Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 7/1/21**
(See policy history boxes for previous effective dates)

Title: Infuse/Mastergraft Posterolateral Revision Device

Description/Background

The Infuse/Mastergraft™ posterolateral revision device consists of a 2-part bone graft replacement (INFUSE® Bone Graft + Mastergraft® Granules) used as part of a 3 component system (INFUSE® Bone Graft + Mastergraft® Granules + supplemental posterior fixation system [e.g., the CD HORIZON® Spinal System). These components must be used as a system for the prescribed indication.

The Infuse/Mastergraft™ posterolateral revision device is designed for the repair of symptomatic, posterolateral lumbar spine pseudoarthrosis. This device is intended to address a small subset of patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion. These patients may be diabetics and smokers. This device is indicated to treat two or more levels of the lumbar spine.

Regulatory Status

On October 10, 2008, the Infuse/Mastergraft™ posterolateral revision device received a Humanitarian Device Exemption (HDE) number, H040004. Applicant's name: Medtronic Sofamor Danek USA, Inc.

According to the FDA site, this device has been withdrawn at the request of the sponsor effective March 23, 2010.

Indications for use: the infuse/Mastergraft™ posterolateral revision device is indicated for the repair of symptomatic, posterolateral lumbar spine pseudarthrosis. This device is intended to address a small subset of patients for whom autologous bone and/or bone marrow harvest are

not feasible or are not expected to promote fusion. These patients are diabetics and smokers. This device is indicated to treat two or more levels of the lumbar spine.

Medical Policy Statement

The use of Infuse/Mastergraft™ posterolateral revision device is considered experimental/investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

22899

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

The INFUSE/MASTERGRAFT™ posterolateral revision device has not been previously tested in controlled human clinical trials for the intended indication. Data supporting its use in symptomatic, multi-level posterolateral revision procedures has been obtained from a small number of patients who were smokers and/or diabetics. In this analysis, no new adverse events were observed. All 3 patients with fusion data were determined to have a solid fusion outcome. Additionally, 4 patients received the INFUSE/MASTERGRAFT™ posterolateral revision device and a small amount of their own bone. Fusion success was achieved in all cases with sufficient follow-up. This study provides insight into the safety and probable benefit of the INFUSE/MASTERGRAFT™ posterolateral revision device.

The combination of INFUSE® Bone Graft and MASTERGRAFT® resorbable ceramic granules with spinal instrumentation has also been evaluated in a different study. This study was intended for patients suffering from single level disease requiring surgical intervention at the operative level for the first time.

The only pilot clinical trial information is available on the FDA's Summary of Safety and Probable Benefit document. There are no published clinical trial studies available at this time.

Summary of Evidence
Supporting evidence in published peer-reviewed literature was not found; therefore INFUSE/MASTERGRAFT™ posterolateral revision device is considered experimental/investigational.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03118505*	A study of Infuse® Bone Graft with Mastergraft® strip and posterior fixation for posterolateral fusion treatment of multilevel degenerative lumbosacral spinal conditions	125	Aug 2020
Unpublished			
NCT01491542*	Infuse® Bone Graft with Mastergraft® granules with CD Horizon® for posterolateral lumbar fusion in patients with degenerative disc disease-pilot study	46	Mar 2007 (completed)
NCT00549913*	Study of 3 doses of NeoFuse combined with Mastergraft granules in subjects requiring posterolateral lumbar fusion	6	Sep 2013 (completed)

*Sponsored or cosponsored by Medtronic
NCT: national clinical trial

Government Regulations

National:
There is no NCD related to this device.

Local:
There is no LCD related to this device.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. U.S. Food and Drug Administration (FDA), Humanitarian Device Exemptions, Summary of Safety and Probable Benefit. H040004. Approval date October 10, 2008. https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions. Accessed February 2021.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2021, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/20	4/14/20		Joint policy established
7/1/21	4/20/21		Routine policy maintenance. Recommend retirement.

Next Review Date: Topic is obsolete and will no longer be reviewed.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INFUSE/MASTERGRAFT POSTEROLATERAL REVISION DEVICE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.