Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

**Definition:** Bone morphogenetic proteins (BMPs) are a family of small molecule growth factors responsible for inducing bone and cartilage formation for fracture healing and musculoskeletal tissue repair. Bone morphogenetic proteins have been investigated as an alternative to autologous bone grafting in orthopedic procedures. Reported advantages of bone morphogenetic proteins include elimination of the additional incision site and pain and morbidity associated with bone graft (autograft) harvesting. Recombinant human bone morphogenetic protein-2 (rhBMP-2) has been approved by the U.S. Food and Drug Administration (FDA) and is available commercially.

Recombinant human bone morphogenetic protein-2 (InFUSE Bone Graft, Medtronic Sofamor Danek) utilized in combination with approved interbody fusion devices (e.g., Inter Fix Threaded Fusion Device, Medtronic Titanium Threaded Interbody Fusion Device, and LT-CAGE Lumbar Tapered Fusion Device) is intended for use in spinal fusion procedures via an anterior open or laparoscopic approach in skeletally mature individuals with single level (L2 to S1) degenerative disc disease. Although published literature is limited, as of December 2015, Infuse Bone Graft was also FDA approved for use with the Clydesdale Spinal System, which can be inserted via an oblique lateral interbody approach for a single level fusion from L2 to L5 and the Perimeter Interbody Fusion Device, which can be place at one or two contiguous levels from L2 to S1, via an anterior, lateral, or oblique approach. Recombinant human bone morphogenetic protein-2 may also be utilized for treatment of open tibial fractures, sinus augmentation, and localized alveolar ridge for extraction socket defects as an alternative to bone grafting.

**Medical Necessity:**

I. **Recombinant human bone morphogenetic protein-2 (Infuse Bone Graft):** The Company considers Infuse Bone Graft (CPT Codes 22899, 27899 and applicable ICD-10-PCS Code(s) medically necessary and eligible for reimbursement providing that at least one of the following medical criteria is met:

- Spinal fusion in skeletally mature individual with single level (L4 to S1) degenerative disc disease and all of the following:
  1. Spondylolisthesis ≤ Grade 1 at the involved level; and
  2. Back pain refractory to ≥ 6 months of conventional medical therapy; and
  3. Treatment will be used in conjunction with an interbody fusion device approved for use with Infuse Bone Graft; and
  4. Implantation will be performed via an anterior lumbar interbody fusion approach; and
5. Autograft is not feasible due to at least one of the following:
   
   a. Previous autograft failure and not a candidate for additional autografting because the tissue
      is no longer available; or
   
   b. Insufficient autogenous tissue for autografting; or
   
   c. Poor candidate for autografting due to at least one (including, but not limited to) of the
      following:
         i. Age ≥ 65 years; or
         ii. Obesity; or
         iii. Concurrent medical condition(s) (e.g., fracture, infection) prevents harvesting
             at autograft donor site; or
         iv. Poor bone quality (e.g., osteoporosis); or
         v. Underlying comorbidities (e.g., diabetes, smoking) increase autograft
            associated risks

   • Acute, open tibial shaft fractures and all of the following:
      
      1. Fracture stabilized with intramedullary nail fixation after appropriate wound management; and
      2. Individual is skeletally mature; and
      3. Applied within 14 days of fracture

   AND

   At least one of the following clinical conditions is present:
   
   • Other intervertebral disc degeneration, lumbar region
   • Fracture of tibia

The Company considers recombinant human bone morphogenetic protein-2 investigational and not eligible for reimbursement for all of the following:

   • Adjunct to cervical or thoracic spinal fusion procedures; or
   • Adjunct to posterior lumbar interbody fusion (PLIF), posterolateral (intertransverse) lumbar fusion (PLF),
     transforminal lumbar interbody fusion (TLIF), or oblique lateral interbody fusion (OLIF); or
   • Early stage femoral head or shaft avascular necrosis; or
   • Adjunct to distraction osteogenesis (Ilizarov procedure); or
   • Craniofacial applications including, but not limited to, periodontal defect regeneration, cleft palate repair,
     cranial defect repair, restoration and maintenance of the alveolar dental ridge.

Benefits for investigational services are subject to each specific benefit plan.

NOTE: OstopAmp, Allograpft Bone Fusion is investigational and not eligible for reimbursement.
Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for CPT Codes 22899†, 24999†, 25999†, 26989†, 27599†, 27899†, and applicable ICD-10-PCS Code(s).

†When unlisted procedure - spine (22899), unlisted procedure - humerus or elbow (24999), unlisted procedure - forearm or wrist (25999), unlisted procedure - hands or fingers (26989), unlisted procedure - femur or knee (27599), or unlisted procedure - leg or ankle (27899) is determined to be recombinant human bone morphogenetic protein-2 and protein-7.
Sources of Information:


<table>
<thead>
<tr>
<th>Applicable Code(s):</th>
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<tbody>
<tr>
<td><strong>CPT:</strong> 22899, 24999, 25999, 26989, 27599 and 27899</td>
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<tr>
<td><strong>HCPCS:</strong> N/A</td>
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<tr>
<td><strong>ICD10 Procedure Codes:</strong> 3E0U0GB, 3E0U3GB, 3E0V0GB and 3E0V3GB</td>
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