MEDICAL POLICY – 6.01.38
Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

BCBSA Ref. Policy: 6.01.38
Effective Date: July 1, 2020
Last Revised: June 4, 2020
Replaces: 6.01.520

RELATED MEDICAL POLICIES:
6.01.25 Percutaneous Vertebroplasty and Sacroplasty

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Kyphoplasty is a type of surgery that stabilizes a vertebra (a bone of the spine) after a compression fracture. A compression fracture usually happens at the front side of the vertebra. The front collapses, leaving a vertebra that looks a bit like a wedge. The goal of kyphoplasty is to reduce pain and return the vertebra to its normal height. A hollow needle or similar instrument is inserted through the skin and into the damaged area of the bone. Either a balloon is inflated or a device is uncoiled to create a hollow space at the front of the bone, bringing it back to its normal height. If a balloon is used, it’s then removed. If a coil device is used, it remains. A type of bone cement is then injected into the hollow space. The cement hardens after a few minutes. This policy describes when this procedure may be considered 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
Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* may be considered medically necessary for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to at least 6 weeks of conservative treatment (eg, analgesics, physical therapy, rest).

Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* may be considered medically necessary for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

*Note: See (Table 2) for list of FDA cleared devices

Percutaneous balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device* are considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device is considered investigational.

*Note: See (Table 2) for list of FDA cleared devices

**Note:** Based on currently available evidence, health outcomes for kyphoplasty, vertebral augmentation, and vertebroplasty appear to be equivalent, therefore, the “least costly alternative” provision of the medically necessary definition may apply.
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:

- Relevant history and physical supporting painful osteoporotic vertebral compression fractures that have failed to respond to at least 6 weeks of conservative treatment (eg, analgesics, physical therapy, rest)

OR

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

Coding

In 2015, the CPT codes combined the kyphoplasty procedure with all of the necessary imaging guidance; they are listed in the table below.

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

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Percutaneous kyphoplasty may be performed by interventional radiologists or orthopedic surgeons. Percutaneous kyphoplasty is a specialized procedure, and thus some patients may seek an out-of-network referral.

Evidence Review

Description

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty (RFK), and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine (ie, multiple myeloma or metastatic malignancies).

Background

Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to 50% of women and 25% of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. A minority of patients will exhibit chronic pain following an 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 bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after 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 is not improved with analgesics and may be better addressed through exercise. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures.
Osteolytic Vertebral Body Fractures

Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, 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 for days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

Summary of Evidence

For individuals with osteoporotic vertebral compression fractures (OVCF) who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Three randomized trials that compared mechanical vertebral augmentation (Kiva or SpineJack) with kyphoplasty have reported similar outcomes for both procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with osteolytic VCF who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and a systematic review of these studies. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs compared balloon kyphoplasty with conservative management and another compared Kiva with balloon kyphoplasty. Results of these trials, along
with case series, would suggest a reduction in pain, disability, and analgesic use in patients with
cancer-related compression fractures. However, because the results of the comparative studies
of vertebroplasty have suggested possible placebo or natural history effects, the evidence these
studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health
outcomes. The evidence is insufficient to determine the effects of the technology on health
outcomes.

For individuals with osteoporotic or osteolytic VCF who receive radiofrequency kyphoplasty, the
evidence includes a systematic review and an RCT. Relevant outcomes include symptoms,
functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only
RCT (n=80) identified showed similar results between radiofrequency kyphoplasty and balloon
kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to
balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small
number of studies as well as possible bias. Corroboration of these results in a larger number of
patients would be needed to determine with greater certainty whether radiofrequency
kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to
determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished clinical 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>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03730207*</td>
<td>A Prospective, 1: 1 Randomized, Single Blind, Multi-center Human Clinical Trial</td>
<td>180</td>
<td>Oct 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
* Denotes industry-sponsored or cosponsored 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 two physician specialty societies and three academic medical centers while this policy was under review in 2014. Input was sought on the treatment of acute vertebral fractures when severe pain 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. Clinical input on these issues was mixed.

