MASSACHUSETTS

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Medical Policy

Bone Morphogenetic Protein

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Policy Number: 097

BCBSA Reference Number: 7.01.100

Related Policies

- Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions, #186
- Ultrasound Accelerated Fracture Healing Device, #497
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #499
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures, #498

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Use of recombinant human bone morphogenetic protein-2 (rhBMP-2, InFUSE) may be considered **MEDICALLY NECESSARY** in skeletally mature patients:

- 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:

- As an alternative to autograft in compromised patients (eg, 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).

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

	Outpatient
Commercial Managed Care (HMO and POS)	Yes
Commercial PPO and Indemnity	No
Medicare HMO Blue℠	Yes
Medicare PPO Blue℠	No

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
20930	Allograft, morselized, or placement of osteopromotive material, for **spine** surgery **only** (Report in addition to the primary spinal fusion procedure)

ICD-9 Procedure Codes

When the following ICD 9 procedure codes are associated with the service(s) described in this document coverage for the service(s) is aligned with the policy statement.

ICD-9-CM procedure codes:	Code Description
84.52	Insertion of recombinant bone morphogenetic protein

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
3E0V0GB	Introduction of Recombinant Bone Morphogenetic Protein into Bones, Open Approach

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.

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. 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; ALIF), lateral (XLIF), or posterior direction (PLIF or TLIF). Surgical procedures may include decompression of the spinal canal and insertion of pedicle screws and rods to increase stability of the spine.

Posterior approaches (PLIF 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 posterolateral intertransverse fusion (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., radiculopathies). Increased risk of bone resorption around rhBMP grafts, heterotopic bone formation, epidural cyst formation, and seromas has also been postulated.

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.
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.

Policy History

Date	Action
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	BCBSA National medical policy review. One FDA-approved indication that had been omitted re-inserted: treatment of tibial

	shaft with BMP-2 (when autograft is unfeasible added); return to use of FDA language regarding treatment of noninstrumented revision posterolateral intertransverse lumbar spinal fusion with BMP-7 where use of autograft is unfeasible. Effective 4/1/2014.
3/2014	BCBSA National medical policy review. New medically and not medically necessary indications described. Effective 3/1/2014.
1/2014	Coding information clarified
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed - Medical Policy Group – Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group – Neurology and Neurosurgery. No changes to policy statements.
12/2010	BCBS Association National Policy Review No changes to policy statements.
7/2010	Reviewed - Medical Policy Group – Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
1/2010	Reviewed - Medical Policy Group – Neurology and Neurosurgery. No changes to policy statements.
1/2010 2/01/2010	BCBS Association National Policy Review. Covered indications for bone morphogenetic protein-2 clarified; bone morphogenetic protein-7 is now covered based on the indications in this policy, effective 2/1/2010.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine, and Rheumatology. No changes to policy statements.
5/1/ 2009	Medical Policy #097 effective 5/1/2009 created.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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13. Valentin-Opran A, Wozney J, Csimma C et al. Clinical evaluation of recombinant human bone morphogenetic protein-2. Clin Orthop Relat Res 2002; 395:110-20.
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