Medical Policy

Bone Graft Substitutes

Policy Number: PG0365
Last Reviewed Date: 04/01/2025
Last Revised: 04/01/2025

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Bone grafts are used to repair and rebuild damaged bones in knees, hips, spine and other problem areas. Bone graft materials can be obtained from several different sources. Autografts are considered the standard graft material and are harvested from the patient. Allografts are obtained from cadaveric bone and avoid complications associated with an additional surgery to harvest bone material. Demineralized bone matrix (DBM) is allograft bone that has been processed to retain mainly the collagen and other important bone growth factors and is often used as an osteoconductive scaffold. Other sources of bone graft and bone graft substitutes include cell-based graft substitutes, synthetic substitutes, and factor-based substitutes.

Recombinant bone morphogenic proteins (rhBMP) are an example of a factor-based bone graft substitute. rhBMPs are a family of small molecule growth factors responsible for inducing bone and cartilage formation for fracture healing and musculoskeletal tissue repair. Recombinant human bone morphogenetic protein-2 (rhBMP-2) has been approved by the U.S. Food and Drug Administration (FDA) as an alternative to autologous bone grafting in orthopedic procedures and is available commercially. rhBMP-2 (InFUSE Bone Graft) utilized in combination with approved interbody fusion devices (e.g., INTER FIX or INTER FIX RP 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, 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.

Bone grafts are used in a variety of surgical procedures including the repair of non-healing fractures, bone defects due to infection, trauma, and other abnormalities as well as joint problems. A common use of bone grafts is in spinal fusion procedures. Spinal fusion is a surgical procedure to join two or more vertebrae into one single structure and thus eliminate movement between them. This is often performed to treat degenerative conditions of the spine due to deformities, trauma or infection.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Bone graft materials that do not require prior authorization:

- **Autografts**
- **Allografts**
- **Demineralized bone matrix (DBM)**

Requires a prior authorization

- **Bone Morphogenetic Protein-2 (rhBMP-2) [INFUSE Bone Graft/LT-CAGE Lumbar Tampered Fusion Device (with titanium cage) (rhBMP-2)]**

Bone graft substitutes that are non-covered, not an all-inclusive listing:

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

COVERAGE CRITERIA:

<u>Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans</u>

Paramount considers the following bone graft materials medically necessary and eligible for reimbursement:

- Autografts including bone marrow aspirate
- Allografts including demineralized bone matrix (DBM)
- Recombinant human bone morphogenetic protein-2 (Infuse Bone Graft) when at least one of the following medical criteria are 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
    3. Implantation will be performed via an anterior, oblique or lateral lumbar interbody fusion approach; and
    4. 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

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

Paramount considers recombinant human bone morphogenetic protein-2 experimental/investigational and not eligible for reimbursement 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 (Iliazarov procedure); or
- Craniomaxillofacial 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.
- Used for any other indications not included above

NOT COVERED

Paramount does not cover the following bone graft substitutes because each is considered experimental/investigational, not an all-inclusive listing:

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
10. Bioactive glass
11. Cell Based Substitutes (e.g., mesenchymal stem cells used alone, added to other biomaterials for grafting, or seeded onto scaffolds)

12. Surgical mesh composed of porcine intestinal submucosa for rotator cuff repair surgery, repair of anorectal fistula, and for other indications

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.

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 07/22/2016

Date	Explanation & Changes
07/22/2016	• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/25/2018	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
07/25/2019	• Policy updated to indicate Recombinant Human Bone Morphogenetic 4 protein is now addressed in Medical Policy PG0456 and as of 9/1/2019 requires a prior authorization Per Administrative Directive • Per ODM requirement additional documentation = Providers can request prior authorization to exceed coverage or benefit limits for members under age 21, Ohio Department of Medicaid
12/22/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/28/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Added medical policy PG0456 Recombinant Human Bone Morphogenetic Protein to this policy • Added noncovered procedure code 0814T
04/01/2025	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Removed related medical policies • Added prior authorization requirement for code 20931, effective 7/1/2025

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to
https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits
U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review