Ultrasound Accelerated Fracture Healing Device

**Introduction**

Ultrasound is a sound wave that humans can’t hear. Ultrasound has been tried to help broken bones heal. It was believed that ultrasound stimulates growth of new bone by activating the growth of new bone cells. The latest large studies, however, show there isn’t enough evidence to conclude that ultrasound waves help bones heal. Using ultrasound on bones that were cut during surgery or broken is not medically necessary.

**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>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-intensity pulsed ultrasound treatment</td>
<td>Low-intensity pulsed ultrasound is considered not medically necessary for the treatment of the following:</td>
</tr>
</tbody>
</table>
### Treatment Medical Necessity

- Fresh fractures (surgically managed or nonsurgically managed)
- Fracture nonunion and delayed union fractures
- Stress fractures, osteotomy and distraction osteogenesis

**Note:** See *Definition of Terms* for more information.

### Treatment Investigational

- **Low-intensity ultrasound treatment**
  - *All other applications of low-intensity ultrasound treatment not listed in this policy are investigational, including, but not limited to, treatment of congenital pseudarthroses, open fractures, fresh surgically treated closed fractures, stress fractures, arthrodesis or failed arthrodesis.*

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>20979</td>
<td><strong>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</strong></td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>E0760</td>
<td><strong>Osteogenesis stimulator, low intensity ultrasound, non-invasive</strong></td>
</tr>
</tbody>
</table>

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### Related Information

**Definition of Terms**

**Fresh (acute) fracture:** There is no standard definition of a “fresh” fracture. A fracture is most commonly defined as fresh for 7 days after the fracture occurs (Heckman et al, 1994; Kristiansen
et al, 1997; Emami et al, 1999), but there is definitional variability. For example, 1 study defined fresh as less than 5 days after fracture (Lubbert et al, 2008), while another defined fresh as up to 10 days postfracture (Mayr et al. [Does low intensity, pulsed ultrasound speed healing of scaphoid fractures?] [German]. Handchir Mikrochir Plast Chir. Mar 2000;32(2):115-122). Most fresh closed fractures heal without complications using standard fracture care (ie, closed reduction and cast or splint immobilization).

**Delayed union:** This is defined as a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

**Jones fracture:** This is a transverse stress fracture of the base of the little toe or fifth metatarsal of the foot.

**Nonunion:** There is no consensus on the definition of nonunion. One definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months postfracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing; Buza & Einhorn, 2016).

The definition of nonunion in the U.S. Food and Drug Administration labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without providing guidance regarding the timeframe of observation. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see **Related Policies**):

- At least 3 months have passed since the date of the fracture

**AND**

- Serial radiographs have confirmed that no progressive signs of healing have occurred

**AND**

- The fracture gap is 1 cm or less

**AND**

- The patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing
Note: Electrical bone growth stimulation for healing is covered in a separate medical policy (see Related Policies).

Benefit Application

The transducer used for ultrasound treatment is categorized as durable medical equipment.

Evidence Review

Description

Low-intensity pulsed ultrasound (LIPUS) has been investigated as a technique to accelerate healing of fresh fractures, surgically treated closed fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis. LIPUS is administered using a transducer applied to the skin surface overlying the fracture site.

Background

Bone Fractures

An estimated 7.9 million fractures occur annually in the United States. Most bone fractures heal spontaneously over the course of several months following standard fracture care (closed reduction if necessary, followed by immobilization with casting or splinting). However, approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. Factors contributing to a nonunion include which bone is fractured, fracture site, degree of bone loss, time since injury, extent of soft tissue injury, and patient factors (eg, smoking, diabetes, systemic disease).

Fracture Nonunion

There is no standard definition of a fracture nonunion. The Food and Drug Administration has defined nonunion as when “a minimum of 9 months has elapsed since injury and the fracture
site shows no visibly progressive signs of healing for a minimum of 3 months.” Other definitions cite 3 to 6 months of time from the original injury, or simply when serial radiographs fail to show any further healing. These definitions do not reflect the underlying conditions in fractures that affect healing, such as the degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock.

