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SHP Bone Scaffolding

AUTH: SHP Medical 02 v2 (AC)

MCG Health
Ambulatory Care
26th Edition

Link to Codes

Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products

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Policy is applicable to all products.

Authorization Requirements

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Pre-certification by the Plan is required.

Description of Item or Service

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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.

Exceptions and Limitations

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- There is insufficient scientific evidence to support the medical necessity of the following bone graft materials as they are not shown to improve health outcomes upon technology review:
    - 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
- There is insufficient scientific evidence to support the medical necessity of bone scaffolding for uses other than those listed in the clinical indications for procedure section.

Clinical Indications for Procedure

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- 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 anorganic 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 graft materials are **NOT COVERED** for **ANY** of the following:
  - 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
  - Bone Marrow Aspirate Concentrate (BMAC)
  - BIO MatrX
  - 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
  - ProDense (calcium sulfate/calcium phosphate composite)
  - Pro Osteon Bone Graft Substitute
  - Pro Osteon Porous Hydroxyapatite Bone Graft Substitute
  - Trinity Evolution Bone Matrix

Document History

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- Revised Dates:
  - 2022: October
  - 2020: January
  - 2015: March, May, June
  - 2013: August
  - 2012: April, September
- Reviewed Dates:
  - 2021: December
  - 2020: December
  - 2019: December
  - 2018: September
  - 2017: November
  - 2016: July, August
  - 2015: August
  - 2014: August
  - 2011: November
- Effective Date: November 2010

Coding Information

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- CPT/HCPCS codes covered if policy criteria is met:
  - CPT 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
  - CPT 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
  - CPT 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
  - CPT 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)
- CPT/HCPCS codes considered not medically necessary per this Policy:
  - CPT 0232T - Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
  - CPT 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

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CPT® : 0219T, 0220T, 0221T, 0222T, 0232T, 0707T

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