

## Corporate Medical Policy

### Bone Morphogenetic Protein

<b>File Name:</b>	bone_morphogenetic_protein
<b>Origination:</b>	10/2004
<b>Last CAP Review:</b>	7/2011
<b>Next CAP Review:</b>	7/2012
<b>Last Review:</b>	7/2011

### Description of Procedure or Service

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Bone morphogenetic proteins (BMP) are members of the family of transforming growth factors. At present, some 15 different BMPs have been identified, all with varying degrees of cartilage and/or bone inductive properties. Two recombinant proteins are now commercially available, rh-BMP-2 and rh-BMP-7. These products have been investigated as an alternative to bone autografting in a variety of clinical situations, including spinal fusions, internal fixation of fractures, treatment of bone defects, and reconstruction of maxillofacial conditions. Rh-BMPs are delivered to the bone grafting site as part of a surgical procedure. A variety of carrier and delivery systems have been investigated. Carrier systems, which are absorbed over time, function to maintain the concentration of the rhBMP at the treatment site, provide temporary scaffolding for osteogenesis, and prevent extraneous bone formation. Carrier systems have included inorganic material, synthetic polymer, natural polymers, and bone allograft. The rhBMP and carrier may be inserted via a delivery system, which may also function to provide mechanical support. For interbody spinal fusion, delivery systems have included interbody fusion cages. The carrier and delivery system are important variables in the clinical use of rhBMPs. For example, different clinical applications will require different dosages of rhBMP with different carriers and delivery systems. Therefore, the results of one clinical application cannot be extrapolated to others.

Two rh-BMPs and associated carrier/delivery systems have received approval from the U.S. Food and Drug Administration (FDA). OP-1 consists of rh-BMP-7 and bovine collagen, which is reconstituted with saline to form a paste. The addition of carboxymethylcellulose forms a putty. The InFUSE system consists of rh-BMP-2 on an absorbable collagen sponge carrier.

Both OP-1 and InFUSE are contraindicated in patients who are pregnant, who may be allergic to any of the materials contained in the devices, who have an infection near the area of the surgical incision, who have had a tumor removed from the area of the implantation site or currently have a tumor in that area, or who are skeletally immature.

Note: This policy only addresses Bone Morphogenetic Proteins. See the BCBSNC policies titled, "Orthopedic Applications of Stem Cell Therapy" and "Growth Factors in Wound Healing" for information regarding treatments for tissue repair and tissue substitutes. For information regarding spinal fusion procedures, please see the BCBSNC policy titled, "Lumbar Spine Fusion Surgery."

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

### Policy

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**BCBSNC will provide coverage for FDA-approved Bone Morphogenetic Proteins when it is determined to be medically necessary because the medical criteria and guidelines show below are**

# Bone Morphogenetic Protein

met.

**BCBSNC will not provide coverage for non FDA-approved BMPs because they are considered investigational. BCBSNC does not cover investigational services.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Bone Morphogenetic Protein is covered

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Use of recombinant human bone morphogenetic protein (rhBMP-2, InFUSE) may be considered medically necessary for the following indications:

1. As an adjunct to anterior lumbar spinal fusion at one or more levels in skeletally mature patients with approved indications for lumbar spine fusion surgery (see medical policy titled, "Lumbar Spine Fusion Surgery").
2. For the treatment of acute, open fracture of the tibial shaft.

Use of recombinant human bone morphogenetic protein-7 (rhBMP-7, OP-1) may be considered medically necessary for the following indication:

1. As an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments (e.g., electrical bone growth stimulation) have failed.

## When Bone Morphogenetic Protein is not covered

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Bone Morphogenetic Proteins are not covered when all of the above criteria are not met.

The use of recombinant human bone morphogenetic protein-2 or recombinant human bone morphogenetic protein-7 is considered investigational for all other indications, including but not limited to:

- As an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion
- As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries.

Use of a non FDA-approved BMP or use of an FDA-approved BMP for an off-label indication is considered investigational.

## Policy Guidelines

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It is likely that hospitals will seek additional payment to cover the additional costs of bone morphogenetic protein.

Use of an autograft may be determined to be unfeasible for any of the following reasons:

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## Bone Morphogenetic Protein

1. The patient has received a previous autograft and is not a candidate for further autografting procedures due to tissue no longer being available, or
2. There is insufficient autogenous tissue for the intended purpose, or
3. The patient is deemed an unacceptable candidate for autograft for one or more of the following reasons:
  - a. obesity
  - b. advanced age (>65 years)
  - c. presence of morbidity (infection, or fracture) preventing harvesting at the autograft donor site
  - d. excessive risk of anatomic disruption (including fracture) from harvesting autograft from the donor site
  - e. patient's bone is poor quality e.g., osteoporosis
  - f. patient has concurrent medical conditions and co-morbidities that increase the risk of autograft

Alternative treatments may include any of the following as appropriate:

- cast immobilization or other non-operative approach
- internal or external fixation
- revision of a previous fixation
- autograft
- cadaver allograft
- compression
- dynamization
- use of bone growth stimulator (ultrasonic or electrical)