**Delayed Union**

Delayed union is generally considered a failure to heal between 3 and 9 months post fracture, after which the fracture site would be considered a nonunion. The delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) It is important to include both radiographic and clinical criteria to determine fracture healing status. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

**Treatment**

Low-intensity pulsed ultrasound (LIPUS) has been proposed to accelerate healing of fractures. LIPUS is believed to alter the molecular and cellular mechanisms involved in each stage of the healing process (inflammation, soft callus formation, hard callus formation, and bone remodeling). The mechanism of action at the cellular level is not precisely known, but it is theorized that LIPUS may stimulate the production or the activities of the following compounds that contribute to the bone healing process: cyclooxygenase-2, collagenase, integrin proteins, calcium, chondroblasts, mesenchymal cells, fibroblasts, and osteoblasts.

LIPUS treatment is self-administered, once daily for 20 minutes, until the fracture has healed, usually for 5 months.

**Summary of Evidence**

For individuals who have fresh fractures (surgically or nonsurgically managed) who receive LIPUS as an adjunct to routine care, the evidence includes randomized controlled trials (RCTs) and several meta-analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The evidence base has recently evolved with the publication of a large RCT
and meta-analysis significantly shifting the weight of the evidence. Conclusions based on several earlier small RCTs, rated at high risk of bias, showed a potential benefit of LIPUS; however, the large RCT published in 2016, rated at low risk of bias, showed no benefit. A 2017 meta-analysis including only trials with low risk of bias found no difference in days to full weight bearing, pain reduction, or days to radiographic healing. Similarly, the overall results of the meta-analysis found no significant difference in return to work, subsequent operations, or adverse effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fracture nonunion or delayed union fracture who receive LIPUS as an adjunct to routine care including surgery if appropriate, the evidence includes only lower quality studies consisting of a small systematic review in scaphoid nonunions, a meta-analysis of nonunion in various locations, 3 low-quality RCTs, and observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Reported outcomes in this subgroup of fractures do not include functional outcomes. A wide range of healing rates have been reported across the observational studies with a lack of comparison with routine surgical care, limiting any meaningful interpretation of these results. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in fracture nonunion or delayed union. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have stress fractures, osteotomy sites, or distraction osteogenesis who receive LIPUS as an adjunct to routine care, the evidence includes only lower quality studies consisting of small RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results do not generally include functional outcomes and results across various outcomes, primarily time to radiographic healing, are inconsistent. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in stress fractures, osteotomy sites, or distraction osteogenesis. 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 review is 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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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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</table>
| NCT02383160^
*a* | A Randomized Controlled Trial Comparing Low-Intensity, Pulsed Ultrasound to Placebo in the Treatment of Operatively Managed Scaphoid Non-unions | 154                | Dec 2018        |
| NCT03382483^
*a* | Observational, Non-Interventional Use of LIPUS to Mitigate Fracture Non-Union in Patients at Risk (BONES) | 3000               | Dec 2019        |

NCT: national clinical trial
*a* denotes an industry-sponsored trial

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.

**2012 Input**

In response to requests, input was received from 4 academic medical centers while this policy was under review in 2012. Input supported the use of low-intensity pulsed ultrasound for delayed unions and nonunions of bones excluding the skull and vertebra, and in fresh closed fractures at high risk for delayed fracture healing or nonunion. Commentators agreed that other applications of low-intensity pulsed ultrasound treatment are investigational, including, but not limited to, treatment of congenital pseudoarthroses, open fractures, stress fractures, arthrodesis, or failed arthrodesis. Additional risk factors were noted, including use of anticoagulants, immunosuppressive drugs or chemotherapy, infection at the fracture site, severe anemia, obesity, and fracture locations more prone to nonunion such as tibial and distal radial fractures.
2011 Input

In response to requests, input was received from 2 physician specialty societies and 1 academic medical center while this policy was under review in 2011. Input supported the use of ultrasound for nonunion and for fresh closed fractures at high risk for delayed fracture healing or nonunion as described in the policy. One reviewer supported including chemotherapy, immunosuppressive agents, history of infection, Charcot neuroarthropathy, and fractures of the tibial shaft or clavicle as additional risk factors, and another supported including fractures of the talus and sesamoids as additional risk factors.

2008 Input

In response to requests, input was received from 1 physician specialty society while this policy was under review in 2008. Physician input obtained through the American Academy of Orthopaedic Surgeons supported the positions on the criteria for medical necessity and the conditions considered investigational (eg, delayed union and open/unstable grade II or III fractures).