2008 Input

In response to requests, input was received from six physician specialty societies (one unsolicited) and two academic medical centers while this policy was under review in 2008. All reviewers disagreed with the proposed policy, referring to a body of evidence from uncontrolled studies that support the use of kyphoplasty.

Practice Guidelines and Position Statements

American College of Radiology et al

The American College of Radiology (2014) and seven other surgical and radiological specialty associations published a joint position statement on percutaneous vertebral augmentation. This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. The statement also indicated that these procedures be offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering the patient’s quality of life.
A joint practice parameter for the performance of vertebral augmentation was updated in 2017.29

**Society of Interventional Radiology**

In a quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology (2014), vertebral augmentation was recommended for compression fractures refractory to medical therapy.28 Failure of medical therapy includes the following situations:

1. Patients who are rendered nonambulatory 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. Patients 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. Patients with a weakened or fractured vertebral body, and 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 (2010) approved clinical guidelines on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering kyphoplasty to patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms ...and who are neurologically intact.”30 The American Academy of Orthopaedic Surgeons indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on literature reviewed through September 2009.

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2013) issued a guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment 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 through physical exam and imaging at the level of the fracture.\textsuperscript{31} This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.

The Institute (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2014 and placed on the static list (no major ongoing studies identified, with the next review in 5 years).\textsuperscript{32} The guidance stated that vertebroplasty or kyphoplasty should be considered for patients who have vertebral metastases and no evidence of spinal cord compression or spinal instability if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of patients, that early surgery may be more effective at maintaining mobility than radiotherapy.

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Polymethyl methacrylate bone cement was available as a drug product before enactment of the FDA’s device regulation and was at first considered what the FDA termed a “transitional device.” It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet “special controls” instead of “general controls” to assure safety and effectiveness. In July 2004, KyphX® HV-RTM bone cement was cleared for marketing by the FDA through the 510(k) process for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement, KYPHON® HV-R® Bone Cement, and Osteopal® V (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX® inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through
the 510(k) process. Additional devices for balloon kyphoplasty are listed in Table 2. There are several mechanical vertebral augmentation devices that have received marketing clearance by the FDA through the 510(k) process; these are listed in Table 2.

StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

FDA product code NDN.

### Table 2. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balloon Kyphoplasty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRACKER Kyphoplasty System</td>
<td>GS Medical Co., Ltd</td>
<td>12/4/2019</td>
<td>K192335</td>
<td>Reduction of fractures or creation of a void</td>
</tr>
<tr>
<td>Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)</td>
<td>Stryker Corporation</td>
<td>12/21/2018</td>
<td>K181752</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>SpineKure Kyphoplasty System</td>
<td>Hanchang Co. Ltd.</td>
<td>5/29/2018</td>
<td>K172871</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters</td>
<td>G-21 s.r.l.</td>
<td>8/23/2017</td>
<td>K172214</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)</td>
<td>Pan Medical Ltd.</td>
<td>11/1/2016</td>
<td>K162453</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>MEDINAUT Kyphoplasty System</td>
<td>Imedicom Co. Ltd.</td>
<td>7/29/2016</td>
<td>K153296</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>AVAflex Vertebral Balloon System</td>
<td>Carefusion</td>
<td>11/24/2015</td>
<td>K151125</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml</td>
<td>Osseon LLC</td>
<td>4/9/2015</td>
<td>K150607</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm)</td>
<td>Pan Medical Ltd</td>
<td>3/6/2015</td>
<td>K150322</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
<td>Indication</td>
</tr>
<tr>
<td>--------------------------------------------</td>
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</tr>
<tr>
<td>GUARDIAN-SG Inflatable Bone Expander System</td>
<td>BM Korea Co. Ltd.</td>
<td>1/16/2015</td>
<td>K143006</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>ZVPLASTY</td>
<td>Zavation LLC</td>
<td>9/12/2014</td>
<td>K141419</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td><strong>Mechanical Vertebral Augmentation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Kiva VCF treatment system</td>
<td>Benvenue Medical Inc.</td>
<td>8/14/2014</td>
<td>K141141</td>
<td>To repair vertebral compression fractures</td>
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<tr>
<td>SpineJack Expansion Kit</td>
<td>Vexim SA</td>
<td>8/30/2018</td>
<td>K181262</td>
<td>To repair vertebral compression fractures</td>
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<tr>
<td>V-Strut Vertebral Implant</td>
<td>Hyprevention SAS</td>
<td>3/5/2020</td>
<td>K191709</td>
<td>Treatment of vertebral fractures in the thoracic and lumbar spine</td>
</tr>
</tbody>
</table>

