Bone Graft Substitutes

Humana®

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Medical Coverage Policy

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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: autograft (the individual's own bones), allograft (a bone bank), 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.

Autograft
Autograft is considered the gold standard for bone grafting and is 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, another type of material must be used for the bone graft. ***In the context of this policy, blood products (including platelets) and bone marrow aspirate (including mesenchymal stem cells) are NOT considered autograft materials.***

Allograft

Allograft is 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, allograft must be processed to decrease the likelihood of disease transmission and immunogenic response. ***In the context of this policy, amniotic membrane/placental membrane, blood products (including platelets) and bone marrow aspirate (including mesenchymal stem cells) are NOT considered allograft materials.***

Bone Morphogenetic Proteins and Recombinant Human Bone Morphogenetic Proteins

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.[123] 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 (it should be noted, however, that rhBMP-7 is no longer marketed or available in the United States). The only rhBMP-2 product with Food & Drug Administration (FDA) approval is the **Infuse Bone Graft**.[159]

rhBMPs serve as alternatives or adjuncts to autologous bone grafts (autografts). They are intended to promote bone formation and enhance fracture healing[126] or may be used in spinal fusion surgery for degenerative disease to promote bone growth that results in fusion.[123] These proteins may also be used for an individual who has up to grade I spondylolisthesis. rhBMPs have been proven safe in L2 (second lumbar vertebra) through S1 (sacral) levels of the spine. Severe life threatening complications have been associated with cervical spine use.[123] Another major application of bone grafting with rhBMP is for bone repair, especially for treatment of delayed union of tibial fractures.[126] rhBMP also plays a role in cartilage formation and repair of other musculoskeletal tissues.

For maximal skeletal formation (healing) the rhBMP is used with a suitable carrier to ensure it stays in the repair area. One of the most common carriers is a collagen sponge.

Ceramics/Bone Void Fillers

Ceramics are synthetically produced bone void fillers. As a conductive technology, ceramics are synthetic materials resulting from heating up chemically formed compounds that consequently bond together. There are many different methods to produce ceramics and numerous chemical compounds that can be combined, including calcium phosphate, calcium sulfate-calcium composite, beta tricalcium phosphate or nanocrystalline hydroxyapatite. **(Refer to Coverage Limitations section regarding beta tricalcium phosphate and nanocrystalline hydroxyapatite)**

Demineralized Bone Matrix

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.

Combination Bone Graft Substitutes

Another practice in bone graft substitutes is the combination of different materials to produce a completely different product, with the theory that each different property working together will aid in the healing and grafting process. **This classification (combination bone graft substitutes) does not refer to the practice of combining *autograft* or *allograft bone* with a bone void filler or DBM, but rather combining different bone graft *substitute products*. (Refer to Coverage Limitations section)**

Coverage Determination

Humana members may be eligible under the Plan for the following **bone graft materials/bone graft substitute products** when criteria are met ***AND*** utilized according to the FDA-approved marketing label indications effective on the date of service:

- Autograft for enhancement of bone healing; **AND**
- Allograft for enhancement of bone healing; **AND**
- Calcium phosphate ceramic/bone void fillers for enhancement of bone healing; **AND**
- Calcium sulfate-calcium composite ceramics/bone void fillers for enhancement of bone healing; **AND**
- Demineralized bone matrix (DBM) for enhancement of bone healing; **AND**
- Recombinant human bone morphogenetic proteins (rhBMP-2) for primary treatment of open tibial fractures when the following requirements are met[159]:
    - Following stabilization with intramedullary nail fixation, within 14 days after the initial fracture; **AND**
    - Individual is skeletally mature (at least 18 years of age or radiographic evidence of epiphyseal closure[159]); **AND**
    - Absence of the following contraindications[159]:
        - Active infection at the operative site
        - Active malignancy or individuals undergoing treatment for a malignancy
        - Compartment syndrome of the affected limb
        - Inadequate neurovascular status
        - Known hypersensitivity to bovine Type I collagen, rhBMP-2 or other components of the formulation
        - Pregnancy

