Magnetic Resonance–Guided Focused Ultrasound

Introduction

Magnetic resonance-guided high-intensity ultrasound uses two technologies: magnetic resonance imaging (MRI) and ultrasound. It is a noninvasive procedure, which means the skin is not cut. MRI uses a magnetic field, radio frequency, and a computer to create detailed images of organs, tissues, and bones. Ultrasound uses sound waves at a higher frequency than a person can hear. Ultrasound is usually used to create images of body structures to help diagnose illnesses. But in this treatment, the ultrasound beams are at a different frequency and are focused on one area. Heat is created at the point where the high frequency beams meet, and the heat ablates (destroys) unhealthy tissue. The MRI is used to both guide the location of the ultrasound beams and to monitor treatment. This policy discusses when magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary and covered by the health plan.

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

#### Service | Medical Necessity
--- | ---
Magnetic resonance-guided high-intensity ultrasound ablation | Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary to help control pain in adults with bone metastases who have failed or are not candidates for radiotherapy.

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for the treatment of medicine-refractory (such as beta-blockers or anticonvulsants) essential tremors.

#### Service | Investigational
--- | ---
Magnetic resonance-guided high-intensity ultrasound ablation | Magnetic resonance-guided high-intensity ultrasound ablation is considered investigational in all other situations including but not limited to:
- Treatment of uterine fibroids
- Treatment of other tumors (eg, brain cancer, prostate cancer, breast cancer, desmoid tumors) (see Related Policy 8.01.61 Focal Treatments for Prostate Cancer)

#### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:
- Documentation that the requested service is for pain control that has failed for patient with bone metastases, or not a candidate for radiotherapy

**OR**
- Documentation that patient has essential tremors not responding to medication (such as beta-blockers or anticonvulsants)

#### Coding
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
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<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed</td>
</tr>
<tr>
<td>0071T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of less than 200 cc of tissue</td>
</tr>
<tr>
<td>0072T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue</td>
</tr>
<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system</td>
</tr>
<tr>
<td>55899</td>
<td>Unlisted procedure, male genital system</td>
</tr>
<tr>
<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical)</td>
</tr>
<tr>
<td>76999</td>
<td>Unlisted ultrasound procedure (eg diagnostic, interventional)</td>
</tr>
</tbody>
</table>

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The procedure may be performed in a magnetic resonance imaging suite with an open magnetic resonance scanner, which might not be available at many institutions. The procedure is performed in an outpatient setting, with the patient under conscious sedation.

**Related Information**

**Consideration of Age**

Magnetic resonance–guided focused ultrasound (MRgFUS) is considered medically necessary for bone metastases in adult patients, age 18 and older. This is based on the randomized controlled trial that studied the use of MRgFUS in patients with bone metastases.

**Evidence Review**
Description

An integrated system providing magnetic resonance–guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids and pain palliation of bone metastases. MRgFUS is also being investigated as a treatment of other benign and malignant tumors as well as essential tremors.

Background

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Treatment

Several approaches currently available to treat symptomatic uterine fibroids include: hysterectomy, abdominal myomectomy, laparoscopic and hysteroscopic myomectomy, hormone therapy, uterine artery embolization, and watchful waiting. Hysterectomy and various myomectomy procedures are considered the criterion standard treatment.

Metastatic Bone Disease

Metastatic bone disease is one of the most common causes of cancer pain.

Treatment

Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who do not respond to these treatments, standard care is external-beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients. One option, radiofrequency ablation, is addressed in a Related Policy.
**Essential Tremors**

Essential tremor (ET) is the most common movement disorder, with an estimated prevalence of 5% worldwide. ET most often affects the hands and arms, may affect the head and voice, and rarely includes the face, legs, and trunk. ET is heterogeneous among patients, varying in frequency, amplitude, causes of exacerbation, and association with other neurologic deficits.

**Treatment**

The neuropathology of ET is uncertain, with some evidence suggesting that ET is localized in the brainstem and cerebellum. If patients with ET experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (β-blockers or anticonvulsants). For medicine-refractory patients, surgery (deep brain stimulation or thalamotomy) may be offered, though high rates of adverse events have been observed.

**Magnetic Resonance‒Guided Focused Ultrasound**

Magnetic resonance-guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines two technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (ie, to 65°C-85°C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging, a temperature “map”, to confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The U.S. Food and Drug Administration (FDA) approved the ExAblate MRgFUS system (InSightec) for two indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specially designed to be compatible with magnetic resonance magnets and is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer. For
treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

MRgFUS is also being investigated for treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma. (For prostate cancer see Related Policy 8.01.61 Focal Treatments for Prostate Cancer.)

