Bone Graft Substitutes

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Platelet-Derived Growth Factors for Wound Healing

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories

LCD LCA	Platelet Rich Plasma Dental Services	L38937 A58609 A59543	J6, JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD LCA	Platelet Rich Plasma Injections for Non-Wound Injections	L39023 A58737	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Platelet Rich Plasma Injections for Non-Wound Injections Dental Services	L39058 A58788 A59447	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Platelet Rich Plasma Injections for Non-Wound Injections Dental Services	L39060 A58790 A59450	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Platelet Rich Plasma	L39068 A58808	JH, JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, DC, MD, NJ, PA
LCD LCA	Platelet Rich Plasma Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound Dental Services	L38745 A58282 L39128 A58883 A59449	JJ, JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Platelet Rich Plasma	L39071 A58810	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

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.
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.[90] 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 healing[175] and may be used in spinal fusion surgery for degenerative disease to promote bone growth that results in fusion.[168] 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.[168] Another major application of bone grafting with rhBMP is for bone repair, especially for treatment of delayed union of tibial fractures.[175] rhBMP also plays a role in cartilage formation and repair of other musculoskeletal tissues.

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.

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*.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria.

The following **bone graft materials/bone graft substitute products** will be considered medically reasonable and necessary when the following requirements 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 Examples of allograft products include, but may not be limited to: • 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	Enhancement of bone healing

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
• Vikos Void Filler	
Calcium Phosphate Ceramic/Bone Void Fillers Examples include, but may not be limited to: • AccuFill • Actifuse • Arthrex Quickset • HydroSet XT • OsteoVation • OsteoVation EX • Norian Drillable • Venado	Enhancement of bone healing
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	Enhancement of bone healing
Demineralized Bone Matrix (DBM) 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) • DBM Plus	Enhancement of bone healing

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
• 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 • OsteoSurge • Physio • PliaFX Prime • PrimaGen Advanced Allograft • PrimaGraft • Prime HD • Promote OsteoPro DBM 100 • Promote OsteoStrip • Propel DBM • Purebone • Puros DBM	

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
• 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	
Recombinant Human Bone Morphogenetic Proteins (rhBMP) • INFUSE Bone Graft (rhBMP-2)	• Absence of contraindications; **AND** • Primary treatment of open tibial fractures; **AND** • 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 closure[207])

Recombinant Human Bone Morphogenetic Proteins (rhBMP)
• INFUSE Bone Graft/LT-CAGE Lumbar Tampered Fusion Device (with titanium cage) (rhBMP-2)
	This product may ***ONLY*** be approved when used with 1 of the 8 cages *approved for use with INFUSE by the FDA*.
	• Absence of contraindications; **AND**
	• *ONLY* for a *SINGLE-LEVEL* ***lumbar*** fusion surgery when lumbar fusion criteria are met; **AND**
	• Used in combination with 1 of the following:
	  ○ 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:
	  ▪ 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**

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCTS	CRITERIA/INDICATIONS FOR COVERAGE
	○ INTER FIX Threaded Fusion Device – single level lumbar fusion, via an open anterior approach; **OR** ○ LT-CAGE Lumbar Tampered Fusion Device – single level fusion, L2-S1 vertebra, via an open or laparoscopic anterior approach; **OR** ○ Perimeter Interbody Fusion Device: ▪ 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

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

No payment may be made for dental services in connection with care, treatment filling, removal or replacement of structures directly supporting teeth, except for the reconstruction of a dental ridge performed because of and at the same time as the surgical removal of a tumor.[11-14]

The use of **INFUSE Bone Graft (rhBMP-2) and/or INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (rhBMP-2)** will **not** be considered medically reasonable and necessary for the following:

- *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 INFUSE Bone Graft/LT-CAGE Lumbar Tampered Fusion Device (rhBMP-2) with *non-FDA* approved spinal cages