  - Utilization in the vicinity of a resected or extant tumor; **AND**

- rhBMP-2 for *SINGLE-LEVEL **lumbar*** spinal surgery when the following requirements are met[160]:
  - Skeletally mature individuals (at least 18 years of age or radiographic evidence of epiphyseal closure[160]) with degenerative disc disease at one level of the lumbar spine; **AND**
  - **MUST** be used with 1 of the 7 cages *approved for use by the FDA*; **AND**
  - Utilize the surgical approach as indicated by the FDA approval; **AND**
  - Absence of the following contraindications[160]:
    - Active infection at the operative site
    - Allergy to titanium or titanium alloy
    - Known hypersensitivity to bovine Type I collagen, rhBMP-2 or other components of the formulation
    - Pregnancy
    - Utilization in the vicinity of a resected or extant tumor

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the use of **rhBMP-2** for any other indication not listed in the Coverage Determination section, which includes, but may not be limited to:

- *Cervical* spinal fusion; **OR**
- Combined with a carrier other than collagen or with a fusion device other than a cage; **OR**
- Craniofacial applications including sinus augmentation and/or alveolar ridge augmentation; **OR**
- *Multilevel* lumbar fusion, regardless of surgical approach; **OR**
- Nonanterior or nonoblique lateral interbody fusion approaches to lumbar fusion; **OR**
- Primary treatment of closed tibial fractures; **OR**
- *Thoracic* spinal fusion; **OR**
- Treatment of delayed union or nonunion of tibial fracture as part of a planned, staged reconstruction; **OR**

- Use of rhBMP-2 with *non-FDA* approved spinal cages

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for use of **any of the following bone graft substitute products** for *ANY* indication:

- Autologous blood product injection (eg, red blood cells [RBC], white blood cells [WBC], whole blood); **OR**
- Beta tricalcium phosphate bone void filler; **OR**
- Bioactive glass; **OR**
- Bone marrow aspirate (BMA) (mixing an individual's bone marrow aspirate with the bone graft substitute; or injection of BMA into a joint, intervertebral disc, ligament/tendon or other structure) for any indication including:
    - As an adjunct to a spinal fusion; **OR**
    - Bone cysts; **OR**
    - Degenerative disc disease; **OR**
    - Nonunion fractures; **OR**
    - Osteoarthritis; **OR**
    - Repair or regeneration of musculoskeletal tissue (including intervertebral disc); **OR**
    - When mixed with any bone graft substitute product; **OR**
- Cell-based substitute products; **OR**
- Combination products:
    - Beta tricalcium phosphate combined with bioactive glass; **OR**
    - Beta tricalcium phosphate combined with bioactive glass and hydroxyapatite; **OR**
    - Beta tricalcium phosphate combined with human platelet derived growth factor (rhPDGF); **OR**
    - Beta tricalcium phosphate combined with calcium sulfate; **OR**
    - Beta tricalcium phosphate combined with hydroxyapatite (also referred to as biphasic calcium phosphate); **OR**
    - Beta tricalcium phosphate combined with magnesium oxide; **OR**

  - Bioactive glass combined with carbonate apatite anorganic bone mineral and Type 1 collagen; **OR**
  - Bioactive glass combined with hyaluronic acid and collagen; **OR**
  - Calcium phosphate combined with hyaluronic acid; **OR**
  - Combination polymer (PLGA) with hyaluronic acid; **OR**
  - DBM combined with bioactive glass; **OR**
  - DBM combined with calcium sulfate; **OR**
  - DBM combined with ceramic bone void filler; **OR**
  - DBM combined with nanocrystalline hydroxyapatite; **OR**
  - Hydroxyapatite combined with beta tricalcium phosphate, bioactive glass and alpha tricalcium phosphate (may also be referred to as quadphasic synthetic bone graft); **OR**
  - Hydroxyapatite combined with calcium carbonate; **OR**
  - Hydroxyapatite combined with calcium sulfate; **OR**
  - Nanocrystalline hydroxycarbonoapatite combined with calcium carbonate; **OR**
  - rhBMP-2 combined with beta tricalcium phosphate and hydroxyapatite; **OR**
- Nanocrystalline hydroxyapatite; **OR**
- Peptide enhanced (P-15) bone graft; **OR**
- Platelet rich plasma (PRP) for any indication including, but may not be limited to:
  - Bone healing and fusion; **OR**
  - Joint pain or repair; **OR**
  - Ligament or tendon injuries; **OR**
  - Osteoarthritis; **OR**
  - Soft tissue injuries; **OR**
  - Used in combination with ANY bone graft substitute product; **OR**
- Products that MUST be mixed with bone marrow aspirate