Practice Guidelines and Position Statements

British Medical Journal Rapid Recommendation

The British Medical Journal (BMJ) Rapid Recommendations are a series of articles, produced by BMJ in collaboration with the MAGIC group, to provide clinicians with practice guidelines. In 2017, BMJ Rapid Recommendations published guidelines on the use of low-intensity pulsed ultrasound (LIPUS) for bone healing. The guidelines were based on a 2017 systematic review, which included 26 randomized controlled trials evaluating patients with fresh fractures not surgically managed, fresh fractures surgically managed, nonunion fractures, osteotomy, and distraction osteogenesis. The committee concluded that there is “moderate to high certainty evidence to support a strong recommendation against the use of LIPUS for bone healing.” Furthermore, the guideline expert panel discussed whether the results of higher quality studies in patients with fresh fractures reported in Schandelmaier et al (2017) would apply to other types of fractures including nonunions and osteotomies. “After extensive deliberations, the panel found no compelling anatomical or physiological reasons why LIPUS would probably be beneficial in these other patient populations.”
**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE) published guidance (2010) on LIPUS to promote fracture healing.\(^{31}\) NICE concluded that this procedure “can reduce fracture healing” and is particularly beneficial for “delayed healing and fracture non-union.”

NICE published guidance (2013) on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing.\(^{32}\) NICE concluded that use of the Exogen bone healing system to treat long-bone fractures with nonunion is supported by “clinical evidence” and “cost savings ... through avoiding surgery.” For long-bone fractures with delayed healing, defined as no radiologic evidence of healing after 3 months, there was “some radiologic evidence of improved healing.” However, due to “substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture” and need for surgery, “cost consequences” were uncertain. The next review of this guidance is in 2018.

**American Academy of Orthopaedic Surgeons**

The American Academy of Orthopaedic Surgeons (2009) published guidelines on the treatment of distal radius fractures.\(^{33}\) The Academy issued a limited recommendation for the use of LIPUS for adjuvant treatment of distal radius fractures. While evidence from 1 study demonstrated an increased rate of healing (measured by the absence of pain and radiographic union), the additional cost of LIPUS, resulted in a “limited” recommendation.

**Medicare National Coverage**

Effective 2001, ultrasonic osteogenic stimulators were covered as medically reasonable and necessary for the treatment of nonunion fractures.\(^{34}\) Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not be used concurrently with other noninvasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions are not covered.
Regulatory Status

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS®; renamed Exogen 2000® and since 2006, Exogen 4000+; Bioventus) was approved by the U.S. Food and Drug Administration through the premarket approval process for treatment of fresh, closed, posteriorly displaced distal radius (Colles) fractures, and fresh, closed, or grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra. Food and Drug Administration product code: LPQ.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Durable Medical Equipment Section - New Policy</td>
</tr>
<tr>
<td>08/17/99</td>
<td>Replace policy - Updated; new indications.</td>
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<tr>
<td>11/05/99</td>
<td>Replace policy - New CPT code; policy unchanged.</td>
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<tr>
<td>09/21/00</td>
<td>Replace policy - New indication for treatment of fracture nonunions.</td>
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<tr>
<td>01/18/01</td>
<td>Replace Policy - Corrections – Policy Guidelines, under fracture location, the name should say “Jones” fracture, not Jone’s; under Nonunions,” fourth bullet should say the patient can be adequately “immobilized,” not “mobilized.”</td>
</tr>
<tr>
<td>04/15/03</td>
<td>Replace policy - Policy reviewed with 2002 updates and new references added. Policy Statement unchanged.</td>
</tr>
<tr>
<td>06/08/04</td>
<td>Replace policy - Policy updated with literature review; policy statement unchanged. No further literature reviewed scheduled.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace policy - Policy updated with literature search; policy statement revised to explicitly state that ultrasound treatment of open fracture is investigational. Information on Medicare policy added.</td>
</tr>
<tr>
<td>08/09/05</td>
<td>Replace policy - Policy updated with literature review for November 2004 through May 2005 and new Medicare coverage decision; policy statement unchanged.</td>
</tr>
<tr>
<td>05/26/06</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 search; no change in policy statement; policy changed from AR to BC. Policy guideline regarding “non-weight bearing removed.</td>
</tr>
<tr>
<td>03/11/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Policy guidelines updated; references added.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>11/10/09</td>
<td>Replace policy - Policy updated with literature search; rationale section extensively revised. Use in stress fractures added as investigational in the policy statement. References added.</td>
</tr>
<tr>
<td>03/08/11</td>
<td>Replace policy - Policy updated with literature search, clinical input reviewed, references reordered. Policy statements modified by moving information from policy guidelines to policy statements about risk factors for nonunion.</td>
</tr>
<tr>
<td>11/08/11</td>
<td>Replace policy – Policy updated with literature search through July 2011; references 12 and 13 added; treatment of delayed unions considered medically necessary. Within the Policy Guidelines, definitions for fresh fracture, nonunion and delayed union have been added or refined.</td>
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<tr>
<td>07/25/12</td>
<td>Update Related Policy – 7.01.529 Title changed to: Electrical Bone Growth Stimulation of the Appendicular Skeleton.</td>
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<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes now have a 10/01/2014 effective date.</td>
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<tr>
<td>11/27/12</td>
<td>Replace policy. Policy revised with arthrodesis added to investigational statement. Policy guidelines revised with definition of delayed unions vs. nonunion. Rationale revised based on literature review through July 2012. References 1, 5, 15 added; other references renumbered or removed. Policy statement had new investigational condition added.</td>
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<tr>
<td>12/19/12</td>
<td>Update Related Policies; change policy title for 7.01.85.</td>
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<tr>
<td>02/13/13</td>
<td>Replace policy. Rationale section updated based on input from 4 academic medical centers and a literature review through July 2012. Practice guidelines updated with addition of American Academy of Orthopaedic Surgeons (AAOS) recommendation. Reference 17 added; others renumbered. Policy statement unchanged.</td>
</tr>
<tr>
<td>03/10/14</td>
<td>Replace policy. Added non-union of previous surgically-treated fractures to medical necessity policy statement and added fresh surgically-treated closed fractures to investigational policy statement. Added Jones Fracture to definition of terms. Policy updated with literature review through November 18, 2013, references 12, 16, and 18 added; others renumbered/removed. Policy statements changed as noted. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in adjudication of the policy.</td>
</tr>
<tr>
<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through November 25, 2014; references 11 and 20 added; reference 5 corrected; policy statements unchanged. Remove ICD-9 and ICD-10 codes removed; these are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>09/01/17</td>
<td>Annual Review, approved August 15, 2017. Policy will become effective December 21, 2017. Policy updated with literature review through January 25, 2017; references 3-4, 7, 17, and 25-26 were added. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 3, 2018. Policy updated with literature review through January 2018; references 5-6 and 16-17 added. Policy statements are unchanged.</td>
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</table>

