Magnetic Resonance–Guided Focused Ultrasound

Introduction

Magnetic resonance-guided high-intensity ultrasound uses two technologies: magnetic resonance imaging (MRI) and ultrasound to treat part of your body. 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

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic resonance-guided high-intensity ultrasound ablation</td>
<td>Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary to help control pain in adult patients with metastatic bone cancer who have failed or are not candidates for radiotherapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| 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, desmoid, and breast cancer) (see Related Policy 8.01.61 Focal Treatments for Prostate Cancer) |

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td></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>
</tbody>
</table>

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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.

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. 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. Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who fail the above treatments, the standard care is to use 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.
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 approximately 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 that provides a temperature “map” that can further 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) has approved the ExAblate® MRgFUS system (InSightec Inc., Haifa, Israel) 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 MR 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 a 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 bone metastases. 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 magnetic resonance-guided focused ultrasound (MRgFUS), the evidence includes two small randomized controlled trials (RCT), nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (N=20 patients) 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. The pivotal Food and Drug Administration trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (N=49) is ongoing; it has provided preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization (UAE). The 2 groups were comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the UAE 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 (UAE) than with MRgFUS. There are insufficient data on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with painful 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. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvement 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 of these were not severe and were transient. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (eg, brain cancer, prostate cancer, breast cancer, desmoid), the evidence includes small case series. 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.

**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>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01965002</td>
<td>A Feasibility Study to Evaluate the Safety and Effectiveness of ExAblate Magnetic Resonance Imaging Guided High-Intensity Focused Ultrasound Treatment of Soft Tissue Tumors of the Extremities</td>
<td>30</td>
<td>Feb 2017 (ongoing)</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 2017</td>
</tr>
<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 2017</td>
</tr>
<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>Oct 2017</td>
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<tr>
<td>NCT00147056</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 2017</td>
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<tr>
<td>NCT01226576</td>
<td>Focal MR Guided Focused Ultrasound Treatment of Localized Low-Intermediate Risk Prostate Cancer: Feasibility Study</td>
<td>8</td>
<td>Dec 2017</td>
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<tr>
<td>NCT00995878</td>
<td>The FIRSTT Study: Comparing Focused Ultrasound and Uterine Artery Embolization for Uterine Fibroids</td>
<td>180</td>
<td>Dec 2017</td>
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<tr>
<td>NCT01091883</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</td>
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<tr>
<td>NCT02968784</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>69</td>
<td>Jun 2019</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>Sep 2019</td>
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<tr>
<td>NCT01657942</td>
<td>Focal MR Guided Focused Ultrasound Treatment of Localized Low and Intermediate Risk Prostate Lesions</td>
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<td>Oct 2019</td>
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<tr>
<td>NCT02794558</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>
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**Unpublished**
<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01285960^a</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>
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<tr>
<td>NCT01620359^a</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>NCT01834937^a</td>
<td>A Post Approval Registry: ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain</td>
<td>17</td>
<td>Apr 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

*Society of Obstetricians and Gynaecologists of Canada*

In 2015, the Society of Obstetricians and Gynaecologists of Canada published clinical practice guidelines on the management of uterine fibroids in women with otherwise unexplained infertility. The guideline found no studies comparing MRgFUS with myomectomy or in women with fibroids who have infertility as their primary complaint, and thus additional data are needed before the treatment is offered to this patient population.

*American Society for Radiation Oncology (ASTRO)*

In 2011, the ASTRO 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 MRgFUS and did not offer specific recommendations for patients who fail or are not candidates for radiotherapy.

*National Comprehensive Cancer Network*

Guidelines from the National Comprehensive Cancer Network on breast cancer (v.2.2017), brain cancer (v.1.2016), and prostate cancer (v.2.2017) do not mention MRgFUS as a treatment option.
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 October 2004, the ExAblate® 2000 System (InSightec, Haifa, Israel) was FDA approved 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 less 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 adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

FDA product code: NRZ.

References


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<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>06/23/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<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>
</tr>
<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.</td>
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<tr>
<td>Date</td>
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<tr>
<td>04/25/12</td>
<td>Reference numbers 10, 21, 22 and 25 added; other references reordered or removed. No change to policy statements. ICD-10 codes added to policy. 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>
</tr>
<tr>
<td>09/25/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<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>
</tr>
<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 statement changed as noted.</td>
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<tr>
<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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<tr>
<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 4/12/16 History note: AIM is not reviewing 47999 and 55899.</td>
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<tr>
<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</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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</tbody>
</table>

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  • Qualified interpreters
  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

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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 S909, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

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Deutsche (German):

Hmoo (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormacion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasjon maiyanggepp iti aplikasyonyo wenn coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramiendiy nga adda sakkay dagiti partikular a naituding nga adda awa napatagay nga coverage a salan-ayyo wenn tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasjon ken tulong iti bukdoyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

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中文 (Chinese):
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Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay nagagaling sa mga paksa sa pamamagitan ng Premera Blue Cross. Maaaring maaaring maaaring ma panahon upang mapanatili ang iyong pag-unawa o tulong na maaaring maarsa o inalagang maaaring maarsa at i iyon o ang mga hakbang na kailangan mo para sa iyong pag-unawa. 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสําคัญเกี่ยวกับการสมัครหรือขอบเขตประกันของคุณผ่าน Premera Blue Cross และมีข้อมูลที่คุณควรทราบในการเก็บรักษาข้อมูลเหล่านี้และเวลาที่คุณตกลงที่จะรับผลกระทบของคุณซึ่งมีความสําคัญที่มีอยู่ในการใช้จ่าย โปรดติดต่อกับ Premera Blue Cross ที่ 800-722-1471 (TTY: 800-842-5357) ทุกทีที่คุณต้องการ.

Română (Romanian):

Український (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 діяти в неприємній ситуації в конкретній кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):