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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 laminar 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)	
20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)	**Not Covered**
20955	Bone graft with microvascular anastomosis; fibula	
20956	Bone graft with microvascular anastomosis; iliac crest	
20957	Bone graft with microvascular anastomosis; metatarsal	
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	
20999	Unlisted procedure, musculoskeletal system, general	
23145	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with autograft (includes obtaining graft)	

23146	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with allograft	
23155	Excision or curettage of bone cyst or benign tumor of proximal humerus; with autograft (includes obtaining graft)	
23156	Excision or curettage of bone cyst or benign tumor of proximal humerus; with allograft	
24115	Excision or curettage of bone cyst or benign tumor, humerus; with autograft (includes obtaining graft)	
24116	Excision or curettage of bone cyst or benign tumor, humerus; with allograft	
24125	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with autograft (includes obtaining graft)	
24126	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with allograft	
24435	Repair of nonunion or malunion, humerus; with iliac or other autograft (includes obtaining graft)	
25125	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with autograft (includes obtaining graft)	
25126	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with allograft	
25135	Excision or curettage of bone cyst or benign tumor of carpal bones; with autograft (includes obtaining graft)	
25136	Excision or curettage of bone cyst or benign tumor of carpal bones; with allograft	
25405	Repair of nonunion or malunion, radius OR ulna; with autograft (includes obtaining graft)	
25420	Repair of nonunion or malunion, radius AND ulna; with autograft (includes obtaining graft)	
25425	Repair of defect with autograft; radius OR ulna	
25426	Repair of defect with autograft; radius AND ulna	
25431	Repair of nonunion of carpal bone (excluding carpal scaphoid (navicular)) (includes obtaining graft and necessary fixation), each bone	
25440	Repair of nonunion, scaphoid carpal (navicular) bone, with or without radial styloidectomy (includes obtaining graft and necessary fixation)	
26205	Excision or curettage of bone cyst or benign tumor of metacarpal; with autograft (includes obtaining graft)	

26215	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger; with autograft (includes obtaining graft)	
26546	Repair non-union, metacarpal or phalanx (includes obtaining bone graft with or without external or internal fixation)	
27065	Excision of bone cyst or benign tumor, wing of ilium, symphysis pubis, or greater trochanter of femur; superficial, includes autograft, when performed	
27066	Excision of bone cyst or benign tumor, wing of ilium, symphysis pubis, or greater trochanter of femur; deep (subfascial), includes autograft, when performed	
27067	Excision of bone cyst or benign tumor, wing of ilium, symphysis pubis, or greater trochanter of femur; with autograft requiring separate incision	
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	
27356	Excision or curettage of bone cyst or benign tumor of femur; with allograft	
27357	Excision or curettage of bone cyst or benign tumor of femur; with autograft (includes obtaining graft)	
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	
27637	Excision or curettage of bone cyst or benign tumor, tibia or fibula; with autograft (includes obtaining graft)	
27638	Excision or curettage of bone cyst or benign tumor, tibia or fibula; with allograft	
27722	Repair of nonunion or malunion, tibia; with sliding graft	
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	
28102	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autograft (includes obtaining graft)	
28103	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with allograft	
28106	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with iliac or other autograft (includes obtaining graft)	
28107	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with allograft	
28322	Repair, nonunion or malunion; metatarsal, with or without bone graft (includes obtaining graft)	

CPT® Category III Code(s)	Description	Comments
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	**Not Covered**
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	**Not Covered**
0814T	Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral	**Not Covered** **New Code Effective 01/01/2024**
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed	**Not Covered** **New Code Effective 07/01/2024**
HCPCS Code(s)	**Description**	**Comments**
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	**Not Covered** **New Code Effective 01/01/2024**
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	**Not Covered**
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	**Not Covered**
L8699	Prosthetic implant, not otherwise specified	**Not Covered if used to report any bone graft substitute outlined in Coverage Limitations section**
P9020	Platelet rich plasma, each unit	**Not Covered if used to report any bone graft substitute outlined in Coverage Limitations section**

