MASSACHUSETTS

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Medical Policy

Bone Morphogenetic Protein

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Policy Number: 097

BCBSA Reference Number: 7.01.100
NCD/LCD: N/A

Related Policies

- 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 the use of autograft is not feasible.
- For instrumented posterolateral intertransverse spinal fusion procedures when the use of autograft is not feasible.
- For the treatment of acute, open fracture of the tibial shaft, when the use of autograft is not feasible.

Use of recombinant human bone morphogenetic protein (rhBMP-2) is considered **NOT MEDICALLY NECESSARY** for all other indications, including but not limited to spinal fusion when the use of autograft is feasible and craniomaxillofacial surgery.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.

Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue[SM]	Prior authorization is **required**.
Medicare PPO Blue[SM]	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

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.

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

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

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-10 Procedure Codes

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

Description

Bone Morphogenetic Protein and Carrier and Delivery Systems

Bone morphogenetic proteins are members of the transforming growth factors family. At present, some 20 bone morphogenetic proteins have been identified, all with varying degrees of tissue-stimulating properties.

The recombinant human bone morphogenetic proteins (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, 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 provide mechanical support.

Applications

The carrier and delivery system are important variables in the clinical use of rhBMPs, and different clinical applications (eg, long-bone nonunion, 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), while rhBMP in a collagen sponge with bone dowels or interbody cages are used for interbody spinal fusion. Also, interbody fusion of the lumbar spine can be approached from an anterior (anterior lumbar interbody fusion), lateral, or posterior direction (posterior lumbar interbody fusion or transforaminal lumbar interbody fusion; see Appendix). Surgical procedures may include decompression of the spinal canal and insertion of pedicle screws and rods to increase the stability of the spine.

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

Summary

Two recombinant human bone morphogenetic proteins (rhBMPs) have been extensively studied: rhBMP-2, applied with an absorbable collagen sponge (Infuse), and rhBMP-7, applied in putty (OP-1). These protein products have been investigated as alternatives 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.

For individuals who are undergoing anterior or posterolateral lumbar spinal fusion and in whom autograft is not feasible who receive rhBMP, the evidence includes randomized controlled trials, systematic reviews, and meta-analyses. The relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. In 2013, 2 systematic reviews of rhBMP-2 trials using manufacturer-provided individual patient-level data were published. Overall, these reviews found little to no benefit of rhBMP-2 over iliac crest bone graft for all patients undergoing spinal fusion, with an uncertain risk of harm. The small benefits reported do not support the widespread use of rhBMP-2 as an alternative to iliac crest autograft. However, the studies do establish that rhBMP-2 has efficacy in promoting bone fusion and will improve outcomes for patients for whom use of iliac crest bone graft is not feasible. The overall adverse event rate was low, though concerns remain about increased adverse event rates with rhBMP-2, including cancer. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing surgery for acute tibial shaft fracture and in whom autograft is not feasible who receive rhBMP, the evidence includes randomized controlled trials and systematic reviews of the randomized controlled trials. The relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Two systematic reviews have concluded that rhBMP can reduce reoperations rates compared with soft-tissue management with or without intramedullary nailing. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals undergoing other surgical procedures (eg, oral and maxillofacial, hip arthroplasty, distraction osteogenesis) who receive rhBMP, the evidence includes a health technology assessment and small case series. The relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The evidence does not permit conclusions about the effect of rhBMP for craniomaxillofacial surgery or tibial shaft fracture nonunion. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2018	New references added from BCBSA National medical policy. Summary clarified.
3/2018	BCBSA National medical policy review. The term “unfeasible” clarified to “not feasible” in the medically necessary statement. The not medically necessary statement was revised to add craniomaxillofacial surgery. Clarified coding information. Effective 3/1/2018.
9/2016	BCBSA National medical policy review.

	FDA approval for rhBMP-2 in oblique lateral interbody fusion added; rhBMP-7 removed from policy statements. Effective 9/1/2016
9/2015	Added coding language.
12/2014	New references added from BCBSA National medical policy.
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. Eeffective 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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