

# **Clinical Policy: Bone Morphogenetic Protein**

Reference Number: PA.CP.MP.OR.1005 Effective Date: 04/01/2020 Last Review Date: NEW POLICY Coding Implications Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

### Common Name: BMP

**Definition:** Bone morphogenetic proteins are growth factors used in orthopedic applications such as spinal fusion and nonunions. Currently the OP-1 (BMP-7) and InFUSE (BMP-2) have received FDA approval for certain clinical indications.

### I. Criteria for Inclusion:

Bone Morphogenic Protein-2 (rhBMP-2, InFUSE) is considered medically necessary when used with the appropriate FDA-approved cage and all of the following are met:

- A. Surgery is planned for one level from L2-S1 for treatment of degenerative disc disease via anterior or oblique lateral approach
- B. There is high risk for failure of fusion (prior failed spinal fusion, current smoker, presence of diabetes or renal disease, alcoholism, long-term steroid use, or osteoporosis)
- C. Autologous bone and/or marrow are not available or not expected to promote fusion
- D. Other uses will require prior authorization and be considered on a case by case basis.

### **II.** Criteria for Exclusion:

- E. The use of rhBMP-2 is considered not medically necessary for all other indications not listed above, or when any of the following are present:
  - 1. Planned posterior approach fusion
  - 2. Cervical or thoracic indications
  - 3. Known sensitivity to implant material or bovine type II collagen, or with an allergy to titanium (including alloys) or polyetheretherketone (PEEK)
  - 4. Use near the site of extant or resected tumor, or for patients with active malignancy or receiving treatment for cancer
  - 5. Infection at the planned operative site
  - 6. Pediatric patients under 18, or skeletal immaturity
  - 7. Female patients who are pregnant

### III. Coding

### A. CPT

_				
20930	Allograft, morselized, or placement of osteopromotive material, for spine			
	surgery only [when specified as recombinant human bone morphogenetic			
	protein]			
20999	Unlisted procedure, musculoskeletal system, general [when specified as			
	placement of recombinant human bone morphogenetic protein for tibial			
	fracture]			

### B. HCPCS

## **CLINICAL POLICY** Bone Morphogenetic Protein



No HCPCS codes

- C. ICD-10 Procedure No ICD-10 Procedure codes
- D. ICD-10 Diagnosis All associated ICD-10 Diagnosis codes



### References

- 1. Smucker, J., Rhee, J., Singh, K., Yoon, S., & Heller, J. (2006). Increased swelling complications associated with off-label usage of rhbmp-2 in the anterior cervical spine. *Spine*, *31*(24), 2813-2819.
- Ratko, T.A., Belison, S.E., Samson, D.J., Claudia, B., Ziegler, K.M., & Aronson, N. (2010) Bone morphogenic protein: the state of the evidence of on-label and off-label use. Retrieved from:

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id75ta.pdf

- 3. Epstein, N. E. (2011). Pros, cons, and costs of infuse in spinal surgery. *Surgical Neurology International*, 2(1), 43. doi:10.4103/2152-7806.76147
- 4. Medtronic. (2004) Infuse bone graft important medical information. Retrieved from http://www.accessdata.fda.gov/cdrh\_docs/pdf/P000054c.pdf
- Deyo, R.A., Ching, A., Matsen, L., Martin, B.I., Kreuter, W., Jarvik, J.G., Angier, H., & Mirza, S.K. (2012). Use of bone morphogenetic proteins in spinal fusion surgery for older adults with lumbar stenosis: trends, complications, repeat surgery, and charges. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/21494195
- 6. Bono, C., & Wetzel, F. (2013). Black, white, or gray: how different (or similar) are yoda and the the spine journal reviews of bmp-2?. *Spine Journal*, *13*(9), 1001-1005.
- Simmonds, M. C., Brown, J. E., Heirs, M. K., Higgins, J. T., Mannion, R. J., Rodgers, M. A., & Stewart, L. A. (2013). Safety and effectiveness of recombinant human bone morphogenetic protein-2 for spinal fusion: a meta-analysis of individual-participant data. *Annals Of Internal Medicine*, *158*(12), 877-889. doi:10.7326/0003-4819-158-12-201306180-00005
- Fu, R., Selph, S., McDonagh, M., Peterson, K., Tiwari, A., Chou, R., & Helfand, M. (2013). Effectiveness and harms of recombinant human bone morphogenetic protein-2 in spine fusion: a systematic review and meta-analysis. *Annals Of Internal Medicine*, *158*(12), 890-902. doi:10.7326/0003-4819-158-12-201306180-00006
- 9. Burkus, J., Gornet, M., Schuler, T., Kleeman, T., & Zdeblick, T. (2009). Six-year outcomes of anterior lumbar interbody arthrodesis with use of interbody fusion cages and recombinant human bone morphogenetic protein-2. *Journal Of Bone & Joint Surgery, American Volume*, *91*(5), 1181-1189. doi:10.2106/JBJS.G.01485
- North American Spine Society. (2014). Recombinant human bone morphogenetic protein (rhBMP-2). Retrieved from https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/rhBMP.pd f
- 11. Glassman, S., Howard, J., Dimar, J., Sweet, A., Wilson, G., & Carreon, L. (2011). Complications with recombinant human bone morphogenic protein-2 in posterolateral spine fusion: a consecutive series of 1037 cases. *Spine*, *36*(22), 1849-1854.
- 12. Heida, K., Ebraheim, M., Siddiqui, S., & Liu, J. (2013). Effects on clinical outcomes of grafts and spacers used in transforaminal lumbar interbody fusion: a critical review. *Orthopaedic Surgery*, (1), 13.
- 13. Crandall, D. G., Revella, J., Patterson, J., Huish, E., Chang, M., & McLemore, R. (2013). Transforaminal lumbar interbody fusion with rhbmp-2 in spinal deformity, spondylolisthesis, and degenerative disease-part 1: large series diagnosis related outcomes and complications with 2- to 9-year follow-up. *Spine*, *38*(13), 1128-1136. doi:10.1097/BRS.0b013e31828864e6

