



PARAMOUNT

ADVANTAGE | ELITE | HMO
INDIVIDUAL MARKETPLACE |
PROMEDICA MEDICARE
PLAN | PPO

Bone Graft Substitutes

Policy Number: PG0365
Last Review: 10/25/2018

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

Professional
 Facility

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. Refer to Medical Policy PG0456.

POLICY

Bone graft materials that do not require prior authorization:

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

Requires a prior authorization as of 9/1/2019, Refer to Medical Policy PG0456.

- **Bone Morphogenetic Protein-2 (rhBMP-2)**

Bone graft substitutes that are non-covered:

- **Bone Morphogenetic Protein-7 (BMP-7), Refer to Medical Policy PG0456.**

- **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**

Refer to these medical policies for coverage determination:

- **PG0190 Chondrocyte Implantation of the Knee**
- **PG0203 Skin Substitutes and Wound Repair Procedures**
- **PG0293 Platelet Rich Plasma**
- **PG0400 Stem Cell Therapy for Orthopedic Applications**

COVERAGE CRITERIA

HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage

COVERED

Autografts are proven to be medically necessary for bone fusion enhancement.

Allografts 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

- DBMPure Macro
- DBMPure 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
- Puros DBM
- StimuBlast
- ViviGen
- Vesuvius Demineralized Fibers
- Xemplifi DBM

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™). Refer to Medical Policy PG0456
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 Bioactive 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

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.

| CPT CODES | |
|-----------|--|
| 20900 | Bone graft, any donor area; minor or small (eg, dowel or button) |
| 20902 | Bone graft, any donor area; major or large |
| 20930 | Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure) |
| 20931 | Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure) |
| 20936 | Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or lamina fragments) obtained from same incision (List separately in addition to code for primary procedure) |
| 20937 | 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) |
| 20999 | Unlisted procedure, musculoskeletal system, general |
| 27899 | Unlisted procedure, leg or ankle |

REVISION HISTORY EXPLANATION

ORIGINAL EFFECTIVE DATE: 07/22/2016

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).

07/25/19: Policy updated to indicate Recombinant Human Bone Morphogenetic 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

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

Industry Standard Review

Hayes, Inc.