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.

DESCRIPTION
Bone grafts may be used in the treatment of delayed fracture unions, in spinal fusions, to bridge major bone defects or fill cavities created by tumor removal, cysts or other causes. Bone graft material may come from a number of sources: the individual's own bones (autograft), a bone bank (allograft), demineralized bone matrix or bone graft substitutes, such as synthetic materials, ceramics (bone void fillers), collagen composites, composite cement materials, bone morphogenetic protein or recombinant human bone morphogenetic protein.

Autografts are considered the gold standard for bone grafting and are taken directly from the individual. The usual site for an autograft harvest is the posterior iliac crest. When autograft material is of an insufficient volume, of poor quality or cannot be used for any other reason, then another type of material must be used for the bone graft.

Allografts are obtained from cadaveric bone and/or tissue from a bone bank and may be used alone or in combination with another material. Even when used alone, allografts must be processed to decrease the likelihood of disease transmission and immunogenic response. Demineralized Bone Matrix (DBM) is a type of allograft that is produced by acid extraction of allograft bone (known as decalcification). Based on manufacturing techniques, DBM may be a freeze-dried powder, granules, gel, putty or strips.

Bone morphogenetic proteins (BMP) are naturally occurring proteins found in human bone and play an active role in bone 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>Bone graft materials that do not require prior authorization:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Autografts</td>
</tr>
<tr>
<td>- Allografts</td>
</tr>
<tr>
<td>- Demineralized bone matrix (DBM)</td>
</tr>
<tr>
<td>- Bone Morphogenetic Protein-2 (rhBMP-2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bone graft substitutes that are non-covered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Bone Morphogenetic Protein-7 (BMP-7)</td>
</tr>
<tr>
<td>- Amniotic Tissue Membrane</td>
</tr>
<tr>
<td>- Human Growth Factor Substitutes</td>
</tr>
<tr>
<td>- Platelet Rich Plasma</td>
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<tr>
<td>- Bone marrow aspirate processed to concentrate growth factors</td>
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<tr>
<td>- Bone graft substitutes containing anorganic bone material</td>
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<tr>
<td>- Allograft bone graft substitutes used exclusively as stand-alone stabilization devices for fusion</td>
</tr>
<tr>
<td>- Bone graft substitutes used to reduce donor site morbidity</td>
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<tr>
<td>- Ceramic Based Substitutes</td>
</tr>
<tr>
<td>- Beta tricalcium phosphate (b-TCP)</td>
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<tr>
<td>- Calcium Phosphate Ceramic/Bone Void Fillers</td>
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<tr>
<td>- Calcium Sulfate-Calcium Composite Ceramics/Bone Void Fillers</td>
</tr>
<tr>
<td>- Bioactive Glass</td>
</tr>
<tr>
<td>- Cell Based Substitutes</td>
</tr>
</tbody>
</table>

Refer to these medical policies for coverage determination:
Autografts are proven to be medically necessary for bone fusion enhancement. Examples include, but may not be limited to:

- Grafton
- OraGraft
- OrthoBlast
- OsteoAMP
- OsteoStrip
- TruFuse
- Vertigraft VG2

Demineralized bone matrix (DBM) is a type of allograft and is proven to be medically necessary for bone fusion enhancement. Examples include, but may not be limited to:

- 3-Denim
- Accell
- Accell Connexus
- AlloFuse DBM
- AlloMatrix
- AlphaGraft DBM
- AlphaGraft ProFuse
- Apex
- BioAdapt DBM
- BioReady DBM Putty
- BioReady DBM Putty with Chips
- BioSet DBM
- Conform DBM
- Connexus
- Connexus Putty
- DBM Pure Macro
- DBM Pure Micro
- DBX DBM
- DynaGraft II
- FUSIONFLEX
- Grafton DBM
- InterGro DBM
- Magnifuse
- Optecure
- Optecure +CCC
- Optefil
- Opteform
- Optium DBM
- Origen DBM
- OrthoBlast
- Osteofil
- OsteoSelect
- OsteoSelect DBM Putty
- OsteoSponge
- Physio
- Progenix
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 in patients who meet all of the following criteria:

- Implanted via an anterior approach and used in conjunction with an Infuse Bone Graft fusion device
  
  Infuse Bone Graft fusion devices include:
  - 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
- No more than Grade I spondylolisthesis at the involved level
- Failure of at least 6 months of non-operative treatment

Infuse® Bone Graft is proven and medically necessary as an adjunct to treatment of open fracture of the tibial shaft, which has been stabilized with intramedullary nail fixation after appropriate wound management.