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Contraindications to the use of **INFUSE Bone Graft (rhBMP-2)** and/or **INFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device** include the following:[207,208]

- 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

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Percutaneous injection of calcium-based biodegradable osteoconductive material (proximal femur, including imaging guidance, unilateral) will **not** be considered medically reasonable and necessary. A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

The use of **any of the following bone graft substitute products** will **not** be considered medically reasonable and necessary for ***ANY*** indication:

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
Augment (including, but not limited to, Augment Injectable)	Comprised of beta tricalcium phosphate and recombinant human platelet derived growth factor (rhPDGF). Proposed as an alternative to autograft in arthrodesis of the ankle and/or hindfoot.
Autologous Blood Product Injection (red blood cells [RBC], white blood cells [WBC], whole blood) including, but not limited to, nSTRIDE Autologous Protein Solution (APS)	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.
Beta Tricalcium Phosphate 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	A synthetically produced bone graft material/ substitute; falls under the broad category ceramics/bone void fillers. 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.
Bioactive Glass Examples include, but may not be limited to: • Bi-Ostetic Bioactive Glass • BioSphere Flex • BioSphere Putty • BonAlive • FIBERGRAFT BG Morsels	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

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
• FIBERGRAFT BG Putty • Interface • NovaBone Morsels • OssiMend (Strips, Blocks, Putty) • PURbridge • Signal Bioactive Fibers • Signify Bioactive • Tornado Bioactive • Vitoss BA • Vitoss BiModal	new bone growth. Over time, the glass dissolves completely and is replaced by bone tissue. Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
Bone Marrow Aspirate (BMA) 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, intervertebral disc, ligament/ tendon or other structure.	**NOT COVERED** for **ANY** orthopedic applications including, but may not be limited to: • 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
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 • ReNu • Stravix • Trinity Elite	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.

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
• Trinity Evolution • ViaCell • Viaflow • Viaflow C	
Combination Bone Graft Substitute • Vitoss BA2X	Beta tricalcium phosphate combined with bioactive glass Proposed for use in orthopedic surgery for filling osteochondral defects.
Combination Bone Graft Substitute Examples include, but may not be limited to: • SignaFuse Bioactive Bone Graft Putty • SignaFuse Bioactive Bone Graft Strip	Beta tricalcium phosphate combined with bioactive glass and hydroxyapatite Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
Combination Bone Graft Substitute • genex	Beta tricalcium phosphate combined with calcium sulfate Proposed for use in bony voids and defects that are not intrinsic to structural stability.
Combination Bone Graft Substitutes Examples include, but may not be limited to: • 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	Beta tricalcium phosphate combined with hydroxyapatite (may also be referred to as a biphasic calcium phosphate) Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
Combination Bone Graft Substitute • OSTEOREVIVE	Beta tricalcium phosphate combined with magnesium oxide Proposed for bony voids or defects of the extremities, posterolateral spine, and pelvis that are not intrinsic to the stability of the bony structure.
Combination Bone Graft Substitute Examples include, but may not be limited to: • BoneSync BioActive • Contour BA • Opus BA Bioactive strip	Bioactive glass combined with carbonate apatite anorganic bone mineral and Type 1 collagen Proposed for use in bony voids or gaps of the skeletal system (extremities, pelvis and spine).

