7.01.100 Bone Morphogenetic Protein

Section 7.0 Surgery
Effective Date January 30, 2015

Subsection 7.01 Surgery
Original Policy Date March 1, 2005
Next Review Date January 2016

Description
Two recombinant human bone morphogenetic proteins (rhBMPs) are now commercially available, rhBMP-2, applied with an absorbable collagen sponge (InFUSE®, Medtronic, Memphis, TN) and rhBMP-7, applied in putty (OP-1®). 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.

Related Policies
- Autologous Platelet-Rich Plasma
- Spinal Fusion
- Ultrasound Bone Growth Stimulation

Policy

Use of recombinant human bone morphogenetic protein-2 (rhBMP-2, InFUSE) may be considered medically necessary in skeletally mature patients for any of the following:
- For anterior lumbar interbody fusion procedures when use of autograft is unfeasible.
- For instrumented posterolateral intertransverse spinal fusion procedures when use of autograft is unfeasible.
- For the treatment of acute, open fracture of the tibial shaft, when use of autograft is unfeasible.

Use of recombinant human bone morphogenetic protein-7 (rhBMP-7, OP-1) may be considered medically necessary in skeletally mature patients for either of the following:
- As an alternative to autograft in compromised patients (e.g., osteoporosis, tobacco use, or diabetes) requiring noninstrumented revision posterolateral intertransverse lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion.*
- For recalcitrant long-bone nonunions where use of autograft is unfeasible and alternative conservative treatments have failed.*

Bone morphogenetic protein (rhBMP-2 or rhBMP-7) is considered not medically necessary for all other indications, including but not limited to spinal fusion when use of autograft is feasible.
*FDA approved under a Humanitarian Device Exemption (HDE). OP-1 is no longer sold in the United States.

**Policy Guidelines**

Use of iliac crest bone graft (ICBG) may be considered unfeasible due to situations that may include, but are not limited to, prior harvesting of ICBG or need for a greater quantity of ICBG than available (e.g., for multilevel fusion).

There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).(1)

The following patient selection criteria are described in the treatment of nonunions:

- At least 3 months have passed since the date of the fracture, AND
- serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- the fracture gap is 1 cm or less, AND
- the patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

A recalcitrant nonunion would thus be considered to be a nonunion with a larger fracture gap (e.g., > than 1 cm) or a nonunion that has persisted for a longer duration of time with no response to conservative treatment (e.g., 3 months of ultrasound or electrical stimulation).

There is no specific CPT or HCPCS code for bone morphogenetic protein. In 2011, CPT code 20930 was revised to include BMP-type materials used in spine surgery:

- 20930: Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure).

In the setting of spinal fusion, bone morphogenetic proteins may be used primarily as an alternative to autologous bone grafting. Since harvesting of autologous bone graft is coded separately from the fusion procedure (i.e., CPT codes 20936-20938), when bone morphogenetic protein is used as an alternative to the bone graft, these codes should no longer be reported. In contrast, the CPT code for treating tibial fracture nonunions with autograft (i.e., CPT code 27724) includes the harvesting component, and, therefore, when bone morphogenetic protein is used as an alternative in this setting, presumably the associated physician’s work would be decreased, since no autologous harvest is required. Finally, for treatment of acute, open tibial fractures, bone morphogenetic protein is not used as an alternative to autologous bone graft, but in addition to standard treatment with an intramedullary nail.

ICD-9 procedure code 84.52 explicitly identifies the use of bone morphogenetic protein:

- 84.52: Insertion of recombinant bone morphogenetic protein rhBMP (via collagen sponge, coral, ceramic, or other carriers)

This ICD-9 code notes that the code 84.52 should be used in conjunction with the primary procedure performed:

- 79.00-79.99: Fracture repair
• 81.00-81.08: Spinal fusion
• 81.30-81.39: Spinal refusion

Note that the code ranges of the above ICD-9 codes include any type of fracture repair or spinal fusion.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

**Background**

Bone morphogenetic proteins (BMPs) are members of the family of transforming growth factors. At present, some 20 different BMPs have been identified, all with varying degrees of tissue stimulating properties. The rhBMPs are delivered to the bone grafting site as part of a surgical procedure; a variety of carrier and delivery systems has 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.