NON-COVERED

Infuse® Bone Graft is unproven and not medically necessary for all other indications not listed above including but not limited to the following:

- Enhancement of bone healing and/or fusion of the lumbar spine via a posterior approach.
- Cervical or thoracic spinal fusions
- Multi-level lumbar fusion, regardless of surgical approach
- Primary treatment of closed tibial fractures
- Treatment of delayed union or nonunion of tibial fracture as part of a planned, staged reconstruction
- Craniofacial applications including sinus augmentation and/or alveolar ridge augmentation

Known contraindications including:
  - Hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation
  - Pregnancy
  - Active infection at operative site or patient has an allergy to titanium or titanium alloy
  - Active malignancy
  - Utilization in the vicinity of a resected or extant tumor
  - Compartment syndrome of the affected limb
  - Inadequate neurovascular status
  - Skeletally immature patient (younger than 18 years of age or 18 years of age or older with no radiographic evidence of epiphyseal closure)

Posterolateral or posterior lumbar interbody fusion utilizing Infuse Bone Graft has not received FDA approval. Available studies have demonstrated increased adverse events with the posterior approach. The safety and effectiveness of Infuse Bone Graft in the cervical spine have not been demonstrated. There is insufficient clinical evidence to support the use of Infuse Bone Graft with devices made of PEEK or other biocompatible materials. In addition, Infuse Bone Graft has not been approved by the FDA for use with PEEK cages.

Paramount does not cover ANY of the following bone graft substitutes because each is considered experimental, investigational or unproven:

1. Bone Morphogenetic Protein-7 (BMP-7) (i.e., OP—1™)
2. Amniotic Tissue Membrane bone graft substitute materials, including amniotic fluid stem cell substitutes
3. Human Growth Factor Substitutes (e.g., fibroblast growth factor, insulin-like growth factor)
4. Platelet rich plasma (e.g., autologous platelet derived growth factor)
5. Bone marrow aspirate processed to concentrate growth factors (e.g., concentrated bone marrow aspirate, centrifuged bone marrow aspirate), used alone or in combination with other bone graft materials (e.g., allograft)
6. Bone graft substitutes containing anorganic bone material (e.g., bovine, coral) when combined with any non-covered bone graft substitute
7. Allograft bone graft substitutes used exclusively as stand-alone stabilization devices for fusion (e.g., TruFuse® for isolated facet fusion, NuFix™ for isolated facet fusion, BacFast® HD for isolated facet fusion)

8. Bone graft substitutes used to reduce donor site morbidity (e.g., iliac crest donor site reconstruction)

9. Ceramic Based Substitutes
   Examples include, but may not be limited to:
   a. Beta tricalcium phosphate (b-TCP)
      • Conduit TCP Granules
      • FM-O2
      • Formagraft Bone Graft
      • GenerOs
      • GranOS
      • Integra Mozaik
      • Integra OS
      • Osteoconductive Scaffold
      • OsSatura TCP
      • Osteomatrix
      • Synthes ChronOS
      • Vitoss
      • Vitoss Bioactive Foam-2X
   b. Calcium Phosphate Ceramic/Bone Void Fillers
      • AccuFill bone substitute material for knee, ankle, hip or shoulder subchondroplasty
      • BoneSave
      • BoneSource BVF
      • Bonext
      • Callos Bone Void Filler
      • HydroSet
      • Norian Drillable
      • Norian SRS
      • Skaffold NMX
   c. Calcium Sulfate-Calcium Composite Ceramics/Bone Void Fillers
      • Actifuse
      • Cem-Ostetic
      • OsteoSet
      • OsteoVation QWIK
      • Plexur M
      • Plexur P
      • PolyGraft
      • ProOsteon 500R
      • Pro-Dense
      • Skaffold ReNu Flow
      • Stimulan
      • TruFit bone plugs
      • TruRepair

10. Bioactive glass
    Examples include, but may not be limited to:
    • BioSphere Putty Bioactive Bone Graft
    • BonAlive
    • CLM Bioative Scaffold
    • FIBERGRAFT BG Morsels
    • Interface
    • NanoFUSE
    • NovaBone
    • NovaBone BIOACTIVE Strip
    • NovaBone-C/M
    • PerioGlas
    • Signify Bioactive

11. Cell Based Substitutes (e.g., mesenchymal stem cells used alone, added to other biomaterials for grafting, or seeded onto scaffolds)
    Examples include, but may not be limited to:
    • Aminovo
    • AmnioFix
    • AmnioPro-A
    • Axograft Dual Layer Amniotic Membrane
    • Bio4 Viable Bone Matrix
- BioDfactor
- BioDFence
- BioD Dry Flex
- Cellentra VCBM
- Cygnus
- NuCel
- OrthoFlo
- Osteocel
- Osteocel Plus
- OsteoVive
- Ovation cellular repair matrix
- Ovation OS
- PalinGen
- PalinGen Flow
- Regenexx
- Trinity Elite
- Trinity Evolution
- Viaflow
- Viaflow C

**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>20900</td>
<td>Bone graft, any donor area; minor or small (eg, dowel or button)</td>
</tr>
<tr>
<td>20902</td>
<td>Bone graft, any donor area; major or large</td>
</tr>
<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>20931</td>
<td>Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>20936</td>
<td>Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>20937</td>
<td>Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (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>27899</td>
<td>Unlisted procedure, leg or ankle</td>
</tr>
</tbody>
</table>

**TAWG REVIEW DATES:** 07/22/2016, 10/25/2018

**REVISION HISTORY EXPLANATION**

**07/22/16:** Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

**10/25/18:** Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.