MEDICAL COVERAGE POLICY	
SERVICE:	**Bone Graft Allografts as Stand-alone Spinal Stabilization Devices**
Policy Number:	**051**
Effective Date:	**12/01/2021**
Last Review:	**10/28/2021**
Next Review Date:	**10/28/2022**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus 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 (EOC) or Summary Plan Description (SPD) 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 Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan 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. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

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

PRIOR AUTHORIZATION: Not applicable.

POLICY: SWHP/FirstCare considers bone graft substitutes as standalone stabilization devices, such as minimally invasive percutaneous facet joint fusion, as experimental and investigational and/or unproven for all indications.

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 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, and 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.

MEDICAL COVERAGE POLICY

SERVICE:	**Bone Graft Allografts as Stand-alone Spinal Stabilization Devices**
Policy Number:	**051**
Effective Date:	**12/01/2021**
Last Review:	**10/28/2021**
Next Review Date:	**10/28/2022**

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 - 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).
ICD-10 codes:	
ICD-10 Not covered:	

CMS: According to LCD L35094 and accompanying and LCA A56967, these procedures are considered not reasonable and necessary. Both documents retired 7/1/2020

POLICY HISTORY:

Status	Date	Action
New	12/6/2010	New policy
Reviewed	12/6/2011	Reviewed.
Reviewed	11/15/2012	Reviewed.
Reviewed	11/14/2013	Extensive revision of overview.
Reviewed	09/25/2014	No changes
Reviewed	10/22/2015	No changes
Reviewed	10/27/2016	Minor updates
Reviewed	09/19/2017	No significant changes
Reviewed	07/17/2018	No significant changes
Reviewed	09/26/2019	Added LCD information
Reviewed	10/24/2020	No changes except to note that LCD has been retired.
Reviewed	10/28/2021	No changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare 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/FirstCare 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.

1. Leclaire, R., Fortin, R., et al. Radiofrequency facet joint denervation in the treatment of low back pain: A placebo controlled clinical trial to assess efficacy. Spine (2001) 26(13): 1411-1416.
2. Park, Y., Kim, J., et al. Facet fusion in the lumbosacral spine: A 2-year follow-up study. Neurosurgery (2002) 51: 88-96.
3. Gibson, J.N., and G. Waddell. Surgery for degenerative lumbar spondylosis: Updated Cochrane Review. Spine (2005) 30(20): 2312-20
4. TruFuse Facet Fusion© miniSURGTM Corp. Clearwater, Florida: TruFUSE® Procedure. <http://www.trufuse.com>. (2016 October 26).
5. Nufix @ https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapid=119033175 (accessed 9/11/2017)
6. BacFast at http://biologixtechnologies.com/bacfast.html
7. Masashi Miyazaki,Hiroshi Tsumura, Jeffrey C. Wang and Ahmet Alanay. An update on bone substitutes for spinal fusion. Eur Spine J. 2009 June; 18(6): 783–799. Published online 2009 March 12. doi: 10.1007/s00586-009-0924-x
8. Cook DJ1, Yeager MS, Oh MY, Cheng BC. Lumbar intrafacet bone dowel fixation. Neurosurgery. 2015 Apr;76(4):470-8; discussion 478.
9. Pirris SM1, Nottmeier EW2, Rahmathulla G3, Deen HG3, Reimer R3, Wharen RE3. Radiographic fusion rate after implantation of facet bone dowels. Spine J. 2014 Sep 1;14(9):2102-11. doi: 10.1016/j.spinee.2013.12.027. Epub 2014 Jan 18.
10. Kadam, Abhijeet et al. “Bone Substitutes and Expanders in Spine Surgery: A Review of Their Fusion Efficacies.” International Journal of Spine Surgery 10 (2016): 33. PMC. Web. 11 Sept. 2017. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5130324/