The carrier and delivery system are important variables in the clinical use of rhBMPs, and different clinical applications, such as long-bone nonunion, or interbody or intertransverse fusion, have been evaluated with different carriers and delivery systems. For example, rhBMP putty with pedicle and screw devices are used for instrumented intertransverse fusion (posterolateral fusion [PLF]), while rhBMP in a collagen sponge with bone dowels or interbody cages are used for interbody spinal fusion. In addition, interbody fusion of the lumbar spine can be approached from an anterior (anterior lumbar interbody fusion), lateral, or posterior direction (posterior lumbar interbody fusion [PLIF] or transforminal lumbar interbody fusion [TLIF]; see appendix). Surgical procedures may include decompression of the spinal canal and insertion of pedicle screws and rods to increase stability of the spine.

Posterior approaches (PLF and TLIF) allow decompression (via laminotomies and facetectomies) for treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum) along with stabilization of the spine and are differentiated from instrumented or noninstrumented PLF, which involves the transverse processes. Due to the proximity of these procedures to
the spinal canal, risks associated with ectopic bone formation are increased (e.g.,
radiculopaties). Increased risk of bone resorption around rhBMP grafts, heterotopic
bone formation, epidural cyst formation, and seromas has also been postulated.

**Regulatory Status**

At the present time, two rhBMPs and associated carrier/delivery systems have received
approval from the U.S. Food and Drug Administration (FDA). The InFUSE® system consists
of rhBMP-2 on an absorbable collagen sponge carrier. The labeled indications for these
devices are summarized here. OP-1® consists of rhBMP-7 and bovine collagen, which is
reconstituted with saline to form a paste. The addition of carboxymethylcellulose forms
putty.

1. InFUSE Bone Graft in conjunction with 1 of 2 interbody fusion devices, i.e., either the LT-
Cage Lumbar Tapered Fusion Device or the Inter Fix RP Threaded Fusion device received
FDA approval through the premarket approval (PMA) process:
   - The device is indicated for spinal fusion procedures in skeletally mature patients
     with degenerative disc disease (DDD) at 1 level from L2-S1. DDD is defined as
discogenic back pain with degeneration of the disc confirmed by patient history,
function deficit, and/or neurologic deficit and radiographic studies. These DDD
patients may also have up to grade I spondylolisthesis at the involved level or
retrolisthesis. The InFUSE™ Bone Graft/LT-CAGE™ devices are to be implanted via
an anterior open or a laparoscopic approach. The InFUSE™ Bone Graft/INTER
FIX™ Threaded Fusion Device; and InFUSE™ Bone Graft/INTER FIX™ RP Threaded
Fusion Device are to be implanted via an anterior open approach only. Patients
receiving the InFUSE™ Bone Graft/Interbody Fusion Device should have had at
least 6 months of nonoperative treatment prior to treatment with the InFUSE™
Bone Graft/Interbody Fusion Device. (Note: A collagen sponge consists of the
carrier, while the interbody fusion device is a delivery system. Use with posterior or
transforaminal lumbar interbody fusion is considered off-label.)
   - For the treatment of acute, open fractures of the tibial shaft
   - For sinus augmentations, and for localized alveolar ridge augmentations for
     defects associated with extraction sockets (P050053, March 2007)

2. OP-1 (Stryker Biotech, Hopkinton, MA) has received 2 FDA approvals through the
Humanitarian Device Exemption (HDE) process. HDE is available to devices intended for
fewer than 4,000 patients per year; as part of this process, the manufacturer is not
required to demonstrate unequivocal benefit but only “probable” benefit. OP-1
received the following labeled indications:
   - “OP-1 Implant is indicated for use as an alternative to autograft in recalcitrant
     long-bone nonunions where use of autograft is unfeasible and alternative
treatments have failed.” FDA product code: MPY
   - “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.” FDA product code: MPY

