Medica Coverage Policy

Policy Name:	**Recombinant Human Bone Morphogenic Protein-2 (rhBMP-2)/InFUSE and Allogeneic Morphogenic Protein (e.g., Osteo- AMP™) - Mayo Medical Plan Only**
Effective Date:	**11/15/2021**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

NOTE: THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: For all other medica members, Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering this service.

Coverage Policy

Recombinant human bone morphogenic protein-2 (rhBMP-2)/InFUSE

NOTE: rhBMP-2/InFUSE *requires prior authorization for spinal fusions*.
See Medica Utilization Management Policies, *Lumbar Spinal Surgeries* and *Cervical Spinal Surgeries,* for specific medical necessity criteria.

rhBMP-2/InFUSE bone graft device systems are **COVERED** for FDA approved indications, including:

1. ***Spinal fusion*** in skeletally mature individuals with degenerative disc disease when using an anterior approach at a single level from the fourth lumbar vertebra (L4) to the first sacral vertebra (S1), and when the individual has failed non-operative treatment.
2. Treatment of acute, open ***tibial shaft fractures*** within two weeks of the initial fracture in skeletally mature individuals and following appropriate wound management and fracture stabilization with standard fixation devices.

RhBMP-2/InFUSE bone graft device systems are considered investigative and unproven and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

Note: If the InFUSE bone graft device system is used with a biologic other than recombinant human bone morphogenic protein-2 (rhBMP-2), these criteria do not apply.

Allogeneic morphogenic protein (e.g., OsteoAMP™)
Allogeneic morphogenic protein (e.g., OsteoAMP™) is considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

- See related Medica coverage policy: *Stem Cell Therapy for Orthopedic Applications.*

Description

Osteogenic proteins (aka bone morphogenetic or morphogenic proteins; BMPs), are a family of bone-matrix polypeptides derived from a variety of mammalian species. Implantation induces a cascade of cellular events which are intended to result in formation of new bone at the treatment site. Seven BMPs have been identified with RhBMP-2/InFUSE (Medtronic, Inc.) and OsteoAMP (Bioventus, LLC) that are commercially available for use in the United States. BMP is being purported for use in treating orthopedic conditions, such as use in spinal fusion and tibial repair procedures. It is used with various types of spinal spacers and fixation instruments.

Recombinant Human Bone Morphogenic Protein

RhBMP-2/InFUSE bone grafting is intended to aid in the fusion of lumbar discs for treatment of degenerative disc disease and in the repair of acute open tibial fractures. InFUSE is comprised of recombinant human bone morphogenic protein-2, which is applied to an absorbable collagen sponge prior to insertion. It is inserted into a titanium cage prior to placement between the affected discs.

Allogeneic Morphogenic Protein

OsteoAMP is comprised of allogeneic bone (i.e., cadaver-derived) with BMP-2, BMP-7 and other endogenous growth factors derived from the allogeneic bone marrow. These other growth factors are additional proteins with osteoinductive, angiogenic, and mitogenic properties and are bound to the bone during the harvesting process. OsteoAMP is available in various forms, including a compressible sponge, putty for mixing with bone marrow or blood, and granules for incorporation with mineralized allograft bone chips.

FDA Approval

Recombinant Human Bone Morphogenic Protein

InFUSE bone graft device systems (Medtronic Sofamor Danek) received initial FDA premarket approval (PMA) (P000058) in July 2002 for use in lumbar spine surgery. The system was approved for use in skeletally mature individuals with degenerative disc disease when using an anterior-approach at a single level from the fourth lumbar vertebra (L4) to the first sacral vertebra (S1), and when the individual has undergone at least six months of non-operative treatment. The original PMA has received multiple supplemental approvals. These device systems are not intended for use without the Medtronic titanium threaded interbody fusion device component.

InFUSE bone graft systems received initial FDA PMA approval (P000054) in April 2004 for treatment of fractures. The system was approved for treating acute, open tibial shaft fractures within two weeks of the initial fracture in skeletally mature individuals and following appropriate wound management and fracture stabilization with standard fixation devices. The original PMA has received multiple supplemental approvals.

Allogeneic Morphogenic Protein

OsteoAMP (Bioventus) is regulated by FDA's Center for Biologics Evaluation and Research as human tissue for transplantation and is supplied, stored, and distributed by licensed tissue banks that are required to register as such with FDA. Bioventus is not a registered tissue establishment and is exempt from tissue establishment licensure. Certificates, licenses, and registrations are listed on the Bioventus website.

Prior Authorization

Prior authorization is not required when using recombinant human bone morphogenic protein for all other covered indications. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s).

Original Effective Date: 9/1/2013

Re-Review Date(s): 11/26/2013
5/1/2015 – administrative update; coding
12/3/2015 – administrative update; note
5/8/2016
11/16/2016
9/19/2018
2/25/2020 – administrative update; format
9/15/2021
5/01/2024 – Administrative update; policy applies to Mayo Medical Plan members only