**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). ©2018 Premera All Rights Reserved.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Guarani: (Amharic):

ูወር ከለበባ ከርከር ሁብ በየሚለበባ ከሚኖርበት ሀገር ለPremera Blue Cross ከተቋር ከረከር ከሚያረጋግጦ ከሚያሰረስ የሚስማት የሚያስማት ያስተካከል የሚሆን ከማት ይቀረበል። ለPremera Blue Cross ከተቋር ከረከር ከሚያረጋግጦ ከሚያሰረስ ያስተካከል የሚሆን ከማት ይቀረበል። （Arabic）:

ويحوي هذا الإشعار المعلومات هامة، قد يحوي هذا الإشعار معلومات مهمة بخصوص طبلك أو طبيبك، قد تكون هناك تاريع مهمة، Premera Blue Cross. يحوي هذا الإشعار معلومات هامة، قد يحوي هذا الإشعار معلومات مهمة بخصوص طبلك أو طبيبك، قد تكون هناك تاريع مهمة، Premera Blue Cross.

Chinese (Cushite):

Oromoo (Cushite):


Français (French):


Kreyòl ayisyen (Creole):


Deutsche (German):


Hmoob (Hmong):

Tsb taww tsajh xo no muaj cov ntsiab lus tseem ceeb. Taem tsaw tsaaw tshaj xo no muaj cov ntsiab lus tseem ceeb xog koj daim ntwaw thov kev pab los yoy koj kvok kev pab cuam los ntsaw Premera Blue Cross. Tje taem muaj cov hunb tseem ceeb cuam los rau hauv daim ntwaw no. Tje taem koj koy juav tau uu qee yam pus koj uut tis pub dhuau cov cajy nyoy uu teev tseg rau hauv daim ntwaw no mas koj koy juav tau baiss kev pab cuam kho moh los yoy kev pab tem tej niq kho moh ntwaw. Koj muaj cai kom lawv muab cov ntsiab lus no uus tau muab sau uu koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

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Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impormasion maipeengge iiti aplikasyon ku ntong coverage banaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelsa iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramideny nga addang sakbay dagiti partikular a naituding nga adda aldaw tapno mapagtalaineyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tungtu iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