Stryker Biotech recently sought FDA permission to expand use of OP-1 Putty to include
use in uninstrumented posterolateral lumbar spinal fusion for the treatment of lumbar
spondylolisthesis. In March 2009, an FDA advisory committee voted 6-1 against
recommending the expanded approval. Olympus Biotech Corp, a subsidiary of Olympus
Both OP-1 and InFuse Bone Graft/LT-Cage Lumbar Tapered Fusion device are contraindicated in patients who are pregnant, may be allergic to any of the materials contained in the devices, have an infection near the area of the surgical incision, 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.

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. The FDA has received reports of complications with the use of rhBMP in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurologic structures in the neck. Some reports describe difficulty swallowing, breathing, or speaking. Severe dysphagia following cervical spine fusion using rhBMP products has also been reported in the literature. As stated in the public health notification, the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved by the FDA for this use.

In 2011, Medtronic received a “nonapprovable letter” from the FDA for AMPLIFY. The AMPLIFY rhBMP-2 Matrix utilizes a higher dose of rhBMP (2.0 mg/mL) with a compression-resistant carrier and is being evaluated for posterolateral fusion of single-level lumbar (L2-S1) degenerative disc disease.

The U.S. Food and Drug Administration’s (FDA) humanitarian device exemptions (HDE) for rhBMP-7 state that use is restricted to patients in whom autologous bone and bone marrow harvest are not feasible or are not expected to promote to promote fusion. Therefore, the policy on rhBMP-7 remains unchanged. As of 2014, rhBMP-7 is no longer marketed in the United States.

**Literature Review**

In 2013, randomized clinical trials supported the use of recombinant human bone morphogenetic protein-2 (rhBMP-2) in the treatment of anterior interbody spinal fusion when used in conjunction with a tapered cage and also in the treatment of open tibial fractures. In addition, a randomized study supported the use of rhBMP-7 in the treatment of recalcitrant nonunions of the long bones. It should be noted that the majority of trials were designed to show that use of rhBMP is equivalent (not superior) to autologous bone grafting. Although the proposed advantage of rhBMP is the elimination of a separate incision site required for harvesting of autologous bone graft and the associated pain and morbidity secondary to this procedure, a 2011 study by Howard et al. raises questions about the magnitude of pain observed with iliac crest bone graft (ICBG) harvesting. In this study, 112 patients who had an instrumented posterolateral lumbar fusion at 1 or 2 levels were seen at a tertiary spine center for a routine postoperative visit. ICBG was harvested in 53 patients (47.3%) through the midline incision used for lumbar fusion and rhBMP-2 was used in 59 patients (52.7%) with no graft harvest. An independent investigator who was not directly involved in the care of the patient and was unaware of the type of bone graft used in the fusion examined the patient’s tenderness over the surgical site, as well as the left and right posterior iliac crest. At a mean follow-up of 41 months (range, 6-211 months), there was no significant difference between the groups in the proportion of patients complaining of tenderness over either iliac crest (3.8 vs 3.6 on a 10-point scale). While 54% of patients complained
of tenderness over one or both iliac crests, only 10 patients (9% of 112) had pain over the same crest from which the graft was harvested (mean pain score of 4.4).

**Spinal Fusion**

In 2013, 2 systematic reviews on the effectiveness and harms of recombinant human bone morphogenetic protein-2 (rhBMP-2) in spine fusion were published.(6,7) These 2 systematic reviews of patient-level data followed a 2011 U.S. Senate investigation of industry influence on Infuse clinical studies and a systematic review by Carragee et al. of emerging safety concerns with rhBMP-2.(8,9) The systematic review by Carragee et al. compared conclusions regarding safety and efficacy from the 13 published rhBMP-2 industry-sponsored trials with available U.S. Food and Drug Administration (FDA) data summaries, subsequent studies, and databases. Evaluation of the original trials suggested methodologic bias against the control group in the study design (discarding local bone graft and failure to prepare facets for arthrodesis) and potential bias (overestimation of harm) in the reporting of iliac crest donor site pain. Comparison between the published studies and FDA documents revealed internal inconsistencies and adverse events that were not reported in the published articles.

