

Bone Graft Substitutes



Medical Coverage Policy

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Change Summary: Updated Provider Claims Codes

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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

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be used for any other reason, another type of material must be used for the bone graft.

NOTE: *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.

NOTE: *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.⁷⁸ 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).

rhBMPs serve as alternatives or adjuncts to autologous bone grafts (autografts). They are intended to promote bone formation and enhance fracture healing¹⁶³ and may be used in spinal fusion surgery for degenerative disease to promote bone growth that results in fusion.¹⁵⁶ 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.¹⁵⁶ Another major application of bone grafting with rhBMP is for bone repair, especially for treatment of delayed union of tibial fractures.¹⁶³ rhBMP also plays a role in cartilage formation and repair of other musculoskeletal tissues.

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The rhBMP needs to stay in the region of repair to influence skeletal formation (healing). In order for this to happen, the rhBMPs must be utilized with a suitable carrier. 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

A newer 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.

NOTE: 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:

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
Autograft	Enhancement of bone healing
Allograft	Enhancement of bone healing

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
<p>Examples of allograft products include, but may not be limited to:</p> <ul style="list-style-type: none"> • Allopure • ArthroCell • Bonus Triad • Graftjacket • Incite Cortical Fibers • IsoTis Cancellous Bone • IsoTis Pure Strip • Kore Fiber • MatriGRAFT • OraGraft • Osteocyte (Putty, Sponge) • OsteoGro Allograft • ReadiGRAFT • SureChip • Tempest Allograft Bone Matrix • Vertigraft • ViBone • Vikos Void Filler 	
<p><u>Calcium Phosphate Ceramic/Bone Void Fillers*</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • AccuFill • Actifuse • Arthrex Quickset • HydroSet XT • OsteoVation • OsteoVation EX • Norian Drillable • Venado 	<p>Enhancement of bone healing</p> <p>*(For information regarding coverage determination/limitations for use of calcium phosphate products with subchondroplasty, please refer to Osteochondral and Subchondral Defects Surgery Medical Coverage Policy)</p>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
<p><u>Calcium Sulfate-Calcium Composite Ceramics/Bone Void Fillers</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Altapore • Altapore Shape • Calcigen S • InterSep • OsteoSet • OsteoVation QWIK • Pro-Dense • Stimulan 	<p>Enhancement of bone healing</p>
<p><u>Demineralized Bone Matrix (DBM)</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • 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) 	<p>Enhancement of bone healing</p>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
<ul style="list-style-type: none"> • DBM Plus • DBMPure Macro • DBMPure Micro • DBX DBM • DynaGraft II • ENHANCE Demineralized Cortical • ExFuse • FenFlex • FiberFuse Advanced • FibreX • FUSIONFLEX • Grafton DBM • GRAFTON PLUS DBM • H-100 DBM • H-Genin • 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 	

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
<ul style="list-style-type: none"> • OsteoSurge • Physio • PliaFX Prime • PrimaGen Advanced Allograft • PrimaGraft • Prime HD • Promote OsteoPro DBM 100 • Promote OsteoStrip • Propel DBM • Purebone • Puros DBM • Reficio • StaGraft Cancellous DBM Sponge • StaGraft Cancellous DBM Strip • 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 Form • VIA Graft • ViviGen • Xemplifi DBM 	
<p><u>Recombinant Human Bone Morphogenetic Proteins (rhBMP)</u></p> <ul style="list-style-type: none"> • INFUSE Bone Graft (rhBMP-2) 	<ul style="list-style-type: none"> • Absence of contraindications; AND • Primary treatment of open tibial fractures; AND

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
	<ul style="list-style-type: none"> • Following stabilization with intramedullary nail fixation; AND • No infection in the affected limb; AND • Skeletally mature (at least 18 years of age or radiographic evidence of epiphyseal closure¹⁹⁵)
<p><u>Recombinant Human Bone Morphogenetic Proteins (rhBMP)</u></p> <ul style="list-style-type: none"> • INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (with titanium cage) (rhBMP-2) 	<p>This product may ONLY be approved when used with 1 of the 8 cages <i>approved for use with INFUSE by the FDA</i>.</p> <ul style="list-style-type: none"> • Absence of contraindications; AND • ONLY for a <u>SINGLE-LEVEL lumbar</u> fusion surgery when lumbar fusion criteria are met (for information regarding coverage determination/limitations, please refer to Spinal Fusion Surgery Medical Coverage Policy); AND • Used in combination with 1 of the following: <ul style="list-style-type: none"> ○ Clydesdale Spinal System – single level fusion, L2-L5 vertebra, via an oblique lateral interbody fusion (OLIF) approach; OR ○ Divergence-L Anterior/Oblique Lumbar Fusion System: <ul style="list-style-type: none"> ▪ Single level fusion, L2-S1 vertebra, via an anterior lumbar interbody fusion (ALIF) approach; OR ▪ Single level fusion, L5-S1 vertebra, via an OLIF approach; OR ○ INTER FIX RP Threaded Fusion Device – single level lumbar fusion, via an open anterior approach; OR ○ INTER FIX Threaded Fusion Device – single level lumbar fusion, via an open anterior approach; OR

