Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Bone graft allografts as Standalone Spinal Stabilization Devices (such as TruFUSE®, NuFix, BacFast®)

PRIOR AUTHORIZATION: Not applicable.

POLICY: SWHP considers bone graft substitutes as standalone stabilization devices, such as minimally invasive percutaneous facet joint fusion, as experimental and investigational for all indications and as NOT a covered benefit.

OVERVIEW: TruFUSE® is a minimally invasive percutaneous facet joint fusion that uses two small cork-shaped dowels made of human bone allografts that are implanted in the plane of the facet joints to stabilize vertebrae and help reduce back pain.

NuFix is a product of NuTech Spine, Inc., a biologics company, that engages in engineering and providing machined allograft tissues for spinal fusion applications. It offers NuFix, a cortical antimigration allograft for the stabilization of the spine. The company’s NuFix is used for various treatment applications, such as fixation and in-situ fusion in laminectomy/discectomy procedure; and treating or preventing adjacent level disease.

BacFast® HD is Hyper-Demineralized to expose the collagen surface of a bone allograft, and is is engineered with a focus on fusion as well as facet stabilization.

Allograft devices are regulated by the FDA as human cells, tissue and cellular and tissue based products, they are generally processed by licensed tissue banks. Due to differences in requirements for regulation for many of these bone graft substitutes, published clinical studies supporting safety and efficacy of these products as stand-alone stabilization devices are not available. The scope and quality of the clinical studies are insufficient to conduct an evidence-based assessment of the safety and efficacy Until published clinical trials are available supporting long-term clinical outcomes, safety, and efficacy, their use is considered unproven, experimental or investigational.

MANDATES: None.
CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:
- CPT Not Covered: 0219T, 0220T, 0221T, 0222T

ICD9 codes:
- ICD9 Not covered:

CMS: No NCD has been issued

POLICY HISTORY:

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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.