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Appendix

Appendix A – Brand Name Bone Graft Substitutes by Product Composition:

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
ALLOGRAFT	Examples of allograft products include, but may not be limited to: • Allopure • ArthroCell • Bonus Triad • Incite Cortical Fibers • IsoTis Pure Strip • Kore Fiber • MatriGRAFT

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
	• OraGraft • Osteocyte (Putty, Sponge) • OsteoGro Allograft • ReadiGRAFT • SureChip • Tempest Allograft Bone Matrix • Vertigraft • ViBone • Vikos Void Filler
BETA TRICALCIUM PHOSPHATE (β-TCP) BONE VOID FILLERS A synthetically produced bone graft material/ substitute; falls under the broad category of ceramics/bone void fillers.	Examples include, but may not be limited to: • Allogran-R • BoneSync • ChronOS • Collage • Integra Mozaik • IsoTis Mozaik • Matriform SI • OSferion • OsteoStrux • OsSatura TCP • OsteoVation B-TCP • Vitoss
BIOACTIVE GLASS Unlike window or household glass, bioactive glass has a different chemical composition (calcium-phosphorus-sodium-silicate) and is reactive to extracellular fluids and therefore bonds to bone. Due to this reaction, it is purported that the glass will release substances that are biocompatible and activate a mechanism that promotes new bone growth. Over time, the glass dissolves completely and is replaced by bone tissue.	Examples include, but may not be limited to: • Bi-Ostetic Bioactive Glass • BioSphere Flex • BioSphere Putty • BonAlive • FIBERGRAFT • Interface • NovaBone Morsels • OssiMend (Strips, Blocks, Putty) • PURbridge • Signal Bioactive Fibers • Signify Bioactive • Tornado Bioactive • Vitoss BA • Vitoss BiModal
CALCIUM PHOSPHATE CERAMIC/BONE VOID FILLERS	Examples include, but may not be limited to: • AccuFill • Actifuse

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
	• Arthrex Quickset • HydroSet XT • Norian Drillable • OsteoVation • OsteoVation EX • Venado
CALCIUM SULFATE-CALCIUM COMPOSITE CERAMICS/BONE VOID FILLERS	Examples include, but may not be limited to: • Altapore • Altapore Shape • Calcigen S • InterSep • OsteoSet • OsteoVation QWIK • Pro-Dense • Stimulan
CELL-BASED SUBSTITUTES Proposed for use in combination with autograft and allograft products; derived from **MESENCHYMAL STEM CELLS**, obtained from **BONE MARROW ASPIRATE**, **AMNIOTIC MEMBRANE** or **PLACENTAL MEMBRANE**; these products are also referred to as cell-based substitutes.	Examples include, but may not be limited to: • AmnioFix • Amniovo • Arthrex Amnion Matrix & Viscous • Bio4 Viable Bone Matrix • BioDFactor • BioDFence • BioDRestore • BioD Dry Flex • Cygnus • ENHANCE Amnion • NuCel • Osteocel Plus • Osteocel Pro • OsteoVive Plus • PalinGen • Regenexx • Stravix • Trinity Elite • Trinity Evolution • ViaCell • Viaflow • Viaflow C