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
• OssiMend Bioactive • VIA Mend	
Combination Bone Graft Substitutes Examples include, but may not be limited to • Kinex Bioactive • Kinex Plus Bioactive	Bioactive glass combined with hyaluronic acid and collagen Proposed for use in bony voids or gaps of the skeletal system (extremities, pelvis and spine).
Combination Bone Graft Substitute • Tactoset	Calcium phosphate combined with hyaluronic acid 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.
Combination Bone Graft Substitute • InQu	Combination polymer (PLGA) with hyaluronic acid 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.
Combination Bone Graft Substitute Examples include, but may not be limited to: • NanoFUSE Bioactive Matrix • NanoFUSE putty, strips	DBM combined with bioactive glass 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.
Combination Bone Graft Substitute Examples include, but may not be limited to: • Allomatrix C • Allomatrix Custom • Allomatrix DR	DBM combined with calcium sulfate 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.
Combination Bone Graft Substitutes Examples include, but may not be limited to: • InterGro DBM Plus • Pro-Stim Injectable Inductive Graft	DBM combined with ceramic bone void filler 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.
Combination Bone Graft Substitutes Examples include, but may not be limited to: • StaGraft DBM Putty • StaGraft DBM PLUS	DBM combined with hydroxyapatite and calcium carbonate Proposed for use in bone voids and gaps in the extremities or pelvis that is not intrinsic to the stability of the structure.
Combination Bone Graft Substitute	DBM combined with nanocrystalline hydroxyapatite

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
• EquivaBone	Proposed for use as bone void fillers of the pelvis, extremities and the posterolateral spine.
Combination Bone Graft Substitute • OsteoFlo NanoPutty	Hydroxyapatite combined with beta tricalcium phosphate, bioactive glass and alpha tricalcium phosphate (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.
Combination Bone Graft Substitutes Examples include, but may not be limited to: • Pro Osteon 200R • Pro Osteon 500R	Hydroxyapatite combined with calcium carbonate Proposed for filling bony voids or gaps caused by trauma or surgery, including use in the maxillofacial and/or mandibular bone.
Combination Bone Graft Substitute • Cerament • Cerament G	Hydroxyapatite combined with calcium sulfate Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
Combination Bone Graft Substitutes Examples include, but may not be limited to: • Agilon Moldable • Aglion Strip • OsteoSpan • Morpheus	Nanocrystalline hydroxycarbonoapatite combined with calcium carbonate 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).
Combination Bone Graft Substitute Examples include, but may not be limited to: • Current • OsteoCurrent	Tricalcium phosphate combined with hydroxyapatite Proposed for use in bony voids or gaps of the skeletal system (posterolateral spine, extremities and pelvis).
i-FACTOR Peptide Enhanced Bone Graft	Composite material consisting of a synthetic peptide (P-15) adsorbed onto calcium phosphate particles, suspended in a hydrogel carrier. Proposed for single level anterior cervical spinal fusion.
INFUSE/MASTERGRAFT (rhBMP-2)	Combination rhBMP-2 and Mastergraft granules (beta tricalcium phosphate and hydroxyapatite). Proposed for use in posterolateral spinal fusion at two or more levels for pseudoarthrodesis.
Nanocrystalline Hydroxyapatite Examples include, but may not be limited to:	A synthetically produced bone graft material/ substitute that is a specific type of ceramic/bone void filler. It

BONE GRAFT MATERIALS/SUBSTITUTE PRODUCT	PURPORTED USE (NOT COVERED FOR ANY INDICATION)
• Beta-BSM Injectable • Cem-Ostetic • Gamma-BSM moldable putty • N-Force Blue • NanoBone • NanOss	consists of a calcium phosphate that has been subjected to additional structural process, which changes the particle size. Proposed for bony voids or gaps that are not intrinsic to the stability of bony structure.ost
Platelet Rich Plasma (PRP) 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 the other components found in blood.	PRP is **NOT** covered for **ANY** indication[16-22] 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
Products That MUST Be Mixed with Bone Marrow Aspirate: Examples include, but may not be limited to: • 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	These products must be mixed with bone marrow aspirate in order to activate their osteoconductive properties for new bone regeneration. Proposed for bony voids or gaps that are not intrinsic to the stability of bony structure.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

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)	**Bundled**
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)	**Bundled**
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)	
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	

0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	
0814T	Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral	
HCPCS Code(s)	**Description**	**Comments**
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	
L8699	Prosthetic implant, not otherwise specified	
P9020	Platelet rich plasma, each unit	

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Change Summary

- 01/01/2024 New Policy.