

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1
1.1 Alternative treatments..... 2
1.2 Medical Term Definitions..... 2
2.0 Eligible Recipients..... 2
2.1 General Provisions..... 2
3.0 When the Procedure, Product, or Service Is Covered..... 2
3.1 General Criteria..... 2
3.2 Specific Criteria..... 3
4.0 When the Procedure, Product, or Service Is Not Covered..... 3
4.1 General Criteria..... 3
4.2 Specific Criteria..... 3
4.3 Policy Guidelines..... 4
5.0 Requirements for and Limitations on Coverage..... 4
5.1 Prior Approval..... 4
6.0 Providers Eligible to Bill for the Procedure, Product, or Service..... 4
7.0 Additional Requirements..... 5
7.1 Compliance..... 5
8.0 Policy Implementation/Revision Information..... 5
Attachment A: Claims-Related Information..... 6
A. Claim Type..... 6
B. Diagnosis Codes..... 6
C. Procedure Code(s)..... 6
D. Modifiers..... 6
E. Billing Units..... 6
F. Place of Service..... 6
G. Co-payments..... 6
H. Reimbursement..... 6

1.0 Description of the Procedure, Product, or Service

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. The labeled indications for these devices are summarized below.

- a. OP-1 received the following labeled indications:
 1. "OP-1 implant is indicated for use as an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed."
 2. "OP-1 Putty is indicated for use 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. Examples of compromising factors include osteoporosis, smoking and diabetes."
- b. InFUSE Bone Graft in conjunction with one of two interbody fusion devices, i.e., either the LT-Cage Lumbar Tapered Fusion Device or the Inter Fix RP Threaded Fusion Device, has received FDA approval through the premarket approval process:
 1. for spinal fusion procedures in skeletally mature patients with degenerative disc disease at 1 level from L2-S1,
 2. for the treatment of acute, open fractures of the tibial shaft,
 3. for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

Draft

Both OP-1 and the InFUSE Bone Graft/LT-Cage Lumbar Tapered Fusion devices 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.

1.1 Alternative treatments

Alternative treatments may include any of the following as appropriate:

- a. cast immobilization or other nonoperative approach
- b. internal or external fixation
- c. revision of a previous fixation
- d. autograft
- e. cadaver allograft
- f. compression
- g. dynamization
- h. use of bone growth stimulator (ultrasonic or electrical)

1.2 Medical Term Definitions

- a. Autograft: transfer of human organ and/or tissue from one site to another in the same recipient.
- b. Autologous: derived from the same organism, i.e., self donation.
- c. Morphogenetic: relating to or concerned with the development of normal organic form.
- d. Non-union: failure of the ends of a fractured bone to unite.
- e. Recalcitrant: resistant to control.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary **AND**

Draft

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

- a. 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 recipients with degenerative disc disease. Recipients should have had at least six (6) months of non-operative treatment prior to treatment with the InFUSE Bone Graft/Interbody Fusion Device;
 2. For the treatment of acute, open fracture of the tibial shaft.
- b. 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.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

The use of recombinant human bone morphogenetic protein-2 or recombinant human bone morphogenetic protein-7 is not covered in the following situations:

- a. When the criteria in **Subsection 3.2** are not met.
- b. The use of recombinant human bone morphogenetic protein-2 or recombinant human bone morphogenetic protein-7 is considered investigational for all other indications including:

Draft

1. As an alternative to autograft in compromised recipients 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,
2. As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries.
- c. Use of a non FDA-approved BMP or use of an FDA-approved BMP for an off-label indication is considered investigational.

4.3 Policy Guidelines

- a. Use of an autograft may be determined to be unfeasible for any of the following reasons:
 1. The recipient 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 recipient is deemed an unacceptable candidate for autograft for one or more of the following reasons:
 - (a) obesity;
 - (b) presence of morbidity (infection, or fracture) preventing harvesting at the autograft donor site;
 - (c) excessive risk of anatomic disruption (including fracture) from harvesting autograft from the donor site;
 - (d) recipient's bone is poor quality e.g., osteoporosis; or
 - (e) recipient has concurrent medical conditions and comorbidities that increase the risk of autograft.
- b. 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.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for Bone Morphogenetic Proteins.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

Draft

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
September 30, 2011	Throughout	Policy date of Termination

Draft

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

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.

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s)

F. Place of Service

Outpatient hospital, inpatient hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges