

InFUSE™ Bone Graft (Recombinant Human Bone Morphogenetic Protein - 2)

MPM 9.4

Disclaimer Refer to the member's specific benefit plan and *Schedule of Benefits* to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.

Description **InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device** (also known as recombinant human Bone Morphogenetic Protein-2) is a device to help fuse vertebrae in the lower spine in order to treat degenerative disc disease. It differs from similar devices in that it uses genetically engineered protein to help build bone tissue in the fusion process, instead of using a graft of the patient's own bone (an autograft). The device consists of three components split among two parts:

1. A metallic tapered spinal fusion cage (known as the LT-CAGE™ Lumbar Tapered Fusion Device; and
2. A bone graft substitute (InFUSE™ Bone Graft) which consists of a genetically engineered human protein along with a carrier/scaffold for the protein that is placed inside the fusion cage.

These components must be used as a system.¹

InFUSE™ Bone Graft for treating tibial fractures consists of two components:

1. A recombinant human Bone Morphogenetic Protein solution; and
2. A carrier/scaffold for the Bone Morphogenetic Protein solution and resulting bone.

These components must be used as a system.²

**Coverage
Determination/
Clinical
Indications**

Benefit Certification is not required. However, all claims are subject to retrospective review, and will only be covered for the indications listed.

As of July 1, 2008, the FDA has issued a Public Health Notification alerting practitioners to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine. Specifically, the safety and effectiveness of rhBMP in the cervical spine has not been demonstrated and these products are not approved by the FDA for this use.³

The FDA has approved the use of two rhBMPs for well-defined medical conditions in limited patient populations.

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For treating vertebra in the lower spine with InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, ALL of the following indications must be met:

- Skeletally mature patient with degenerative disc disease (DDD) at one level from L4 to S1.
- Patient does not have greater than Grade I spondylolisthesis at the involved level.
- Patients have had at least six months of nonoperative treatment prior to treatment with the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device.
- InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach.¹

For treating tibial fractures with InFUSE™ Bone Graft, ALL of the following indications must be met:

- Skeletally mature patients with acute, open tibial shaft fractures that have been stabilized with IM nail fixation after appropriate wound management.
- InFUSE™ Bone Graft must be applied within 14 days after the initial fracture.²

Contraindications

The FDA has determined the following contraindications to InFUSE Bone Graft and InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device:

- The device should not be used in patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation.
- The device should not be used in the vicinity of a resected or extant tumor.
- The device should not be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).
- The device should not be used in pregnant or nursing women. Women of childbearing potential should be advised to not become pregnant for one year following implantation of the device.
- The device should not be implanted in patients with an active infection at the operative site.
- The device should not be implanted in patients with an allergy to titanium or titanium alloy.

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- InFUSE™ Bone Graft should not be used in patients with an inadequate neurovascular status, e.g., high risk of amputation, or with compartment syndrome of the affected limb.^{1,2}

Coding

The coding listed in this Medical Policy is for reference only. Covered and non-covered procedures are within this list.

CPT Codes	Description
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s) threaded bone dowel(s), methymethacrylate) to vertebral defect or interspace

ICD-9© Diagnosis Codes	Description
715.90 – 715.98	Osteoarthritis, unspecified whether generalized or localized
722.51	Degeneration of intervertebral disc, thoracic or thoracolumbar
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.73	Intervertebral lumbar disc disorder with myelopathy, lumbar region
722.83	Postlaminectomy syndrome, lumbar region
724.9	Other unspecified back disorder
733.81	Malunion of fracture
733.82	Nonunion of fracture
756.11	Spondylolysis, lumbosacral region
756.12	Spondylolisthesis
806.4	Closed fracture of lumbar spine with spinal cord injury
823.0 – 823.92	Fracture of tibia and fibula
905.5	Late effect of fracture of multiple and unspecified bones

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[MPM071006]

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Reviewed by: 1. Mark D. Erasmus, MD. Presbyterian Medical Group Neurosurgery.
Albuquerque, NM. July 2010.

- References:**
1. U.S. Food and Drug Administration, Summary of Safety and Effectiveness Data, PMA P000058. Device trade name: InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device. July 2, 2002
 2. U.S. Food and Drug Administration, Summary of Safety and Effectiveness Data, PMA P000054. Device trade name: InFUSE™ Bone Graft. April 30, 2004.
 3. U.S. Food and Drug Administration Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion. Issued July 1, 2008. Page last updated 06-19-09. Accessed on the Internet 07-29-10 at:
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM062000>
 4. Hayes Directory. Copyright © Winifred S. Hayes, Inc. 2006. Recombinant Human Bone Morphogenetic Protein for Use in Spinal Fusion. September 10, 2006. Update Search 06-21-09
 5. Hayes Directory. Copyright © Winifred S. Hayes, Inc. 2006. Recombinant Human Bone Morphogenetic Protein for Use in Tibia Repair. September 10, 2006. Update Search 08-15-09.

**Approval
Signatures****Clinical Quality Committee:** Mark Whitaker, MD**Medical Director:** Norman White, MD**Date:** July 28, 2010

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07-21-08: Transitioned to Medical Policy
07-28-10: Review

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available on the Internet at:
<http://www.phs.org/phs/healthplans/providers/healthservices/Medical/index.htm>

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