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
	<ul style="list-style-type: none"> ○ LT-CAGE Lumbar Tapered Fusion Device – single level fusion, L2-S1 vertebra, via an open or laparoscopic anterior approach; OR ○ Perimeter Interbody Fusion Device: <ul style="list-style-type: none"> ▪ Single level fusion, L5-S1 vertebra, via an OLIF approach; OR ▪ Single level fusion, L2-S1 vertebra, via retroperitoneal anterior lumbar interbody fusion (ALIF) ○ Pivox Oblique Lateral Spinal System – single level fusion, L2-L5 vertebra, via an OLIF approach

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the use of **INFUSE Bone Graft (rhBMP-2) and/or INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (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**

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- Thoracic spinal fusion; **OR**
- Treatment of delayed union or nonunion of tibial fracture as part of a planned, staged reconstruction; **OR**
- Use of INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (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.

Contraindications to the use of **INFUSE Bone Graft (rhBMP-2)** and/or **INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device** include the following:^{195,196}

- Active infection at the operative site; **OR**
- Active malignancy; **OR**
- Compartment syndrome of the affected limb; **OR**
- Inadequate neurovascular status; **OR**
- Known hypersensitivity to bovine Type I collagen, rhBMP-2 or other components of the formulation; **OR**
- Pregnancy; **OR**
- Skeletally immature (18 years of age or younger, or have no radiographic evidence of epiphyseal closure); **OR**
- Utilization in the vicinity of a resected or extant tumor

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This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use 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:

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
<p><u>Augment</u> (including, but not limited to, Augment Injectable)</p>	<p>Comprised of beta tricalcium phosphate and recombinant human platelet derived growth factor (rhPDGF).</p> <p>Proposed as an alternative to autograft in arthrodesis of the ankle and/or hindfoot.</p>
<p><u>Autologous Blood Product Injection</u> (red blood cells [RBC], white blood cells [WBC], whole blood) including, but not limited to, nSTRIDE Autologous Protein Solution (APS)</p>	<p>Blood is withdrawn from an individual, and the desired component is extracted; it is then either injected into a joint (proposed as a treatment for osteoarthritis) or injured tendon, or is mixed with/combined with a bone graft substitute product.</p> <p>(For information regarding coverage determination/limitations for the use of autologous blood injection for plantar fasciitis, please refer to Plantar Fasciitis Treatments Medical Coverage Policy)</p>
<p><u>Beta Tricalcium Phosphate Bone Void Fillers</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Allogran-R • BoneSync • ChronOS • Collage 	<p>A synthetically produced bone graft material/substitute; falls under the broad category ceramics/bone void fillers.</p> <p>Proposed for use as a bone graft substitute or bone graft extender to fill in and promote healing of bone voids or gaps in the skeletal system.</p>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
<ul style="list-style-type: none"> • Integra Mozaik • IsoTis Mozaik • Matriform SI • OSferion • OsteoStrux • OsSatura TCP • OsteoVation B-TCP • Vitoss 	
<p><u>Bioactive Glass</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Bi-Ostetic Bioactive Glass • BioSphere Flex • BioSphere Putty • BonAlive • FIBERGRAFT BG Morsels • FIBERGRAFT BG Putty • Interface • NovaBone Morsels • OssiMend (Strips, Blocks, Putty) • PURbridge • Signal Bioactive Fibers • Signify Bioactive • Tornado Bioactive • Vitoss BA • Vitoss BiModal 	<p>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.</p> <p>Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).</p>
<p><u>Bone Marrow Aspirate (BMA)</u> Mixing an individual's bone marrow aspirate with the bone graft substitute, rather than blood or autologous bone; or injection of BMA into a joint,</p>	<p>NOT COVERED for ANY orthopedic applications including, but may not be limited to:</p> <ul style="list-style-type: none"> • As an adjunct to a spinal fusion; OR • Bone cysts; OR • Degenerative disc disease; OR • Nonunion fractures; OR

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
intervertebral disc, ligament/tendon or other structure.	<ul style="list-style-type: none"> • Osteoarthritis; OR • Repair or regeneration of musculoskeletal tissue (including intervertebral disc); OR • When <i>mixed</i> with <u>any</u> bone graft substitute
<p><u>Cell-Based Substitutes</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • 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 • ReNu • Stravix • Trinity Elite • Trinity Evolution • ViaCell • Viaflow • Viaflow C 	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.