Summary of Evidence

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes two small RCTs, nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (N=20) has reported some health outcomes, but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in quality of life outcomes between active and sham treatment groups, but it did find lower fibroid volumes after active treatment. This trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond one year. The second RCT (N=49) is ongoing; preliminary results at six weeks posttreatment, comparing MRgFUS with uterine artery embolization have shown that the two groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with metastatic bone cancer who failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial and several case series. The relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvements after MRgFUS in a composite outcome comprised of reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of patients in the treatment group experienced adverse events, but most events were transient and not severe. The case series reported reductions in pain following MRgFUS treatment, consistent with the RCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid tumors, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes small case series. The relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes 2 systematic reviews that identified an RCT and several observational studies. The relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The assessment did not pool study results but concluded that overall, MRgFUS decreased tremor severity and improved quality of life. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after 3 months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the 2-year follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some 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>
</tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
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<tr>
<td>NCT00981578*</td>
<td>A Feasibility Study to Evaluate the Safety and Initial Effectiveness of ExAblate MR Guided Focused Ultrasound Surgery in the Treatment of Pain Resulting from Metastatic Bone Tumors with the ExAblate 2100 Conformal Bone System</td>
<td>50</td>
<td>Jun 2019 (ongoing)</td>
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<tr>
<td>NCT01833806*</td>
<td>A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain</td>
<td>70</td>
<td>Oct 2020</td>
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<tr>
<td>NCT01473485*</td>
<td>A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors</td>
<td>10</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<td>NCT00147056a</td>
<td>A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors</td>
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<td>Dec 2022</td>
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<tr>
<td>NCT02252380a</td>
<td>A Feasibility Clinical Trial of the Magnetic Resonance Guided Focused Ultrasound (MRgFUS) for the Management of Treatment-Refractory Movement Disorders</td>
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<td>Dec 2020</td>
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<tr>
<td>NCT02260752</td>
<td>Comparing Options for Management: Patient Centered Results for Uterine Fibroids</td>
<td>10,000</td>
<td>Apr 2020</td>
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<tr>
<td>NCT02968784a</td>
<td>Focal ExAblate MR Guided Focused Ultrasound Treatment for Management of Organ-Confined Intermediate Risk Prostate Cancer: Evaluation of Safety and Effectiveness</td>
<td>68</td>
<td>Jun 2020</td>
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<tr>
<td>NCT01657942a</td>
<td>Focal MR Guided Focused Ultrasound Treatment of Localized Low and Intermediate Risk Prostate Lesions</td>
<td>100</td>
<td>Oct 2020</td>
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<tr>
<td>NCT02794558a</td>
<td>A Clinical Study to Evaluate the Safety and Effectiveness of MR Guided Focused Ultrasound Surgery in the Treatment of Early Breast Carcinomas</td>
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<td>Apr 2021</td>
</tr>
<tr>
<td>NCT01285960a</td>
<td>A Clinical Study to Evaluate Safety of the ExAblate Model 2100 Type 1.1 System in the Treatment of Symptomatic Uterine Fibroids</td>
<td>106</td>
<td>Apr 2016 (completed)</td>
</tr>
<tr>
<td>NCT01620359a</td>
<td>Study of ExAblate Focused Ultrasound Ablation of Breast Cancer under MR Guidance and MRI Evaluation of Ablation</td>
<td>14</td>
<td>Jul 2016 (completed)</td>
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<tr>
<td>NCT01834937a</td>
<td>A Post Approval Registry: ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain</td>
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<td>Apr 2017 (completed)</td>
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<tr>
<td>NCT01091883a</td>
<td>Phase IIIA Study Comparing the Safety and Effectiveness of MR Guided Focused Ultrasound and External Beam Radiation for Treatment of Metastatic Bone Tumors and Multiple Myeloma</td>
<td>60</td>
<td>Mar 2018 (unknown)</td>
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<tr>
<td>NCT01226576a</td>
<td>Focal MR Guided Focused Ultrasound Treatment of Localized Low-Intermediate Risk Prostate Cancer: Feasibility Study</td>
<td>8</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
Practice Guidelines and Position Statements

American Society for Radiation Oncology

The American Society for Radiation Oncology (2017) published guidelines on palliative radiotherapy for bone metastases, which stated that external-beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. The guidelines do not mention magnetic resonance-guided focused ultrasound. If patients experience persistent or recurrent pain more than one month after initial treatment, the guidelines recommended retreatment with external-beam radiotherapy. As for advanced radiotherapy such as stereotactic body radiotherapy for retreatment of recurrent pain in spine bone lesions, these “may be feasible, effective, and safe, but the panel recommends that this approach should be limited to clinical trial participation or on a registry given limited data supporting routine use.”

National Comprehensive Cancer Network


Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In October 2004, the ExAblate® 2000 System (InSightec) was approved by FDA through the premarket approval process for “ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.” Treatment is indicated for women with a uterine gestational size of fewer than 24 weeks who have completed childbearing.

In October 2012, the ExAblate® System, Model 2000/2100/2100 VI, was approved by FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy. The device was evaluated through an
expedited review process. FDA required a postapproval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

In July 2016, FDA approved the use of the ExAblate® Neuro System for the treatment of essential tremors in patients who have not responded to medication ($\beta$-blockers or anticonvulsant drugs) through the premarket approval process.

