Introduction

Osteoporosis or cancer in the bones can cause the vertebrae (the bone in the spine) to weaken. They may become so weak that they collapse. This is known as a compression fracture. The collapse usually happens at the front side of the vertebra, creating a vertebra that looks a bit like a wedge. Percutaneous vertebroplasty is a non-surgical procedure to stabilize a spinal compression fracture. A hollow needle is inserted through the skin and into the damaged bone. Bone cement is then injected into the bone. This policy describes when this procedure may be considered medically necessary. Percutaneous sacroplasty is a similar procedure, but the bone cement is placed in the sacrum. The sacrum is the bone at the bottom of the spine and forms the back of the pelvis. Using this technique for the sacrum is investigational. There are not yet enough medical studies to show whether percutaneous sacroplasty is effective.

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.
Percutaneous vertebroplasty may be considered medically necessary for the treatment of:

- Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, analgesics, physical therapy, and rest) for at least 6 weeks

OR

- Symptomatic osteoporotic vertebral fractures that happened less than 6 weeks ago and have led to hospitalization or persist at a level that prevents ambulation

OR

- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies

Note: There is considerable variability in pain scores based on the literature review. If the patient is in intractable pain that cannot be managed safely with conservative treatment for at least 1 week, then percutaneous vertebroplasty surgery may be considered sooner than 6 weeks.

Percutaneous vertebroplasty is considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma that have not led to hospitalization or prevent ambulation.

Percutaneous sacroplasty is considered investigational for all indications, including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies or multiple myeloma.

Documentation Requirements

Clinical documentation of one of the following conditions:

- Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, analgesics, physical therapy, and rest) for at least 6 weeks

OR
Documentation Requirements

- Symptomatic osteoporotic vertebral fractures that happened less than 6 weeks ago and have led to hospitalization or persist at a level that prevents walking

OR

- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td>0200T</td>
<td>Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles</td>
</tr>
<tr>
<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles</td>
</tr>
<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
</tr>
<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
</tr>
<tr>
<td>22512</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22513</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic</td>
</tr>
<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar</td>
</tr>
<tr>
<td>22515</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>
Related Information

Benefit Application

Percutaneous vertebroplasty/sacroplasty may be performed by interventional radiologists or orthopedic surgeons.

Evidence Review

Description

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a weakened vertebral body. The technique has been investigated to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies), as a treatment for sacral insufficiency fractures, and as a technique to limit blood loss related to surgery.

Background

Osteoporotic Fracture

Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to one-half of women and approximately one-quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with the ability to ambulate and is not responsive to usual medical management. Also, a minority of patients
will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

**Treatment**

Chronic symptoms do not tend to respond to the management strategies for acute pain, such as bed rest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after a vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently does not improve with analgesics and may be better addressed through exercise. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

**Sacral Insufficiency Fractures**

Sacral insufficiency fractures (SIFs) are the consequences of stress on weakened bone and often cause low back pain in the elderly population. Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie (1982) and presents as lower back and buttock pain with or without referred pain in the legs. Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention.

**Treatment**

Similar interventions are used for sacral and vertebral fractures and include bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.

**Vertebral and Sacral Body Metastasis**

Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint.
**Treatment**

While radiotherapy and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain strength in the vertebrae/sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Improvements in pain and function are the primary outcomes of interest for treatment of bone malignancy with percutaneous vertebroplasty or sacroplasty.

**Surgical Treatment Options**

**Percutaneous Vertebroplasty**

Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss]®) into a fractured vertebra. It has been suggested that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers.

**Percutaneous Sacroplasty**

Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical to vertebroplasty, entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive alternative to conservative management for SIFs.

Pain and function are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may vary. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of vertebroplasty and sacroplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with alternatives such as continued medical management.
In all clinical situations, adverse events related to complications from vertebroplasty and sacroplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA or another injectate.