References

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


15. Ong KL, Beall DP, Frohbergh M et al. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty “sham” trials?. Osteoporos Int. 2018 Feb;29(2). PMID 29063215


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/12/12</td>
<td>New policy, add to Radiology section. Policy replaces 6.01.520 in conjunction with 6.01.25.</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>06/10/13</td>
<td>Replace policy. Policy updated with literature review through March 5, 2013; references 17, 30, 31 added and references reordered; statement added that all other percutaneous mechanical vertebral augmentation devices, including but not limited to Kiva, are considered investigational. CPT codes 22520 – 22522 added to policy.</td>
</tr>
<tr>
<td>08/12/13</td>
<td>Clarification. Policy statement clarified by adding &quot;less than 6 weeks old&quot;. Percutaneous balloon kyphoplasty is considered investigational for all other indications, including use in acute (less than 6 weeks old) vertebral fractures due to osteoporosis or trauma.</td>
</tr>
<tr>
<td>06/09/14</td>
<td>Annual Review. Policy updated with literature review through March 27, 2014, references 31-32, 34-35, 37-39, and 41-42 added; and references reordered. Vertebral body stenting added to investigational statement. Coding update: ICD-9 and ICD-10 procedure and diagnosis codes removed – these are not utilized in adjudication of the policy.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Coding update. ICD-9 procedure code 81.66 and corresponding ICD-10-PCS codes added per remediation efforts.</td>
</tr>
<tr>
<td>08/11/15</td>
<td>Annual Review. Kiva® mechanical vertebral augmentation added as Medically Necessary (previously considered investigational) when criteria are met and Investigational for all other indications. Rationale added for vertebral augmentation with the Kiva® VCF System® compared with balloon kyphoplasty. Policy updated with literature review through March 3, 2015. References 32-34 added; others renumbered/removed. New CPT codes 22513-22515 effective 01/01/15 added to Coding table. Policy statements changed as noted.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
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</tr>
<tr>
<td>01/08/16</td>
<td>Minor update. CPT codes deleted effective 12/31/15 removed from policy: 22520-22525, 72291-72292. No other changes.</td>
</tr>
<tr>
<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy guidelines updated to remove the following statement: “Based on currently available evidence, health outcomes for kyphoplasty, Kiva® and vertebroplasty appear to be equivalent, therefore the “least costly alternative” provision of the medically necessary definition may apply” as it duplicates information in the Benefit Application section. Policy reviewed with literature search through June 2016. Policy statements unchanged.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim review, approved December 13, 2016. Policy statement revised for clarity to state “...medically necessary for symptomatic vertebral fractures due to osteoporosis or trauma that have failed to respond to 6 weeks of conservative treatment.” The last investigational policy statement was revised to delete the wording, “including but not limited to vertebral body stenting.” Removed information about vertebral hemangiomas. Table of ACR recommendations for compression fracture treatment added to Policy Guidelines. Policy updated with literature review through October 2016; some references deleted.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references 32-33 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>07/01/20</td>
<td>Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; references added. Policy statements clarified that the medically necessary statements on compression fractures apply to the thoracolumbar spine. The tradename “Kiva” was removed from policy statements and replaced with “FDA cleared device”.</td>
</tr>
</tbody>
</table>

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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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