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<p><u>Combination Bone Graft Substitute</u></p> <ul style="list-style-type: none"> • Vitoss BA2X 	<p><u>Beta tricalcium phosphate combined with bioactive glass</u></p> <p>Proposed for use in orthopedic surgery for filling osteochondral defects.</p>
<p><u>Combination Bone Graft Substitute</u></p> <p>Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • SignaFuse Bioactive Bone Graft Putty • SignaFuse Bioactive Bone Graft Strip 	<p><u>Beta tricalcium phosphate combined with bioactive glass and hydroxyapatite</u></p> <p>Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).</p>
<p><u>Combination Bone Graft Substitute</u></p> <ul style="list-style-type: none"> • genex 	<p><u>Beta tricalcium phosphate combined with calcium sulfate</u></p> <p>Proposed for use in bony voids and defects that are not intrinsic to structural stability.</p>
<p><u>Combination Bone Graft Substitutes</u></p> <p>Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Amplify • AttraX Putty/Scaffold • Bi-Ostetic • Bicera • Eclipse Granules/Putty • MagnetOs • Mastergraft (granules, strip or putty) • Montage Bone Putty • OsteoMatrix+ • Osteon • VENADO Foam Strip/Granules 	<p><u>Beta tricalcium phosphate combined with hydroxyapatite</u> (may also be referred to as a biphasic calcium phosphate)</p> <p>Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).</p>

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<p><u>Combination Bone Graft Substitute</u></p> <ul style="list-style-type: none"> • OSTEOREVIVE 	<p><u>Beta tricalcium phosphate combined with magnesium oxide</u></p> <p>Proposed for bony voids or defects of the extremities, posterolateral spine, and pelvis that are not intrinsic to the stability of the bony structure.</p>
<p><u>Combination Bone Graft Substitute</u></p> <p>Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • BoneSync BioActive • Contour BA • Opus BA Bioactive strip • OssiMend Bioactive • VIA Mend 	<p><u>Bioactive glass combined with carbonate apatite anorganic bone mineral and Type 1 collagen</u></p> <p>Proposed for use in bony voids or gaps of the skeletal system (extremities, pelvis and spine).</p>
<p><u>Combination Bone Graft Substitutes</u></p> <p>Examples include, but may not be limited to</p> <ul style="list-style-type: none"> • Kinex Bioactive • Kinex Plus Bioactive 	<p><u>Bioactive glass combined with hyaluronic acid and collagen</u></p> <p>Proposed for use in bony voids or gaps of the skeletal system (extremities, pelvis and spine).</p>
<p><u>Combination Bone Graft Substitute</u></p> <ul style="list-style-type: none"> • Tactoset 	<p><u>Calcium phosphate combined with hyaluronic acid</u></p> <p>Proposed for filling bone voids or defects of the skeletal system (extremities and pelvis), which are not intrinsic to the stability of the bone, created during surgery or resulting from traumatic injury.</p>
<p><u>Combination Bone Graft Substitute</u></p> <ul style="list-style-type: none"> • InQu 	<p><u>Combination polymer (PLGA) with hyaluronic acid</u></p>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
	Proposed for use as a bone graft substitute in the skeletal system (extremities and pelvis) and as a bone graft extender in the spine when combined with bone autograft.
<p><u>Combination Bone Graft Substitute</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • NanoFUSE Bioactive Matrix • NanoFUSE putty, strips 	<p><u>DBM combined with bioactive glass</u></p> <p>Proposed for use as a bone graft substitute in the skeletal system (extremities and pelvis) and as a bone graft extender in the posterolateral spine when combined with bone autograft.</p>
<p><u>Combination Bone Graft Substitute</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Allomatrix C • Allomatrix Custom • Allomatrix DR 	<p><u>DBM combined with calcium sulfate</u></p> <p>Proposed for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine.</p>
<p><u>Combination Bone Graft Substitutes</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • InterGro DBM Plus • Pro-Stim Injectable Inductive Graft 	<p><u>DBM combined with ceramic bone void filler</u></p> <p>Proposed for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine.</p>
<p><u>Combination Bone Graft Substitutes</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • StaGraft DBM Putty • StaGraft DBM PLUS 	<p><u>DBM combined with hydroxyapatite and calcium carbonate</u></p> <p>Proposed for use in bone voids and gaps in the extremities or pelvis that is not intrinsic to the stability of the structure.</p>
<p><u>Combination Bone Graft Substitute</u> <ul style="list-style-type: none"> • EquivaBone </p>	<p><u>DBM combined with nanocrystalline hydroxyapatite</u></p>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
	Proposed for use as bone void fillers of the pelvis, extremities and the posterolateral spine.
<u>Combination Bone Graft Substitute</u> <ul style="list-style-type: none"> • OsteoFlo NanoPutty 	<u>Hydroxyapatite combined with beta tricalcium phosphate, bioactive glass and alpha tricalcium phosphate</u> (may also be referred to as quadphasic synthetic bone graft) Proposed for bony voids or gaps of the skeletal system (extremities and pelvis) not intrinsic to the stability of the bony structure.
<u>Combination Bone Graft Substitutes</u> Examples include, but may not be limited to: <ul style="list-style-type: none"> • Pro Osteon 200R • Pro Osteon 500R 	<u>Hydroxyapatite combined with calcium carbonate</u> Proposed for filling bony voids or gaps caused by trauma or surgery, including use in the maxillofacial and/or mandibular bone.
<u>Combination Bone Graft Substitute</u> <ul style="list-style-type: none"> • Cerament • Cerament G 	<u>Hydroxyapatite combined with calcium sulfate</u> Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
<u>Combination Bone Graft Substitutes</u> Examples include, but may not be limited to: <ul style="list-style-type: none"> • Agilon Moldable • Aglion Strip • OsteoSpan • Morpheus 	<u>Nanocrystalline hydroxycarbonoapatite combined with calcium carbonate</u> Proposed for bony voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (the extremities, posterolateral spine and pelvis).
<u>Combination Bone Graft Substitute</u> Examples include, but may not be limited to:	<u>Tricalcium phosphate combined with hydroxyapatite</u>