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with BIOACTIVE GLASS	An example includes, but may not be limited to: • Vitoss BA2X
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with BIOACTIVE GLASS AND HYDROXYAPATITE	Examples include, but may not be limited to: • SignaFuse Bioactive Bone Graft Putty • SignaFuse Bioactive Bone Graft Strip
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with CALCIUM SULFATE	An example includes, but may not be limited to: • genex
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with HYDROXYAPATITE (may also be referred to as a biphasic calcium phosphate)	Examples include, but may not be limited to: • Amplify • AttraX Putty/Scaffold • Bi-Ostetic • Bicera • Cove (Putty, Strip) • Eclipse Granules/Putty • MagnetOs • Mastergraft (granules, strip or putty) • Montage Bone Putty • OsteoMatrix+ • Osteon (Osteon II, Osteon III) • Synthetic Bone Putty • VENADO Foam Strip/Granules
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with MAGNESIUM OXIDE	An example includes, but may not be limited to: • OSTEOREVIVE
COMBINATION BONE GRAFT SUBSTITUTE: BETA TRICALCIUM PHOSPHATE combined with HUMAN PLATELET DERIVED GROWTH FACTOR (rhPDGF)	An example includes, but may not be limited to: • Augment
COMBINATION BONE GRAFT SUBSTITUTE: BIOACTIVE GLASS combined with CARBONATE APATITE ANORGANIC BONE MINERAL and TYPE 1 COLLAGEN	Examples include, but may not be limited to: • BoneSync BioActive • Contour BA • Opus BA Bioactive strip • OssiMend Bioactive • VIA Mend

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
COMBINATION BONE GRAFT SUBSTITUTE: BIOACTIVE GLASS combined with HYALURONIC ACID and COLLAGEN	Examples include, but may not be limited to • Kinex Bioactive • Kinex Plus Bioactive
COMBINATION BONE GRAFT SUBSTITUTE: CALCIUM PHOSPHATE combined with HYALURONIC ACID	An example includes, but may not be limited to: • Tactoset
COMBINATION BONE GRAFT SUBSTITUTE: Combination POLYMER (PLGA) with HYALURONIC ACID	An example includes, but may not be limited to: • InQu
COMBINATION BONE GRAFT SUBSTITUTE: DBM combined with BIOACTIVE GLASS	Examples include, but may not be limited to: • NanoFUSE Bioactive Matrix • NanoFUSE putty, strips
COMBINATION BONE GRAFT SUBSTITUTE: DBM combined with CALCIUM SULFATE	Examples include, but may not be limited to: • Allomatrix C • Allomatrix Custom • Allomatrix DR
COMBINATION BONE GRAFT SUBSTITUTE: DBM combined with CERAMIC BONE VOID FILLER	Examples include, but may not be limited to: • InterGro DBM Plus • Pro-Stim Injectable Inductive Graft
COMBINATION BONE GRAFT SUBSTITUTE: DBM combined with NANOCRYSTALLINE HYDROXYAPATITE	An example includes, but may not be limited to: • EquivaBone
COMBINATION BONE GRAFT SUBSTITUTE: HYDROXYAPATITE combined with BETA TRICALCIUM PHOSPHATE, BIOACTIVE GLASS and ALPHA TRICALCIUM PHOSPHATE (may also be referred to as quadphasic synthetic bone graft)	An example includes, but may not be limited to: • OsteoFlo NanaPutty
COMBINATION BONE GRAFT SUBSTITUTE: HYDROXYAPATITE combined with CALCIUM CARBONATE	Examples include, but may not be limited to: • Pro Osteon 200R • Pro Osteon 500R
COMBINATION BONE GRAFT SUBSTITUTE: HYDROXYAPATITE combined with CALCIUM SULFATE	Examples include, but may not be limited to: • Cerament • Ceramet G

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
COMBINATION BONE GRAFT SUBSTITUTE: NANOCRYSTALLINE HYDROXYAPATITE combined with CALCIUM CARBONATE	Examples include, but may not be limited to: • Agilon Moldable • Aglion Strip • Morpheus • OsteoSpan
COMBINATION BONE GRAFT SUBSTITUTE: rhBMP-2 combined with BETA TRICALCIUM PHOSPHATE and HYDROXYAPATITE	An example includes, but may not be limited to: • Infuse/Mastergraft
DEMINERALIZED BONE MATRIX (DBM) **DEMINERALIZED BONE MATRIX (DBM), continued**	Examples include, but may not be limited to: • 3D ProFuse • 3-Demin • Accell Connexus • Accell EVO3c • Accell Total Bone Matrix • AlloFlex Plus • AlloFuse • Allomatrix • AlloSync • AlphaGraft DBM • Apex • Ballast • BIO DBM • BioAdapt DBM • BioReady DBM Putty • BioReady DBM Putty with Chips • BioSet DBM • Conform (Cube, Flex, Sheet) • DBMPure Macro • DBMPure Micro • DBX DBM • DynaGraft II • ENHANCE Demineralized Cortical • ExFuse • FiberFuse Advanced • FibreX • FUSIONFLEX • Grafton DBM • Grafton DBF • Grafton PLUS DBM • H-100 DBM • H-Genin

