Recombinant Human Bone Morphogenetic Protein
Policy Number: PG0456
Last Review: 12/09/2020

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
X Facility

DESCRIPTION
Bone morphogenetic proteins (BMP) are naturally occurring proteins found in human bone and play an active role in inducing bone and cartilage formation. There are currently fourteen BMPs that have been identified. In addition to the fourteen BMPs, there are several recombinant human bone morphogenetic proteins (rhBMPs). Currently there are only two, which have been developed for use, rhBMP-2 and rhBMP-7. An important use of rhBMP is for bone repair, especially in bones that have delayed union or nonunion of a fracture and to promote fusion of vertebrae. rhBMP also plays a role in cartilage formation and repair of other musculoskeletal tissues.

POLICY

<table>
<thead>
<tr>
<th>HMO, PPO, Individual Marketplace, Advantage</th>
<th>Elite/ProMedica Medicare Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Morphogenetic Protein-2 (rhBMP-2) requires a prior authorization as of 10/1/2019.</td>
<td>Bone Morphogenetic Protein-2 (rhBMP-2) requires a prior authorization as of 1/1/2020.</td>
</tr>
</tbody>
</table>

Bone Morphogenetic Protein-7 (BMP-7) (i.e., OP–1™) is not covered for all product lines.

COVERAGE CRITERIA
Paramount utilizes InterQual® criteria sets for medical necessity determinations. HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

Paramount will provide coverage for FDA-approved Bone Morphogenetic Proteins when it is determined to be medically necessary because the medical criteria and guidelines show below are met.

Infuse® Bone Graft, also known as Bone Morphogenetic Protein-2 (rhBMP-2), is proven and medically necessary for the enhancement of bone healing and/or fusion of the lumbar spine, single level (L2-S1) degenerative disc disease in patients who meet all of the following criteria:

- Back pain refractory to ≥ 6 months of conventional medical therapy; and
- Implanted via an anterior approach and used in conjunction with an Infuse Bone Graft fusion device

Infuse Bone Graft fusion devices include: and

- Infuse bone graft/LT-Cage
- Infuse bone graft/Lumbar Tapered Fusion Device
- Infuse bone graft/InterFix™ threaded fusion device
- Infuse bone graft/Inter Fix™ RP threaded fusion device

- Skeletally mature patient (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease at one level from L2–S1; and
- No more than Grade I spondylolisthesis at the involved level; and
- Failure of at least 6 months of non-operative treatment

Non-coverage when at least one of the following:
- Previous autograft failure and not a candidate for additional autografting because the tissue is no longer available; or
- Insufficient autogenous tissue for autografting; or
- Poor candidate for autografting due to at least one (including, but not limited to) of the following:
  - Age ≥65 years; or
  - Obesity; or
  - Concurrent medical condition(s) (e.g., fracture, infection) prevents harvesting at autograft donor site; or
  - Poor bone quality (e.g., osteoporosis); or
  - Underlying comorbidities (e.g., diabetes, smoking) increase autograft associated risks

Recombinant human bone morphogenetic protein-2 is considered experimental/investigational for the following, not all-inclusive:
- Adjunct to cervical or thoracic spinal fusion procedures; or
- Adjunct to posterior lumbar interbody fusion (PLIF), posterolateral (intertransverse) lumbar fusion (PLF), transforaminal lumbar interbody fusion (TLIF), or oblique lateral interbody fusion (OLIF); or
- Treatment of acute, open fracture of the tibial shaft when use of autograft is feasible, or
- Early stage femoral head or shaft avascular necrosis; or
- Adjunct to distraction osteogenesis (Ilizarov procedure); or
- Craniofacial surgery; 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.

Bone Morphogenetic Protein-7 (BMP-7) (i.e., OP–1™):
Paramount does not cover Bone Morphogenetic Protein-7 (BMP-7) (i.e., OP–1™) as this is considered experimental, investigational or unproven:

**Advantage**
Providers can request prior authorization to exceed coverage or benefit limits for members under age 21, Ohio Department of Medicaid.

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20930</td>
<td>Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system, general</td>
</tr>
<tr>
<td>22899</td>
<td>Unlisted procedure –spine</td>
</tr>
<tr>
<td>24999</td>
<td>Unlisted procedure-humerus or elbow</td>
</tr>
</tbody>
</table>

There is not a CPT or HPCPS code for bone morphogenetic protein. In 2011, CPT code 20930 was revised to include BMP-type materials used in spine surgery.
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</tr>
</thead>
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<tr>
<td>25999</td>
<td>Unlisted procedure-forearm or wrist</td>
</tr>
<tr>
<td>26989</td>
<td>Unlisted procedure-hands or fingers</td>
</tr>
<tr>
<td>27599</td>
<td>Unlisted procedure-femur or knee</td>
</tr>
<tr>
<td>27899</td>
<td>Unlisted procedure, leg or ankle</td>
</tr>
</tbody>
</table>

**REVISION HISTORY EXPLANATION**

**ORIGINAL EFFECTIVE DATE: 09/01/2019**

- **12/1/2019**: Updated policy to include the Elite Product requiring a prior authorization as of 1/1/2020

**REFERENCES/RESOURCES**

- Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
- Ohio Department of Medicaid
- Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
- Industry Standard Review
- Hayes, Inc.