Sentara Health Plans

Medicaid

Bone Scaffolding, Medical 02

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual *.

Description & Definitions:

Bone scaffolding (also known as bone grafting) uses live and/or man-made materials such as synthetics, ceramics, autograft bone, allograft bone etc. to repair or replace bone void defect and new bone can form or attach to.

Arthrodesis is a surgical procedure in which two or more bones are fused together with bone grafts or device implants.

Allograft bone graft (cadaver) is from another persons, or Demineralized Bone Matrix (DBM)/ Demineralized Freeze-Dried Bone Allograft (DFDBA)

Autologous bone grafts (autograft) is from one part of persons body and transplanted to another part

Biologics - Growth factors: Bone Morphogenetic Proteins (BMPs) - Naturally occurring proteins, Bone marrow concentration (BMC), Bone marrow aspirate (BMA)

Bone graft substitutes - Alloplast, Synthetics, Graft Composites, Ceramics

Other common names: Live bone implants, Synthetic bone implant, InFuse, bridging bone, Augment Bone Graft, Grafton

Criteria:

Bone scaffolding (bone graft) is considered medically necessary with **ALL** of the following met:

- Skeletally mature patient (older than 18 years of age or radiographic evidence of epiphyseal closure) unless undergoing bone graft procedures for scoliosis (there isn't a specific age limit)
- Individual does not have any known contraindications including pregnancy or hypersensitivity/ allergy to materials
- Alternative treatments have failed including **1 or more** of the following:
  - An initial fracture that your healthcare provider suspects won't heal without a graft.
  - A fracture of a diseased bone, such as osteonecrosis or cancer.
  - Cast immobilization or other non-operative approaches
  - Fixation (internal and external)
  - Need for a Revision of fixation
  - Compression
  - Dynamization

- At least 3 months of non-operative treatment

- Bone Graft Materials/Substitutes are medically necessary when used independently or together for the enhancement of bone healing for **1 or more** of the following:
  - Autologous (autograft),Recombinant Human Bone Morphogenetic Protein (rhBMP-2, InFuse, bone morphogenic, or morphogenetic protein-2, BMP-2), or Demineralized Bone Matrix (DBM) for **1 or more** of the following:
    - Anterior lumbar interbody fusion (ALIF) or lateral lumbar interbody fusion (i.e., XLIF) at a single level
    - The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications, contraindications, warnings, and precautions in individuals who meet **ALL** of the following criteria:
      - Implanted via a posterolateral approach
      - Presence of symptomatic posterolateral lumbar spine pseudoarthrosis
      - Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure)
      - Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion
    - Acute, open tibial shaft fractures that have been stabilized with intramedullary fixation
  - Demineralized Bone Matrix (DBM)/Demineralized Freeze-Dried Bone Allograft (DFDBA) for filling osteochondral defects (bone void fillers)
  - Polymethylmethacrylate (PMMA) Bone Cement or Calcium Sulfate (e.g., Osteoset Resorbable Mini-Bead) Antibiotic Beads for **1 or more** of the following:
    - treatment of chronic osteomyelitis
    - arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.
  - Bone Marrow Aspirate(BMA)/ hybrid or composite grafting for postero-lateral lumbar spinal fusion surgery (spondylodesis) with or without spinal instrumentation

Bone scaffolding (bone graft) is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Actifuse silicated calcium sulphate
- Allograft bone graft substitutes used exclusively as stand-alone stabilization devices for fusion (e.g., TruFuse® for isolated facet fusion, NuFix™ for isolated facet fusion, BacFast® HD for isolated facet fusion)
- Anterior cruciate ligament-derived stem cells for ligament tissue engineering
- BIO MatrX
- Bioactive Glass used alone or in combination with other grafts including Bone Marrow Aspirate
- Cell-based substitutes other than a bone marrow aspirate (e.g., mesenchymal stem cell therapy, Osteocel®, ViviGen®, Trinity®) when used to enhance bone healing
- Ceramic-based products (e.g., β-TCP)
- Human amniotic membrane bone graft substitute
- Human growth factors (e.g. fibroblast growth factor, insulin-like growth factor, etc.)
- OptiMesh deployable grafting system
- Platelet-rich plasma, alone or in conjunction with bone grafting materials
- Pro Osteon Bone Graft Substitute & Pro Osteon Porous Hydroxyapatite Bone Graft Substitute
- ProDense (calcium sulfate/calcium phosphate composite)
- rhBMP-7 (i.e., OP–1™)
- Three dimensional printed grafts
- Trinity Evolution Bone Matrix

Document History:

Revised Dates:

- 2025: September – Implementation date of January 1, 2026. Full annual review. New criteria and Housekeeping. Remove codes from other policies and new format.

- 2025: January – Procedure codes updated to align with changes in service authorizations.
- 2022: October
- 2020: January
- 2015: March, May, June
- 2013: August
- 2012: April, September

Reviewed Dates:

- 2024: September – no criteria changes, references updated.
- 2023: October
- 2021: December
- 2020: December
- 2019: December
- 2018: September
- 2017: November
- 2016: July, August
- 2015: August
- 2014: August
- 2011: November

Origination Date: November 2010

Coding:

Medically necessary with criteria:

Coding	Description
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)
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)
20933	Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)
20934	Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (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)

Considered Not Medically Necessary:

Coding	Description
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic

0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed.
0707T	Injection(s), bone-substitute material (e.g., calcium phosphate) into subchondral bone defect (i.e., bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization.
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
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)

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device code(s) does not constitute or imply member coverage or provider reimbursement.

Policy Approach and Special Notes: *

- Coverage
  - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products
  - Policy is applicable to Sentara Health Plan Virginia Medicaid Products
- Authorization requirements
  - Precertification required by Plan
- Special Notes:
  - This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
  - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.
  - The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. EPSDT Supplement B (updated 5.19.22)_Final.pdf

- Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Keywords:

Bone Scaffolding, SHP Medical 02, SHP Medical 2, cell-based mesenchymal stem cell MSC, MCS, ceramic-based bone graft substitutes, InFUSE™ bone graft/LT-Cage, InFUSE™ bone graft/Lumbar Tapered Fusion Device, InFUSE™ bone graft/InterFix™ threaded fusion device, InFUSE™ bone graft, Inter Fix™ RP threaded fusion device, Osteogenic Protein-1 Implant, OP-1, Osteogenic protein-1 Implant, bone morphogenic, morphogenetic protein-7, BMP-7, Bone Scaffolding, Human Recombinant Morphogenetic Protein Injection, Osteogenic Protein-1, Implant, Bone Morphogenic Protein-2, OP1, OP-1, Recombinant Human Bone Morphogenetic Proteins rhBMPs, Actifuse silicated calcium sulphate, NuFix, Anterior cruciate ligament-derived stem cells, Bone Marrow Aspirate Concentrate, BMAC, BIO MatrX, Bone void fillers Opteform, Integra Mozaik, Osteoconductive Scaffold putty, mesenchymal stem cell therapy, Ceramic based, beta tricalcium phosphate, b-TCP, DBX Demineralized Bone Matrix, Grafton demineralized bone matrix, Human growth factors, fibroblast growth factor, Mastergraft putty, Mesenchymal stem cell, OptiMesh, Osteocel, Platelet-rich plasma, ProDense, calcium sulfate, calcium phosphate composite, Pro Osteon Bone Graft Substitute, Pro Osteon Porous Hydroxyapatite, Trinity Evolution Bone Matrix