/01/18</td>
<td>Minor update; added Documentation Requirements section. Updated Related Policy number; 6.01.23 changed to 6.01.524.</td>
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<tr>
<td>07/01/18</td>
<td>Interim Review, minor update approved June 22, 2018. Added cooled radiofrequency ablation to list of all other methods of denervation which are considered investigational. Reference 45 added.</td>
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<td>12/01/18</td>
<td>Annual Review, approved November 21, 2018. Policy updated with literature review; no references added. Policy statements unchanged.</td>
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<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; no references added. Policy statements unchanged.</td>
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**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.
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LifeWise:
- 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.

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Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.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/office/file/index.html.

Deutsche (German):

Français (French):

Kreyòl ayisyen (Creole):

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Oregon. 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 800-596-3440 (TTY: 800-842-5357).

Arabic (Arabic):
لا يوجد هذه الإشعار معلومات هامة. قد يوجد هذه الإشعار معلومات مهمة بخصوص تكلفة أو طبيعة التي تعرّف عليها فيGH. هذه الإشعار معلومات مهمة في هذا الإشعار. قد تتمحور إجراءات واتخاذ الخدمات الطبية على تكلفة وبطاقات التغطية. يحق الحصول على هذه المعلومات والمساعدة في تكلفة في 800-596-3440 (TTY: 800-842-5357) مجانًا.

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過LifeWise Health Plan of Oregon提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費為您的母語得到本訊息和幫助。請撥電話 800-596-3440 (TTY: 800-842-5357).

Italiano (Italian):