Both of the 2013 studies conducted meta-analyses on individual patient data, both published and unpublished, that was provided by the manufacturer through the Yale University Open Data Access (YODA) Project. One meta-analysis was conducted by Simmonds et al. from the University of York in the United Kingdom; the other was by Fu et al. from the Oregon Health and Science University.

The meta-analysis by Simmonds et al. included patient-level data from 12 randomized controlled trials (RCTs, n=1408), regardless of spinal level or surgical approach, and adverse event data from an additional 35 observational studies.(6) rhBMP-2 increased the rate of radiographic fusion by 12% compared to ICBG, with substantial heterogeneity across trials. A small improvement in the Oswestry Disability Index (ODI, 3.5 percentage points) did not reach the previously defined threshold for a clinically significant effect. The review also found a small improvement in back pain (1 point on a 20-point scale) and Short Form-36 physical component score (PCS, 1.9 percentage points). There was no significant difference between the groups for leg pain. There was a potential for bias in the pain and functional outcomes since outcomes were patient-reported and patients were not blinded to the treatment received. Overall, the increase in successful fusion at up to 24 months did not appear to be associated with a clinically significant reduction in pain.

The meta-analysis by Fu et al. included individual-patient data from 13 RCTs (n=1981) and 31 cohort studies.(7) The review found moderate evidence of no consistent differences between rhBMP-2 and ICBG in overall success, fusion rates, or other effectiveness measures for anterior lumbar interbody fusion (ALIF) or posterolateral fusion (PLF). A small RCT and 3 cohort studies revealed no difference in effectiveness outcomes between rhBMP and ICBG for anterior cervical fusion. Reporting in the original published trials was found to be biased, with journal publications selecting analyses and results that favored rhBMP over ICBG.

Both studies found that cancer risk may be increased with rhBMP-2, although the number of events was low and there was heterogeneity in the types of cancer. In the Simmonds analysis, combined analysis revealed a relative risk of 1.84 for cancer in the BMP group, but this increased rate did not reach statistical significance (95% confidence interval [CI], 0.81 to 4.16). Fu et al. performed a combined analysis of cancer incidence at 24 months and 48 months posttreatment. At 24 months, there was a significant increase in cancer
for the BMP group (risk ratio [RR]=3.45; 95% CI, 1.98 to 6.0), and at 48 months, there was a smaller increase that did not reach statistical significance (RR=1.82; 95% CI, 0.84 to 3.95).

Other adverse events were also increased for the BMP group. Simmonds et al. found a higher incidence of early back and leg pain with rhBMP-2 in the analysis of patient-level data. The studies consistently reported increased rates of heterotopic bone formation, leg pain/radiculitis, osteolysis, and dysphagia, but combined analysis for these outcomes was not performed. The Fu study reported that BMP-2 was associated with a nonsignificantly increased risk for urogenital problems when used for anterior lumbar fusion and an increased risk for wound complications and dysphagia when used for anterior cervical spine fusion. Fu et al. documented that the information on adverse events in the published literature was incomplete in comparison to the total amount of information available.

Off-label use of BMP can include multiple levels and dosages greater than the FDA-approved dose of rhBMP-2 for single-level fusion. In 2013, Carragee et al. assessed cancer risk after high-dose rhBMP-2 (40 mg) using publicly available data from the pivotal, multicenter, randomized controlled trial of AMPLIFY (n=463). The study found an increase in the incidence of cancer, a reduction in the time to first cancer, and a greater number of patients with multiple cancers. For example, at 2 years there were 15 new cancer events in 11 patients in the rhBMP-2 group compared with 2 new cancer events in 2 patients treated with autogenous bone graft, with an incidence rate ratio of 6.75. When calculated in terms of the number of patients with one or more cancer events 2 years after surgery, the incidence rate per 100 person-years was 2.54 in the rhBMP-2 group compared with 0.50 in the control group, and the incidence rate ratio was 5.04. The mean time to development of cancer was 17.5 months after use of rhBMP-2 compared with 31.8 months in the controls. Three patients in the rhBMP-2 group and none in the control group developed multiple new cancers.