**Summary of Evidence**

For individuals who have symptomatic osteoporotic vertebral fractures that are between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes 2 randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and systematic reviews of these RCTs. The relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies, which included the 2 sham-controlled trials, have demonstrated mixed results. The 2 studies had methodologic issues, including the choice of sham procedure and the potential effect of the sham procedure to have a therapeutic effective by reducing pain. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of patients with chronic pain. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with symptomatic osteoporotic vertebral fractures that are less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and other nonblinded RCTs comparing vertebroplasty with conservative management. The relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option, and symptoms will resolve in a large percentage of patients with conservative treatment only. However, a sham-controlled randomized trial in patients who had severe pain of fewer than 6 weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fractures at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain and reductions in the duration of bed rest. Given the high morbidity associated with extended bed rest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes 2 prospective cohort studies, several retrospective reviews, and a case series. The relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. No RCTs have been reported. The available evidence includes a prospective cohort study and a retrospective series with 243 patients. These studies have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional literature has mostly reported immediate improvements following the procedure. However, due to the small size of the evidence base, the harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Ongoing trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02902250</td>
<td>The Comparative Study About the Effect of Vertebral Body Decompression Procedure and Conservative Treatment for Benign Vertebral Compression Fracture - Prospective Randomized Control Study</td>
<td>80</td>
<td>Apr 2020</td>
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<tr>
<td>NCT02489825</td>
<td>Pilot Study: Does Preventive Adjacent Level Cement Augmentation Positively Affect Reoperation Rates After Osteoporotic Vertebral Compression Fractures?</td>
<td>100</td>
<td>June 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical 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.

2014 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. Input was sought on the treatment of acute vertebral fractures when there is severe pain that has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after six weeks of conservative treatment. Input on these issues was mixed.

2008 Input

In response to requests, input was received from 5 physician specialty societies and 2 academic medical centers while this policy was under review in 2008. Unsolicited input was received from a sixth physician specialty society. All reviewers disagreed with the proposed policy and provided references in support of the use of vertebroplasty.

Practice Guidelines and Position Statements

American College of Radiology

The American College of Radiology (2018) revised its ACR Appropriateness Criteria for the use of percutaneous vertebral augmentation in the management of vertebral compression fractures.43 Table 2 shows the appropriateness categories for each variant.
Table 2. ACR Appropriateness Criteria for the use of Percutaneous Vertebral Augmentation for the Management of Vertebral Compression Fractures

<table>
<thead>
<tr>
<th>Variants</th>
<th>Appropriateness Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;New symptomatic compression fracture identified on radiographs or CT. No known malignancy.&quot;</td>
<td>May Be Appropriate</td>
</tr>
<tr>
<td>&quot;Osteoporotic compression fracture, with or without edema on MRI and no ‘red flags.’ With or without spinal deformity, worsening symptoms, or pulmonary dysfunction.&quot;</td>
<td>Usually Appropriate</td>
</tr>
<tr>
<td>&quot;Asymptomatic pathologic spinal fracture with or without edema on MRI.&quot;</td>
<td>May Be Appropriate</td>
</tr>
<tr>
<td>&quot;Pathologic spinal fracture with severe and worsening pain.&quot;</td>
<td>Usually Appropriate</td>
</tr>
<tr>
<td>&quot;Pathologic spinal fracture with spinal deformity or pulmonary dysfunction.&quot;</td>
<td>Usually Appropriate</td>
</tr>
</tbody>
</table>

CT: computed tomography; MRI: magnetic resonance imaging; ACR: American College of Radiology

American College of Radiology et al

The American College of Radiology (2014) and 4 other medical specialty associations updated a 2012 joint position statement on percutaneous vertebral augmentation. The statement indicated that percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in accordance with public standards. The document also stated that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering patients' quality of life.

Society for Interventional Radiology

The Society of Interventional Radiology (2014) issued a joint position statement with 7 other societies on percutaneous vertebral augmentation noting that "percutaneous vertebral augmentation (PVA) with the use of vertebroplasty and kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in a manner in accordance with published standards." The society states that percutaneous vertebral augmentation should be "offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the
patient’s quality of life.” Finally, the society notes that “the benefits of PVA outweigh its risk and the risks of non-operative medical therapy, and the success rate in appropriately selected patients is consistently high.”

In a quality improvement guideline from Society for Interventional Radiology (2014), failure of medical therapy is defined as follows:

1. For a patient rendered non-ambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;

2. For a patient with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or

3. For any patient with a weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.

**American Academy of Orthopaedic Surgeons**

The American Academy of Orthopaedic Surgeons (AAOS) (2010) approved practice guidelines on the treatment of osteoporotic spinal compression fractures. The AAOS approved a strong recommendation against the use of vertebroplasty for patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.” With this recommendation, the AAOS expressed its confidence that future evidence is unlikely to overturn the existing evidence.

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (NICE) (2003) concluded in its guidance on percutaneous vertebroplasty that the current evidence on the safety and efficacy of vertebroplasty for vertebral compression fractures appeared “adequate to support the use of this procedure” to “provide pain relief for people with severe painful osteoporosis with loss of height and/or compression fractures of the vertebral body...” The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A NICE (2013) guidance indicated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty “are recommended as options for treating osteoporotic
vertebral compression fractures” in persons having “severe, ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management” and whose “pain has been confirmed to be at the level of the fracture by physical examination and imaging.”

The NICE (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. This guidance indicated that vertebroplasty or kyphoplasty should be considered for “patients who have vertebral metastases and no evidence of MSCC [metastatic spinal cord compression] or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse.”

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval.

Polymethylmethacrylate (PMMA) bone cement was available as a drug product before enactment of FDA’s device regulation and was at first considered what FDA terms a “transitional device.” It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet “special controls” instead of “general controls” to assure safety and effectiveness. Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were cleared for marketing by FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of PMMA in sacroplasty is an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement [Teknimed] and Osteopal® V [Heraeus]), because the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included. FDA product code: NDN.
In 2009, Cortoss® (Stryker) Bone Augmentation Material was cleared for marketing by FDA through the 510(k) process. Cortoss® is a nonresorbable synthetic material that is a composite resin-based, bis-glycidal dimethacrylate. FDA classifies this product as a PMMA bone cement.

In 2010, the Parallax® Contour® Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

References

15. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008;Volume 23:Tab 5.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
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<tr>
<td>06/12/12</td>
<td>New policy, add to Radiology section. Policy replaces 6.01.520 in conjunction with 6.01.38.</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>07/24/13</td>
<td>Replace policy. Rationale updated based on a literature review through March 2013. ACR 2012 practice guideline added. References 31, 33, 34, 37 added; others renumbered or removed. Policy statements unchanged.</td>
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<td>06/19/14</td>
<td>Annual Review. Policy updated with literature review through March 25, 2014; references 22, 31, 40-42, and 45-46 added; policy statements unchanged. ICD-9 procedure code 81.65 removed; this is performed outpatient – ICD-10 procedure codes also removed, along with both sets of diagnosis codes.</td>
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<td>01/12/15</td>
<td>Coding update. New CPT codes 22510-22515, effective 1/1/15, added to policy; notation made regarding CPT codes 22520-22522 and 72291-72292, deleted as of 12/31/14.</td>
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<td>08/11/15</td>
<td>Annual Review. Policy updated with literature review through March 3, 2015; references 18 and 27 added; Reworded the third policy statement for clarity: Percutaneous vertebroplasty is considered investigational for all other indications not listed above.</td>
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<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. No change to policy statements. No new RCTs identified.</td>
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<td>06/06/17</td>
<td>Coding update, removed HCPCS codes S2360 and S2361 as they were terminated 01/01/16.</td>
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<td>08/01/17</td>
<td>Annual Review, approved July 18, 2017. Policy moved into the new format. Policy updated with literature review through March 23, 2017; references 9, 16, 26-27, and 30-31 added; vertebroplasty may be medically necessary in vertebral fractures of less than 6 weeks in duration that prevent ambulation.</td>
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<td>07/01/18</td>
<td>Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 20, 28, and 36 added. Policy statements unchanged.</td>
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<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.</td>
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Email AppealsDepartmentInquiries@Premera.com

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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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Arabic (Arabic):
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Français (French):

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Iloko (Ilocano):
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