# Delta Dental of Virginia Clinical Policy # 403

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<th>Subject</th>
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<td>Biological Materials to Aid in Soft and Osseous Tissue Regeneration</td>
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<th>Type:</th>
<th>New</th>
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<td>Date:</td>
<td>11/15/2009</td>
<td>Revision Date:</td>
<td>01/16/2016</td>
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## Preamble:

The Clinical Policy Bulletin is an expression of Delta Dental of Virginia’s (DDVA) determination regarding whether certain services or supplies are medically or dentally necessary. DDVA bases its conclusions on a review of currently available clinical literature. This includes, but is not limited to, clinical outcome studies published in the peer-reviewed medical and dental literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians and dentists practicing in relevant clinical areas, and other relevant factors. DDVA reserves the right to revise these policies as new clinical information is available and we welcome submission of further relevant information.

A group may define covered dental services under their dental plan, as well as those services that may be subject to dollar caps or other limits. The plan documents outline covered benefits, exclusions and limitations. DDVA advises dentists and enrollees to consult the plan documents to determine if there are exclusions or other benefit limitations applicable to the service request. The conclusion that a particular service is medically or dentally necessary does not constitute an indication or warranty that the service requested is a covered benefit payable by DDVA. Some plans exclude coverage for services that DDVA considers either medically or dentally necessary. When there is a discrepancy between DDVA’s clinical policy and the group’s plan documents, DDVA is to defer to the group’s plan documents as to whether the dental service is a covered benefit. In addition, if state or federal regulations mandate coverage then DDVA will adhere to the applicable regulatory requirement.

## History:

When deemed necessary and appropriate, biological materials to aid in soft and osseous tissue regeneration are utilized as adjunctive components of various periodontal surgical procedures to help facilitate the formation of the periodontal attachment apparatus, including bone, cementum and fibers of the periodontal ligament. These biological materials may be used in gingival flap, osseous surgery and soft tissue grafting procedures to improve clinical attachment levels and enhance the restoration of the supporting structures lost through periodontal disease processes or adverse periodontal events.

Research using various biological materials is ongoing and the results of clinical
trials have been mixed. Bone morphogenic proteins (BMPs), transforming growth factor (TGF), platelet derived growth factor (PDGF), insulin-like growth factor (IGF), fibroblast growth factor (FGF), platelet rich plasma (PRP), vascular endothelial growth factor (VEGF), recombinant human bone morphogenic protein-2 (rhBMP2), recombinant human beta-nerve growth factor (rhβ-NGF), and enamel matrix derivative (EMD), and xenogenic collagen matrix (CM) are all matrix proteins/biological growth factors that have been investigated in periodontal research(1,2,7,10,11,12). Of these materials, enamel matrix derivative (EMD), a group of enamel matrix proteins derived from developing porcine teeth, and bone morphogenic protein (BMP-2), have been approved by the FDA for intraoral use(1,2). However, these materials have not been approved for regenerative procedures when used for dental implants.

EMD has shown inconsistent histological evidence of regeneration of the periodontal attachment apparatus(3,4,5), but clinically EMD has been shown to improve attachment levels and periodontal pocket depth measurements(1,2,6). The long-term benefits of EMD as a regenerative material have not yet been established(6).

### Policy/Therapy Guidelines:

**DDVA Guidelines:**

1. Adjunctive regenerative therapy utilizing biological materials is to be used for the treatment of periodontal disease defects of natural teeth only.

2. DDVA considers this procedure to be experimental and investigational and is evaluated on a case by case basis.

3. Indications for the use of biologic materials must be documented by x-rays and a periodontal charting showing the presence of pocket depths to 5mm.

4. The use of biological materials will not be considered when used in conjunction with soft tissue grafting, bone grafts, guided tissue regeneration, ridge augmentation, periradicular surgery, at extraction sites, or when utilized with other regenerative materials.

### ADA/CDT Codes (8):

D4265

### References:


4. Yukna RA and Mellonig JT. Histologic evaluation of periodontal healing in