FDA product codes: NRZ, POH.

References


**History**

<table>
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<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
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<tr>
<td>09/14/04</td>
<td>Add to OB/GYN Section - New Policy</td>
</tr>
<tr>
<td>08/09/05</td>
<td>Replace Policy - Policy updated with June 2005 TEC Assessment; references added; policy statement unchanged.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
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<tr>
<td>06/23/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<tr>
<td>09/12/06</td>
<td>Replace Policy - Policy updated with literature review; title expanded to include, “and Other Tumors” reflecting indications other than uterine fibroids; “MRI-guided high intensity ultrasound ablation of other tumors...is considered investigational” added to policy statement; references added.</td>
</tr>
<tr>
<td>03/13/07</td>
<td>Replace Policy - Policy moved from OB/GYN to Surgery section and assigned a new number (previously BC.4.01.20).</td>
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<tr>
<td>04/08/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>03/10/09</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. Title updated to remove “High-intensity” and “ablation of”. References added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Replace Policy - Policy updated with literature search. Policy statement updated to include palliative treatment of bone metastases added to the investigational statement regarding treatment of conditions other than uterine fibroids. References added.</td>
</tr>
<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature review through December 2010. Reference numbers 10, 21, 22 and 25 added; other references reordered or removed. No change to policy statements. ICD-10 codes added to policy.</td>
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<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature review through December 2011. Reference numbers 7, 8 and 10 added; other references reordered or removed. No change to policy statements.</td>
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<tr>
<td>09/25/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<tr>
<td>11/20/12</td>
<td>Code update: CPT codes 19499, 55899 and 58999 added to the policy to support policy information and tumors.</td>
</tr>
<tr>
<td>02/15/13</td>
<td>Update Related Policies, add 7.01.548.</td>
</tr>
<tr>
<td>04/08/13</td>
<td>Replace policy. Policy updated with literature review. Policy changed to single investigational statement; no change to intent of policy. Policy title changed to MRI-Guided Focused Ultrasound (MRgFUS). References 10 and 17 added; other references renumbered or removed. CPT code 58999 corrected; it previously appeared as 55899, which is not the correct code.</td>
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<tr>
<td>05/05/14</td>
<td>Annual Review. Policy updated with literature review through January 6, 2014; references 2, 6, and 14 added; other references renumbered or removed. Coding update: add CPT code 55899 and remove 55999 (wrong code); update descriptor for 58999.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Annual Review. Policy updated with literature review through January 6, 2015. Statement added that MRgFUS may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer. (Previously considered Investigational). References 12, 21-22 added; others renumbered or removed. Policy</td>
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<td>Comments</td>
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<td>08/25/15</td>
<td>Update Related Policies. Remove 7.01.548 as it was archived and add 8.01.61.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy updated with literature review through December 15, 2015; references 2 and 23 added. Policy coverage unchanged. Global change to policy to remove “imaging” (e.g., title, policy statement) to standardize terminology to magnetic resonance-guided focused ultrasound (MRgFUS). Coding update; CPT codes 47999 and 55899 removed from policy; these are moving to review by AIM.</td>
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<td>06/24/16</td>
<td>Minor update. Removed codes 77299 and 77499 from information in the coding section that discusses radiation oncology unlisted codes. Correction to 05/01/16 History note: AIM is not reviewing 47999 and 55899.</td>
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<td>09/30/16</td>
<td>Coding update. Added CPT code 55899.</td>
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<tr>
<td>11/08/16</td>
<td>Minor update. Language added to Rationale section to indicate that MRgFUS is considered medically necessary only in those age 18 and older based on randomized controlled trials.</td>
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<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 22, 2017. Policy moved into new format. Reference to policy 8.01.61 added for prostate cancer diagnosis. No changes to policy statement.</td>
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<tr>
<td>10/01/18</td>
<td>Annual Review, approved September 11, 2018. Policy updated with literature review through May 2018; references 23-26 and 28 added. A policy statement added that MRgFUS ablation may be considered medically necessary for the treatment of medicine-refractory essential tremors. Added CPT codes 0398T, 53899, 55899, and 76999.</td>
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<tr>
<td>05/10/19</td>
<td>Coding update. Added CPT code 58999 to policy (inadvertently removed). Removed verbiage in the coding section that is no longer applicable.</td>
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</table>

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To file 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 filling a grievance, the Civil Rights Coordinator is available to help you.

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

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

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Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaar malabing nga adda ket naglaon iti napateg nga impomarsion maiagangep iti aplikayosyon nga要闻 coverage babaen iti Premera Blue Cross. Daytoy ket malabing dagiti importante a pelsa iti daytoy a pakdaar. Malabing nga adda rumbeng nga aramidenyo nga adda sabkyab dagiti partikular a naalitud nga adda taaw napo napagatayondyo ti coverage ti salun-atyo nga tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tulong iti bukodyo a pagasasao nga awan ti bayadano. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Português (Portuguese):
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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.