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
DEMINERALIZED BONE MATRIX (DBM), continued	• Indux Cortical Cancellous Sponge • Indux Cortical Cancellous Strip • Intergro Fibers • Magnifuse • Optecure • Optecure +CCC • Optium DBM • OrthoBlast II • Ossify DBM • OsteoAmp • OsteoAmp Select • OsteoBallast • OsteoGro V • OsteoSelect DBM Putty • OsteoSelect PLUS • OsteoSparx • OsteoSponge • OsteoStrand • OsteoSurge • Physio • PliaFX Prime • PrimaGen Advanced Allograft • PrimaGraft • Prime HD • Promote OsteoPro DBM 100 • Promote OsteoStrip • Propel DBM • Purebone • Puros DBM • Reficio • StaGraft Fiber • Sterifuse DBM Putty; Sterifuse Crunch • StimuBlast • SXDBM • SXDBM Fiber • TENSIX • Vega Graft • Vesuvius DBM (DBM Putty; DBM Putty 100; Demineralized Fibers; Demineralized Sponge) • VIA DBM Plus • VIA Form • VIA Graft • ViviGen

CATEGORY OF BONE GRAFT SUBSTITUTE	PRODUCT/BRAND NAME
	• Xemplifi DBM
NANOCRYSTALLINE HYDROXYAPATITE A synthetically produced bone graft material/ substitute that is a specific type of ceramic/bone void filler. It consists of a calcium phosphate that has been subjected to additional structural process, which changes the particle size.	Examples include, but may not be limited to: • Beta-BSM Injectable • Cem-Ostetic • Gamma-BSM moldable putty • N-Force Blue • NanoBone • NanOss
PEPTIDE ENHANCED BONE GRAFT Composite material consisting of a synthetic peptide (P-15) adsorbed onto calcium phosphate particles, suspended in a hydrogel carrier.	An example includes, but may not be limited to: • i-Factor
PRODUCTS THAT MUST BE MIXED WITH BONE MARROW ASPIRATE These products must be mixed with bone marrow aspirate in order to activate their osteoconductive properties for new bone regeneration.	Examples include, but may not be limited to: • ATEC Neocore • CopiOs Bone Void Filler Paste • CopiOs Bone Void Filler Sponge • FIBERGRAFT • Ignite • Influx • Mastergraft Matrix EXT • Mastergraft Strip • PLATFORM CM • Sorrento • ViaSorb

Appendix B – FDA Approved Spinal Fusion Cages for use with Infuse Bone Graft (rhBMP-2)

SPINAL CAGE BRAND NAME	FDA-APPROVED INDICATION
Clydesdale Spinal System	• Single level fusion, L2-L5 vertebra, via an oblique lateral interbody fusion (OLIF) approach
Divergence-L Anterior/Oblique Lumbar Fusion System	• Single level fusion, L2-S1 vertebra, via an anterior lumber interbody fusion (ALIF) approach; **OR** • Single level fusion, L5-S1 vertebra, via an OLIF approach
INTER FIX RP Threaded Fusion Device	• Single level lumbar fusion, via an open anterior approach
INTER FIX Threaded Fusion Device	• Single level lumbar fusion, via an open anterior approach

LT-CAGE Lumbar Tampered Fusion Device	• Single level fusion, L2-S1 vertebra, via an open or laparoscopic anterior approach
Perimeter Interbody Fusion Device	• Single level fusion, L5-S1 vertebra, via an OLIF approach; **OR** • Single level fusion, L5-S1 vertebra, via a retroperitoneal ALIF
Pivox Oblique Lateral Spinal System	• Single level fusion, L2-L5 vertebra, via an OLIF approach

Change Summary

12/19/2024 Annual Review, Coverage Change.