### **CLINICAL POLICY Bone Morphogenetic Protein**



- 14. Crandall, D., Revella, J., Patterson, J., Huish, E., Chang, M., & McLemore, R. (2013). Transforaminal lumbar interbody fusion with rhbmp-2 in spinal deformity, spondylolisthesis, and degenerative disease-part 2 bmp dosage-related complications and long-term outcomes in 509 patients. *Spine*, 38(13), 1137-1145.
- 15. Singh, K., Nandyala, S. V., Marquez-Lara, A., Cha, T. D., Khan, S. N., Fineberg, S. J., & Pelton, M. A. (2013). Clinical study: clinical sequelae after rhBMP-2 use in a minimally invasive transforaminal lumbar interbody fusion. *The Spine Journal*, 131118-1125. doi:10.1016/j.spinee.2013.07.028
- 16. Hodges, S., Eck, J., & Newton, D. (2012). Retrospective study of posterior cervical fusions with rhBMP-2. *Orthopedics*, *35*(6), E895-E898.
- Fahim, D., Whitehead, W., Curry, D., Dauser, R., Luerssen, T., & Jea, A. (2010). Routine use of recombinant human bone morphogenetic protein-2 in posterior fusions of the pediatric spine: safety profile and efficacy in the early postoperative period. *Neurosurgery*, 67(5), 1195-1204.
- 18. Abd-El-Barr, M., Cox, J., Antonucci, M., Bennett, J., Murad, G., & Pincus, D. (2011). Recombinant human bone morphogenetic protein-2 as an adjunct for spine fusion in a pediatric population. *Pediatric Neurosurgery*, 47(4), 266-271.
- 19. Klimo, P., & Peelle, M. W. (2009). Use of polyetheretherketone spacer and recombinant human bone morphogenetic protein-2 in the cervical spine: a radiographic analysis. *The Spine Journal*, (12), 959. doi:10.1016/j.spinee.2009.05.008



#### **Regulatory Data**

Policy Number/Name:	PA.CP.MP.OR.1005 Bone Morphogenetic Protein
Initial Approval and Effective Date:	01/13/2015
Reviewed Dates:	01/13/2015; 1/22/2016; 8/2/2016; 3/3/2017; 1/29/2018;
	3/1/2019
All Approval Dates:	01/13/2015; 1/22/2016; 3/3/2017; 1/29/2018; 3/5/2019
Approval Authority:	Utilization Management Committee
Business Owner:	Utilization Management
Applicable lines of business:	All
Board approval, if appropriate:	n/a
Approval Signature:	On file
URAC Standards:	
State Requirements:	
CMS/Federal Requirements:	
Corresponding policies:	

Revie	ws, Revisions, and Approvals	Date	Approval Date
•	New Policy created.	03/20	8/3/2020
•	Policy administered by Turning Point Healthcare Solutions		

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by PA Health & Wellness, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

### **CLINICAL POLICY** Bone Morphogenetic Protein



This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <u>http://www.cms.gov</u> for additional information.

©2018 PA Health & Wellness. All rights reserved. All materials are exclusively owned by PA Health & Wellness and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of PA Health & Wellness. You may not alter or remove any trademark, copyright or other notice contained herein. PA Health & Wellness<sup>®</sup> is a registered trademarks exclusively owned by PA Health & Wellness.