02-20000-32

Original Effective Date: 01/01/06

Reviewed: 12/08/23

Revised: 01/01/24

Next Review: No Longer Scheduled for Routine Review (NLR)

Subject: Bone Morphogenetic Protein (BMP)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

DESCRIPTION:

Bone morphogenetic proteins (BMPs) are members of the family of transforming growth factors. At present, more than 20 different BMPs have been identified, all with varying degrees of tissue-stimulating properties.

The recombinant human bone morphogenetic proteins (rhBMPs) are delivered to the bone grafting site as part of a surgical procedure; a variety of carrier and delivery systems has been investigated. Carrier systems, which are absorbed over time, maintain the concentration of the rhBMP at the treatment site; provide temporary scaffolding for osteogenesis; and prevent extraneous bone formation. Carrier systems have included inorganic material, synthetic polymer, natural polymers, and bone allograft. The rhBMP and carrier may be inserted via a delivery system, which may also provide mechanical support.

The carrier and delivery system are important variables in the clinical use of rhBMPs, and different clinical applications have been evaluated with different carriers and delivery systems. For example, rhBMP putty with pedicle and screw devices are used for instrumented intertransverse fusion (posterolateral fusion), while rhBMP in a collagen sponge with bone dowels or interbody cages are used for interbody spinal fusion. In addition, interbody fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction. Surgical procedures may include decompression of the spinal canal and insertion of pedicle screws and rods to increase stability of the spine.

Posterior approaches allow decompression (via laminotomies and facetectomies) for treatment of spinal canal pathology (eg, spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum) along with stabilization of the spine and are differentiated from instrumented or noninstrumented posterolateral fusion, which involves the transverse processes. Due to the proximity of

these procedures to the spinal canal, risks associated with ectopic bone formation are increased (eg, radiculopathies). Increased risk of bone resorption around rhBMP grafts, heterotopic bone formation, epidural cyst formation, and seromas has also been postulated.

Regulatory Status

The INFUSE® Bone Graft product (Medtronic) consists of rhBMP-2 on an absorbable collagen sponge carrier; it is used in conjunction with several carrier and delivery systems. The INFUSE® line of products has been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process.

Recombinant human bone morphogenetic protein-7 (rhBMP-7) [e.g., OP-1® Putty (Stryker Biotech)], consists of rhBMP-7 and bovine collagen and carboxymethylcellulose, and forms a paste or putty when reconstituted with saline. The rhBMP-7 product is no longer marketed in the U. S.

POSITION STATEMENT:

Use of recombinant human bone morphogenetic protein-2 (rhBMP-2, InFUSE™) **meets the definition of medical necessity** in skeletally mature individuals for the following indications:

- For anterior lumbar interbody fusion procedures when the use of autograft is not feasible*, **OR**
- For instrumented posterolateral intertransverse spinal fusion procedures when the use of autograft is not feasible*, **OR**
- For the treatment of acute, open fracture of the tibial shaft, when the use of autograft is not feasible*

*NOTE: Use of autograft via iliac crest bone graft (ICBG) may be considered not feasible due to situations that may include, but are not limited to, prior harvesting of ICBG, or a need for a greater quantity of ICBG than is available (eg, for multilevel fusion).

Bone morphogenetic protein (rhBMP-2, InFUSE™) **does not meet the definition of medical necessity** for all other indications, including but not limited to:

- Spinal fusions when the use of autograft is feasible
- Craniomaxillofacial surgeries

BILLING/CODING INFORMATION:

There is no specific CPT or HCPCS code for bone morphogenetic protein. In 2011, CPT code 20930 was revised to include BMP-type materials used in spine surgery.

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical, initial assessment, procedure note, visit note.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative

Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician procedure note	11505-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Autograft: a tissue (or an organ) transferred by grafting into a new position in the body of the same individual.

Morphogenetic (morphogenesis): the ability of a molecule or group of molecules to assume a certain shape; differentiation of cells and tissues in the early embryo that establishes the form and structure of the various organs and parts of the body.

Posterolateral: behind and to one side of, specifically to the outer side.

RELATED GUIDELINES:

None applicable.

OTHER:

Other index terms for bone morphogenetic protein:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Morphogenic or morphogenetic protein-2

BMP-2

INFUSE® Bone Graft

INFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device

INFUSE™ Bone Graft/Medtronic Interbody Fusion Device

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/08/23.

GUIDELINE UPDATE INFORMATION:

01/01/06	New Medical Coverage Guideline.
09/15/06	Scheduled review; expand coverage statement to include multiple level spinal fusions; remove non-coverage statement regarding multiple level spinal fusion procedures.
09/15/07	Scheduled review; typographical corrections were made; reformatted guideline; updated references.
07/15/08	Scheduled review; no change in position statement; references updated; guideline is moved to “no longer scheduled for routine review” status.
11/15/10	Reviewed and revised to clarify Position Statements; formatting changes; references updated.
09/15/11	Revision; formatting changes.
04/15/12	Scheduled review; Position Statement revised; references updated; formatting changes.
05/11/14	Revision: Program Exceptions section updated.
10/15/14	Revision: Billing and Coding Information section.
06/15/16	Scheduled review. Revised description section, Position Statement, and Billing/Coding Information section. Updated references. Reformatted guideline.
07/01/19	Revision: Deleted statements regarding anterior approach from the position statement section. Reformatted guideline.
08/15/19	Scheduled review. Revised description, position statement, definitions, and index terms. Updated references.

12/15/20	Scheduled review. Maintained position statement and updated references.
09/15/22	Scheduled review. Revised description. Maintained position statement and updated references.
05/23/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.