

Policy Name: Recombinant Human Bone Morphogenic Protein-2, Long Bones and Allogeneic Morphogenic Protein (e.g., OsteoAMP™)

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: Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering medical necessity criteria for recombinant human bone morphogenic protein (rhBMP-2) used in spinal fusion. See criteria within the Carelon policy, *Spine Surgery - Bone Graft Substitutes and Bone Morphogenetic Proteins*.

Coverage Policy

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

rhBMP-2/InFUSE bone graft device systems are **COVERED** for 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 long bone 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 efficacy or effects on health care outcomes.

See related Medica position statements: *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. RhBMP-2/InFUSE (Medtronic, Inc.) and OsteoAMP (Bioventus, LLC) 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.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

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

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| Original Effective Date: | 11/16/2016 |
| Re-Review Date(s): | 09/19/2018 |
| | 02/25/2020 – administrative update; format |
| | 09/15/2021 |
| | 05/01/2024 – administrative update; removed recombinant human bone morphogenic protein (rhBMP-2) for use in the spine |