Medical Policy
Bone Morphogenetic Protein

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Policy Number: 097
BCBSA Reference Number: 7.01.100
NCD/LCD: N/A

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 BlueSM and Medicare PPO BlueSM 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.

Bone morphogenetic protein (rhBMP-2 is considered NOT MEDICALLY NECESSARY for all other indications, including but not limited to spinal fusion when use of autograft is feasible.

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.
N/A indicates that this service is primarily performed in an inpatient setting.

| Commercial Managed Care (HMO and POS) | Yes |
Commercial PPO and Indemnity | No
Medicare HMO BlueSM | Yes
Medicare PPO BlueSM | No

**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**

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>20930</td>
<td>Allograft, morselized, or placement of osteopromotive material, for <strong>spine</strong> surgery only (Report in addition to the primary spinal fusion procedure)</td>
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**ICD-9 Procedure Codes**

<table>
<thead>
<tr>
<th>ICD-9-CM procedure codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>84.52</td>
<td>Insertion of recombinant bone morphogenetic protein</td>
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**ICD-10 Procedure Codes**

<table>
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<tr>
<th>ICD-10-PCS procedure codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>3E0V0GB</td>
<td>Introduction of Recombinant Bone Morphogenetic Protein into Bones, Open Approach</td>
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**Description**

Bone morphogenetic proteins (BMPs) are members of the transforming growth factors family. At present, some 20 BMPs 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.

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 [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 transforaminal lumbar interbody fusion).
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, TLIF) 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 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 (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 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.

The evidence for rhBMP in individuals who are undergoing anterior or posterolateral lumbar spinal fusion and in whom autograft is not feasible includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. In 2013, 2 systematic reviews of rhBMP-2 trials 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 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 rate of adverse events was a low, though concerns remain about increased adverse event rates with rhBMP-2, including cancer. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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

Use of rhBMP has not been shown to be as beneficial as the established alternative and evidence is insufficient to permit conclusions about the effect of rhBMP for all other indications including:

- Tibial shaft fracture nonunion
- Craniomaxillofacial surgeries.

Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>9/2016</td>
<td>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</td>
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<tr>
<td>9/2015</td>
<td>Added coding language.</td>
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<tr>
<td>12/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>5/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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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.


1/2014 Coding information clarified.


1/2010 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.


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