In July 2008, the FDA issued a public health notification regarding life-threatening complications associated with recombinant human bone morphogenetic protein in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Severe dysphagia following cervical spine fusion using rhBMP products has also been reported in the literature. The FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies

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## Bone Morphogenetic Protein

on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There is no specific CPT code for bone morphogenetic proteins. Services should be submitted in the form of an unlisted code (such as 20999, 22899, or 27899). Medical records for the explanation of the service rendered may be necessary.*

*In the setting of spinal fusion, bone morphogenetic proteins are used primarily as an alternative to autologous bone grafting. Since harvesting of autologous bone graft is coded separately from the fusion procedure, when bone morphogenetic protein is used, these codes should no longer be reported.*

*In contrast, the CPT code for treating tibial fracture non-unions with autograft includes the harvesting component, and therefore, when bone morphogenetic protein is used as an alternative in this setting, presumably the associated physician work would be decreased since no autologous harvest is required.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Scientific Background and Reference Sources

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ECRI Health Technology Assessment. (December 2003). Interbody cage with bone morphogenetic protein for degenerative disc disease. Retrieved September 16, 2004 from [http://www.ta.ecri.org/Med\\_Tech/Prod/summary/detail.aspx?doc\\_id=6926&q=infuse&anm](http://www.ta.ecri.org/Med_Tech/Prod/summary/detail.aspx?doc_id=6926&q=infuse&anm).

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U.S. Food and Drug Administration. InFUSE Bone Graft/LT-Cage. P000058. Rockville, MD: FDA; Issued July 2, 2002. Retrieved September 16, 2004 from <http://www.fda.gov/cdrh/mda/docs/p000058.html>.

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Ontario Ministry of Health and Long-Term Care. Medical Advisory Secretariat (April 2005). Osteogenic Protein-1 for Long Bone Nonunion. Retrieved 2/22/07 from

## Bone Morphogenetic Protein

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Vaidya R, Carp J, Sethi A, Bartol S, Craig J, Les CM. Complications of anterior cervical discectomy and fusion using recombinant human bone morphogenetic protein-2. *Eur Spine J* 2007; 16(8): 1257-1265

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.100, 4/24/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.100, 6/11/09

Specialty Matched Consultant Advisory Panel review 7/2010

Senior Medical Director review 3/2011

BCBSA Medical Policy Reference Manual 7.01.100, 8/12/10

National Institutes of Health (NIH) Evaluation of Radiculitis Following Use of Bone Morphogenetic Protein-2 for Interbody Arthrodesis in Spinal Surgery. Clinical Trial #NCT00984672. Retrieved on June 10, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00984672>

Specialty Matched Consultant Advisory Panel review 7/2011

### Policy Implementation/Update Information

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10/14/04 New policy initiated. Bone Morphogenetic Protein is considered medically necessary when FDA-approved, used for FDA-approved indications, and medical criteria and guidelines are met. References added. Effective 10/14/2004.

6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to the policy statement. References added.

7/2/07 Deleted the following statement from the Non Covered section: treatment of multiple levels of spinal fusion, or spinal fusion in the thoracic or cervical vertebrae. Vertebral span changed from L4-S1 to L2-S1 to reflect supplemental FDA approval from 2004. References updated. Specialty Matched Consultant Advisory Panel review 5/18/07. (adn)

7/6/09 Added the following to Item 2 in the Description of Procedure section: for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets. Revised the section "When Bone Morphogenetic Protein is covered" to read: Use of recombinant human bone morphogenetic protein (rhBMP-2, InFUSE) may be considered medically necessary for the following indications: As an adjunct to anterior lumbar spinal fusion at one or more levels in skeletally mature patients with degenerative disc disease. Patients should have had at least 6 months of nonoperative treatment prior to treatment with the InFUSE Bone Graft/Interbody Fusion Device; For the treatment of acute, open fracture of the tibial shaft. Use of recombinant human bone morphogenetic protein-7 (rhBMP-7, OP-1) may be considered medically necessary for the following indication: As an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments (e.g., electrical bone growth stimulation) have failed. Revised the section "When Bone Morphogenetic Protein is not covered" to read: The use of recombinant human bone morphogenetic protein-2 or recombinant human bone morphogenetic protein-7 is considered investigational for all other indications, including but not limited to: As an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion; As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries. Added the FDA's July 2008 public health notification regarding life-threatening complications

## Bone Morphogenetic Protein

associated with recombinant human bone morphogenetic protein in cervical spine fusion to the Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review meeting 5/21/09. No change to the policy statement. (adn)

- 8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. References updated. Removed policy number. (mco)
- 4/12/11 Description section revised. Reference added for the BCBSNC policy “Lumber Spinal Fusion Surgery.” Deleted information regarding label indications and interbody fusion devises used in conjunction with InFUSE bone graft. Deleted the following wording from the “When Covered” section: “...with degenerative disc disease. Patients should have had at least 6 months of non-operative treatment prior to treatment with InFUSE Bone Graft.”(mco)
- 8/16/11 Specialty Matched Consultant Advisory Panel review. References updated. No changes to policy statements. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.