**BONE MORPHOGENETIC PROTEIN (BMP)**

**Description:** Bone morphogenetic proteins (BMP) are naturally occurring substances in the human body that stimulate production of new bone. Fifteen different BMPs have been identified, all with varying degrees of cartilage and/or bone inductive properties.

Two recombinant BMPs have been developed and are 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, using a variety of carrier and delivery systems. Carrier systems, which are absorbed over time, function to maintain the concentration of the rh-BMP at the treatment site, provide temporary scaffolding for osteogenesis, and prevent extraneous bone formation. These systems may be composed of inorganic material, synthetic polymer, natural polymers, and bone allograft. The rh-BMP and carrier may be inserted via a delivery system, which also functions 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 rh-BMP because different clinical applications will require different dosages of rh-BMP 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). The InFUSE® system (Medtronic, Inc.) consists of rh-BMP-2 on an absorbable collagen sponge carrier. Osteogenic Protein-1™ (OP-1™, Stryker Biotech) consists of rh-BMP-7 and bovine collagen, which is reconstituted with saline to form a paste.
Definitions:  

**Autograft:** A portion of bone taken from one area of an individual and transplanted to another location on the same individual.

**Posterolateral intertransverse spinal fusion:** A type of spinal fusion surgery where the surgeon approaches the surgical site from the back and side of the patient; the sites of fusion are the transverse processes.

Policy:

I. Use of recombinant human bone morphogenetic protein-2 (rhBMP-2) may be considered **MEDICALLY NECESSARY** for the following indications:
   A. As an adjunct to an anterior lumbar interbody fusion procedure when use of an autograft is unfeasible (e.g., need for a greater quantity of autograft than is available); **OR**
   B. For instrumented posterolateral intertransverse spinal fusion when use of an autograft is unfeasible (e.g., need for a greater quantity of autograft than is available); **OR**
   C. As an adjunct to treatment of open fracture of the tibial shaft when use of an autograft is unfeasible (e.g., need for a greater quantity of autograft than is available).

II. Use of recombinant human bone morphogenetic protein-7 (rhBMP-7) may be considered **MEDICALLY NECESSARY** for the following indications:
   A. In recalcitrant long bone non-unions where use of an autograft is unfeasible (e.g., need for a greater quantity of autograft than is available) and alternative treatments have failed; **OR**
   B. For revision posterolateral intertransverse spinal fusion procedures in compromised patients when use of an autograft is unfeasible (e.g., need for a greater quantity of autograft than is available).

III. Use of recombinant human bone morphogenetic protein-2 (rhBMP-2) or recombinant human bone morphogenetic protein-7 (rhBMP-7) is considered **INVESTIGATIVE** for all other indications, including but not limited to:
   A. As an adjunct to thoracic and cervical fusion procedures;
   B. As initial treatment or revision of posterolateral spinal fusion, except as indicated above;
   C. As management of early stages of osteonecrosis of the vascular head or femoral shaft;
   D. As an adjunct to distraction osteogenesis (Ilizarov procedure)
   E. Craniofacial applications including, but not limited to, periodontal defect regeneration, cleft palate repair, cranial defect repair, sinus augmentation, and localized alveolar ridge augmentations for defects associated with extraction sockets.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.
Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member’s summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT:
20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only (list separately in addition to code for primary procedure
20931 Allograft, structural, for spine surgery only (list separately in addition to code for primary procedure

ICD-9 Procedure:
84.52 Insertion of recombinant bone morphogenetic protein

ICD-10 Procedure:
3E0V3GB Introduction of Recombinant Bone Morphogenetic Protein into Bones, Percutaneous Approach
3E0U0GB Introduction of Recombinant Bone Morphogenetic Protein into Joints, Open Approach
3E0U3GB Introduction of Recombinant Bone Morphogenetic Protein into Joints, Percutaneous Approach
3E0V0GB Introduction of Recombinant Bone Morphogenetic Protein into Bones, Open Approach

Policy History: Developed December 10, 2008

Most recent history: