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) utilized in combination with approved interbody fusion devices (e.g., INTER FIX or INTER FIX RP Threaded Fusion Device, MedtronicTitanium Threaded Interbody Fusion Device, and LT-CAGE Lumbar Tapered Fusion Device) is intended for use in spine fusion procedures via an anterior, oblique or lateral approach in skeletally mature individuals with single level (L2 to S1) degenerative disc disease. 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 20930, 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 (L2 to S1) degenerative disc disease and all of the following:
  1. Back pain refractory to ≥ 6 months of conventional medical therapy; and
  2. Infuse bone graft will be used in conjunction with a cage; and

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3. Implantation will be performed via an anterior, oblique or lateral lumbar interbody fusion approach; and
4. Autograft is not feasible due to \textbf{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 \textbf{at least one} (including, but not limited to) of the following:
   
   i. Age $\geq 65$ 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 \textbf{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

\textbf{AND}

\textbf{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 \textbf{investigational} and \textbf{not} eligible for reimbursement for \textbf{all} of the following:

- Adjunct to cervical or thoracic spinal fusion procedures; or
- Early stage femoral head or shaft avascular necrosis; or
- Adjunct to distraction osteogenesis (Iliizarov 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, Allograft 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 20930†, 22899‡, 27899‡, and applicable ICD-10-PCS Code(s).

†When allograft, molselized, or placement of osteopromotive material, for spine surgery only (20930), unlisted procedure - spine (22899), or unlisted procedure - leg or ankle (27899) is determined to be recombinant human bone morphogenetic protein-2 and protein-7.
Sources of Information:


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### Applicable Code(s):

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<td>ICD10 Code</td>
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