Sentara Health Plans

Medicaid

Bone Scaffolding

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Next Review Date	10/2024
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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 be 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 *.

Purpose:

This policy addresses the medical necessity of Bone Scaffolding

Description & Definitions:

Bone scaffolding uses live 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.

Criteria:

Bone scaffolding is considered medically necessary with **1 or more** of the following:

- Live implants (e.g. 0steogenic Protein-1 (OP-1), recombinant human bone morphogenetic proteins (rhBMPs), morphogenetic protein-7, BMP-7, etc.) as an alternative or adjunct to autologous bone grafts (autograft) for **ALL** of the following:
  - The implant is to be used for **1 or more** of the following:
    - Spinal fusion with **ALL** of the following:
      - An autograft is unfeasible due to **1 or more** of the following:
        - Individual has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available.
        - There is insufficient autogenous tissue for the intended purpose.
        - Individual is obese.
        - Individual is over 65 years old.
        - Individual has presence of morbidity (infection, or fracture) preventing harvesting at autograft donor site.

        - Individual has excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site.
        - Individual's bone is of poor quality (e.g. osteoporosis, etc.)
        - Individual has concurrent medical condition and co-morbidities that increase the risk of autograft.
    - Long-bone non-union with **All** of the following:
        - An autograft is unfeasible due to **1 or more** of the following:
            - Individual has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available.
            - There is insufficient autogenous tissue for the intended purpose.
            - Individual is obese.
            - Individual is over 65 years old.
            - Individual has presence of morbidity (infection, or fracture) preventing harvesting at autograft donor site.
            - Individual has excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site.
            - Individual's bone is of poor quality (e.g. osteoporosis, etc.)
            - Individual has concurrent medical condition and co-morbidities that increase the risk of autograft.
        - Alternative treatments have failed including **3 or more** of the following:
            - Cast immobilization or other non-operative approaches.
            - Fixation (internal and external)
            - Revision of fixation
            - Autograft
            - Cadaveric allograft
            - Compression
            - Dynamization
- Synthetic implant Bone Morphogenic Protein-2 (e.g. InFuse bone graft, etc.) with **All** of the following:
    - Individual has degenerative disc disease confirmed by radiographic studies.
    - The degenerative disc disease affects a single vertebrae within (and including) the level of the fourth lumbar (L4) and the first sacral vertebrae (S1)
    - Individual does not have greater than Grade I spondylolysthesis at the involved level.
    - Individual has had at least 6 months of non-operative treatment.
    - The implant is to be done via an anterior approach.
    - In combination with a fusion device for a single-level anterior interbody lumbar fusion
    - An autograft is unfeasible due to **1 or more** of the following:
        - Individual has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available.
        - There is insufficient autogenous tissue for the intended purpose.
        - Individual is obese.
        - Individual is over 65 years old.
        - Individual has presence of morbidity (infection, or fracture) preventing harvesting at autograft donor site.
        - Individual has excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site.
        - Individual's bone is of poor quality (e.g. osteoporosis, etc.)
        - Individual has concurrent medical condition and co-morbidities that increase the risk of autograft.
- The implant is to be used for **1 or more** of the following:
    - Orthopedic procedure that requires bone grafting that meets **ALL** of the following:
        - 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:
            - Allograft-based, including demineralized bone matrix (DBM)

- Autografts
- Bone graft substitutes containing an organic bone material (e.g., bovine, coral) when used alone or combined with another covered bone graft substitute.
- Ceramic or polymer-based synthetic bone graft substitutes.

Bone Scaffolding 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)
- Anterior cruciate ligament-derived stem cells for ligament tissue engineering
- BacFast HD for isolated facet fusion
- BIO MatrX
- Bone Marrow Aspirate Concentrate (BMAC)
- Bone void fillers (e.g. Opteform, a demineralized bone matrix-based allograft; Integra Mozaik Osteoconductive Scaffold putty, etc.)
- Cell-based substitutes (e.g. mesenchymal stem cell therapy, etc.)
- Human growth factors (e.g. fibroblast growth factor, insulin-like growth factor, etc.)
- Mesenchymal stem cell therapy for spinal fusion and other orthopedic indications
- OptiMesh
- Osteocel
- 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)
- Trinity Evolution Bone Matrix

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.
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)

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: October
- 2020: January
- 2015: March, May, June
- 2013: August
- 2012: April, September

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- 2023: October
- 2021: December

- 2020: December
- 2019: December
- 2018: September
- 2017: November
- 2016: July, August
- 2015: August
- 2014: August
- 2011: November

Effective Date:

- November 2010

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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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. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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