Long-Bone Fractures and Nonunions

A 2010 Cochrane review evaluated the effectiveness and costs of rhBMP on fracture healing in acute fractures and nonunions compared with standards of care. The literature was searched to October 2008, and 11 RCTs (976 participants) and 4 economic evaluations were included in the review. The times to fracture healing were comparable between the rhBMP and control groups. There was some evidence for increased healing rates, mainly for open tibial fractures without secondary procedures (RR=1.19). Three trials indicated that fewer secondary procedures were required for acute fractures treated with rhBMP (RR=0.65). The authors concluded that limited evidence suggests that rhBMP may be more effective than standard care for acute tibial fracture healing; however, the use of rhBMP for treating nonunion remains unclear (RR=1.02).

In 2014, Lyon et al reported a manufacturer-funded randomized double-blind trial of injectable rhBMP-2 in a calcium phosphate matrix for closed tibial diaphyseal fractures. The study had a target enrollment of 600 patients but was stopped after interim analysis with 387 patients enrolled. Addition of the injectable rhBMP-2 paste to the standard of reamed intramedullary nail fixation did not shorten the time to fracture healing, resulting in the study termination due to futility.

Oral and Maxillofacial Procedures

A 2010 AHRQ technology assessment on the state of the evidence of on-label and off-label use of rhBMP(13) included the following conclusions:
- The strength of the body of evidence on clinical outcomes is moderate that rhBMP-2 does not provide an advantage in prosthesis implantation and functional loading compared to autograft plus allograft bone.

- There is moderate evidence that oral sensory loss associated with autograft bone harvest can be avoided by use of rhBMP-2.

Through April 30, 2011, the FDA’s Manufacturer and User Facility Device Experience (MAUDE) received 83 reports of adverse events involving rhBMP-2 in oral and maxillofacial operations. rhBMP-2 was used off-label in 66.3% of these cases and included reconstruction of the mandible after fracture or cancer and alveolar cleft repair. The most frequently reported adverse events were local edema/pain, surgical site infections/wound complications, and graft failure.

Overall, the evidence does not support a health benefit of rhBMP in oral and maxillofacial procedures.

Additional Applications

There has been research interest in the following applications: management of early stages of osteonecrosis of the vascular head, as an adjunct to hip arthroplasty to restore bone defects in the acetabulum or femoral shaft, and as an adjunct to distraction osteogenesis (i.e., Ilizarov procedure). The literature regarding these applications consists of small case series; no controlled trials have been identified.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov in July 2013 identified several ongoing studies. Of particular interest is an industry-sponsored Phase II randomized controlled dose-finding study of intra-articular BMP-7 for osteoarthritis of the knee (NCT01111045). The study lists an enrollment of 355 subjects and is described as completed as of January 2012. As of October 2014, no publications from this study have been identified.

Summary

In 2013, 2 systematic reviews on recombinant human bone morphogenetic protein-2 (rhBMP-2) that used manufacturer-provided individual patient data were published. Overall, these systematic reviews found little to no benefit of rhBMP-2 over iliac crest bone graft for spinal fusion, with an uncertain risk of harm. The small benefits reported do not support the widespread use of rhBMP-2, but do leave the possibility that rhBMP-2 may lead to clinically significant improvements in selected subgroups, such as patients in whom use of iliac crest bone graft (ICBG) is unfeasible and have a high risk of fusion failure. While there was a low adverse event rate overall, concerns remain about the possibility of increased adverse event rates with rhBMP-2, including cancer. Based on this new evidence, it is not possible to conclude that the small benefits of rhBMP-2 outweigh the risks. Therefore, rhBMP-2 is considered to be not medically necessary when use of ICBG is feasible. In cases where use of ICBG is not feasible, such as when previous bone harvest has been performed, the benefit of rhBMP in promoting fusion will likely outweigh the adverse effects, and therefore rhBMP-2 may be considered medically necessary.

