Clinical Review Criteria Related to INFUSE Bone Graft

I. Criteria for Approval

A. Minuteman Health Insurance (MHI) considers the INFUSE Bone Graft/LT-Cage lumbar tapered Fusion Device medically necessary for spinal fusion procedures in skeletally mature patients with degenerative disc disease only for a single level from the fourth lumbar vertebra (L4) to the first sacral vertebra (S1) in persons who meet the following criteria:

1. Member has degenerative disc disease, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies; and

2. Member does not have greater than grade I Spondylolisthesis at the involved level; and

3. Member had at least 6 months of non-operative treatment prior to treatment with the INFUSE Bone Graft/LT-CAGE device; and

4. Member has no known or suspected malignancy, or a history of malignancy; and

5. Member has no known autoimmune disease or immunodeficiency, including chronic steroid treatment; and

6. INFUSE bone Graft/LT Cage device is to be implanted via an anterior approach.

B. Also used in surgical repair of an acute open tibial shaft fracture when BOTH of the following criteria are met:

1. Acute open fracture of the tibial shaft.

2. RhBMP-2 is applied within 14 days of the fracture.

II. Required Documentation

A. Clinical notes from treating provider referencing above criteria
III. What is Not Covered

A. MHI considers use of the INFUSE Bone Graft (rhBMP-2) Experimental/Investigational for the following:

1. Multilevel spinal fusions
2. Posterior lumbar fusion, transforaminal fusions
3. An alternative or adjunct treatment for sinus augmentation and/or alveolar ridge augmentation for the treatment of cervical spine conditions

IV. CPT/ICD-10/HCPCS Codes

Applicable Coding: Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20930</td>
<td>Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to the primary spinal fusion)</td>
</tr>
<tr>
<td>20931</td>
<td>Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>20938</td>
<td>Structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified</td>
</tr>
</tbody>
</table>

ICD 10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M47.817</td>
<td>Lumbosacral spondylosis without myelopathy or radiculopathy, lumbosacral region</td>
</tr>
<tr>
<td>M47.16 Other</td>
<td>Spondylosis with myelopathy, lumbar region</td>
</tr>
<tr>
<td>M51.36</td>
<td>Degeneration of lumbar or lumbosacral intervertebral disc</td>
</tr>
<tr>
<td>M51.06</td>
<td>Intervertebral disc disorder with myelopathy, lumbar region</td>
</tr>
</tbody>
</table>
S82.209B Open fracture of shaft tibia alone

V. References

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A


VI. Summary of Changes

4/13/2017
- New Criteria under I., Criteria for Approval:
A. 4. Member has no known or suspected malignancy, or a history of malignancy; and
5. Member has no known autoimmune disease or immunodeficiency, including chronic steroid treatment; and

VII. Review Dates

MHI Review Dates: 10/23/14, 01/16/15, 07/02/2015, 04/21/2016, 04/13/2017