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
<ul style="list-style-type: none"> • Current • OsteoCurrent 	Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
<u>i-FACTOR Peptide Enhanced Bone Graft</u>	<p>Composite material consisting of a synthetic peptide (P-15) adsorbed onto calcium phosphate particles, suspended in a hydrogel carrier.</p> <p>Proposed for single level anterior cervical spinal fusion.</p>
<u>INFUSE/MASTERGRAFT (rhBMP-2)</u>	<p>Combination rhBMP-2 and Mastergraft granules (beta tricalcium phosphate and hydroxyapatite).</p> <p>Proposed for use in posterolateral spinal fusion at two or more levels for pseudoarthrodesis.</p>
<p><u>Nanocrystalline Hydroxyapatite</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • Beta-BSM Injectable • Cem-Ostetic • Gamma-BSM moldable putty • N-Force Blue • NanoBone • NanOss 	<p>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.</p> <p>Proposed for bony voids or gaps that are not intrinsic to the stability of bony structure.ost</p>
<p><u>Platelet Rich Plasma (PRP)</u> PRP, which is harvested from an individual's own blood, has been proposed as a treatment to accelerate healing of tendon/ligament injuries or aid in bone healing or grafting. PRP is prepared by obtaining a small amount of the individual's blood, which is then centrifuged to separate the platelets from</p>	<p>PRP is NOT covered for ANY indication including, but may not be limited to:</p> <ul style="list-style-type: none"> • 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

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BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR <u>ANY</u> INDICATION)
the other components found in blood.	<p>(For information regarding coverage determination/limitations for the use of PRP for plantar fasciitis, please refer to Plantar Fasciitis Treatments Medical Coverage Policy)</p> <p>(For information regarding coverage determination/limitations for the use of PRP in wound healing, please refer to Platelet-Derived Growth Factors for Wound Healing Medical Coverage Policy)</p>
<p><u>Products That MUST Be Mixed With Bone Marrow Aspirate:</u> Examples include, but may not be limited to:</p> <ul style="list-style-type: none"> • ATEC Neocore • CopiOs Bone Void Filler Paste • CopiOs Bone Void Filler Sponge • FIBERGRAFT BG Matrix • Grafton DBF • Ignite • Influx • Mastergraft Matrix EXT • Mastergraft Strip • PLATFORM CM • Sorrento • ViaSorb 	<p>These products must be mixed with bone marrow aspirate in order to activate their osteoconductive properties for new bone regeneration.</p> <p>Proposed for bony voids or gaps that are not intrinsic to the stability of bony structure.</p>

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.

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Background Additional information about **bone grafting, degenerative disc disease, fractures, spinal fusion and spondylolisthesis** may be found from the following websites:

- [American Academy of Orthopaedic Surgeons](#)
- [National Library of Medicine](#)
- [North American Spine Society](#)

Medical Alternatives Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider Claims Codes Any CPT, HCPCS or ICD codes listed on this medical coverage 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)	

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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)	

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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	

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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

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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
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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