The U.S. Food and Drug Administration’s humanitarian device exemptions (HDE) for rhBMP-7 state that use is restricted to patients in whom autologous bone and bone marrow harvest are not feasible or are not expected to promote to promote fusion. Therefore, the policy on rhBMP-7 remains unchanged. As of 2014, rhBMP-7 is no longer marketed in the United States.
Use of rhBMP has not been shown to be as beneficial as the established alternative (ICBG) and evidence is insufficient to permit conclusions concerning the effect of rhBMP for other indications, including but not limited to:

- Cervical spinal fusion
- Posterior or transforaminal lumbar interbody spinal fusion (this is considered investigational because of safety concerns related to ectopic bone formation in the spinal canal);
- Treatment of noninstrumented posterolateral intertransverse spinal fusion when autograft is feasible and expected to promote fusion;
- As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries.

**Practice Guidelines and Position Statements**

Guidelines on lumbar spinal fusion from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons were updated in 2014.(17) AANS/CNS gave a Grade B recommendation (multiple level II studies) for the use of rhBMP-2 as a substitute for autologous iliac crest bone for anterior lumbar interbody fusion and single-level posterolateral instrumented fusion. Grade C recommendations were made for rhBMP-2 as an option for PLIF and TLIF, posterolateral fusion in patients older than 60 years, and as a graft extender for either instrumented or noninstrumented posterolateral fusions. AANS/CNS also gave a Grade C recommendation (based on multiple level IV and V studies) that the use of rhBMP-2 as a graft option has been associated with a unique constellation of complications of which the surgeon should be aware when considering the use of this graft extender/substitute.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force has not addressed the use of bone morphogenetic protein. None identified.

**Medicare National Coverage**

The Centers for Medicare and Medicaid Services (CMS) has established an add-on to the diagnosis-related group (DRG) payment to cover a portion of the cost of new technologies during the 2-year period before charge data for the technologies are incorporated into the DRG weights. To qualify, a technology must be new, must provide verifiable improvement in the treatment or diagnosis of beneficiaries, and the mean standardized charge for treatment using the new technology must be at least 1 standard deviation above the mean standardized charge for treating the same case without the new technology. In 2004, CMS concluded that the InFUSE™ Bone Graft/LT-CAGE met these criteria and will receive an add-on payment to DRGs 497 or 498. Medtronic, the manufacturer of the InFUSE device, has applied for a new technology add-on payment for the FDA-approved indication of treatment of open acute fractures of the tibial shaft.

**References**


**Documentation Required for Clinical Review**

History and physical and/or consultation report(s) including:

- Description of the patient’s current condition and treatment plan
• Duration and degree of illness or injury
• Progress notes pertaining to request (if applicable)
• Proposed procedure(s), type of rhBMP product, medical device/implants (if applicable) and rationale for treatment
• Summary of past failed treatments and treatment duration (conservative (non-operative) treatments or other surgical interventions)

Post Service
• Operative report(s)
• Product (rhBMP etc.) invoice

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/NMN

The following services may be considered medically necessary when policy criteria are met. Services are considered not medically necessary when policy criteria are not met.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>20930</td>
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<td>81.30 – 81.39</td>
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<td>84.52</td>
<td>Insertion of recombinant bone morphogenetic protein rhBMP via collagen sponge, coral, ceramic or other carriers</td>
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Medical Policy

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
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<td>3/1/2005</td>
<td>New policy MPC reviewed and accepted CTAF February 2005 technology review.</td>
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<td>10/15/2007</td>
<td>Policy revision without position change Policy updated BCBSA MPP (07/07).</td>
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<td>4/3/2009</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.
**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.