Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP281

Section: Medical Benefit Policy

Subject: Bone Morphogenetic Protein

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Bone Morphogenetic Protein

II. Purpose/Objective:

To provide a policy of coverage regarding Bone Morphogenetic Protein

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Bone morphogenetic protein is naturally occurring protein found in human bone which plays an active role in bone formation. There are several bone morphogenetic proteins (BMPs) that have been identified. Additionally, there are several recombinant human bone morphogenetic proteins (rhBMPs). However, at present, there are only two which have been developed for use: rhBMP-2 and rhBMP-7.

INDICATIONS:
Use of recombinant human bone morphogenetic protein-2 (rhBMP-2, InFUSE, etc.) is considered medically necessary for any of the following indications:

- anterior spinal interbody fusion, in conjunction with an FDA-approved interbody fusion device, at one or more levels in skeletally mature patients with degenerative disc disease from L2-S1. Patients should have failed at least 6 months of conservative treatment.
- use with spine implants made of polyetheretherketone (PEEK) in oblique lateral interbody fusion (OLIF) and anterior lumbar interbody fusion (ALIF) procedures as follows:
    - •OLIF with certain sizes of the PEEK Perimeter Implant at a single level from L5 to S1.
    - •OLIF with certain sizes of the PEEK Clydesdale Implant at a single level from L2 to L5.
    - •ALIF with certain sizes of the PEEK Perimeter Implant at a single level from L2 to S1
- instrumented posterolateral intertransverse spinal fusion procedures, in conjunction with an FDA-approved device, at one or more levels in skeletally mature patients with degenerative disc disease from L2-S1. Patients should have failed at least 6 months of conservative treatment.
- treatment of acute, open fracture of the tibial shaft
- localized alveolar ridge augmentation for defects associated with extraction sockets and sinus augmentation

Use of recombinant human bone morphogenetic protein-7 (rhBMP-7, OP-1) is considered medically necessary for any of the following indications:

- As an alternative to autograft in patients at increased risk of autograft failure (e.g., osteoporosis, tobacco use, or diabetes) requiring non-instrumented revision posterolateral intertransverse lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion; or
- As an alternative to autograft in long bone non-unions where use of autograft is not feasible and alternative conservative treatments have failed

EXCLUSIONS:
Bone morphogenetic protein (rhBMP-2 or rhBMP-7) is considered **experimental, investigational or unproven** for all other indications, including but not limited to:

- Cervical spinal fusion
- Posterior or transforaminal lumbar interbody spinal fusion
- As initial treatment or revision of non-instrumented posterolateral intertransverse spinal fusion that does not meet the criteria listed above
- As an alternative or adjunct to bone grafting in other locations, including craniomaxillofacial surgeries
- Proficient

Ceramic-Based Products [e.g., beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate] used alone or in combination with other grafts including Bone Marrow Aspirate is considered to be of unproven value and therefore not medically necessary. There is insufficient evidence in the published, peer-reviewed medical literature to support the clinical value of this material compared with established alternatives . It is therefore considered to be unproven and **NOT COVERED.**

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only
20931 Allograft, structural, for spine surgery only
C9359 Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc
C9362 Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc
C1602 Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)
0814T Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. **For PA Medicaid Business segment, this policy applies as written.**

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/14

Revised: 1/16 (added indications), 1/18 (clarified indication); 1/22 (add oral surgery indication); 1/24 (add exclusion)

Reviewed: 1/15, 1/17, 1/19, 1/20, 1/21, 1/23

CMS UM Oversight Committee Approval: 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies