

Delta Dental of Virginia Clinical Policy # 403

Subject Biological Materials to Aid in Soft and Osseous Tissue Regeneration	Originating Department Clinical Professional Services
	Signature Authority Dental Director

Type: New Replacement Revision Clarification

Date: 11/15/2009 **Revision Date:** 11/15/2011

Preamble:	<p>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.</p> <p>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.</p>
History:	<p>Periodontitis is an inflammatory disease of the supporting tissues of teeth and is a major cause of tooth loss in adults. The onset and progression of periodontal disease is attributed to the presence of elevated levels of a consortium of pathogenic bacteria.</p> <p>When deemed necessary and appropriate, one adjunctive treatment modality includes the use of biological materials with surgical treatment for periodontal disease. 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 are used in gingival flap, osseous surgery and soft tissue grafting procedures to improve the clinical attachment levels and enhance the restoration of the supporting structures lost through periodontal disease processes or adverse periodontal events.</p> <p>Research using various biological materials is ongoing and the results of clinical trials have been mixed. Bone morphogenic proteins (BMPs), transforming growth</p>

	<p>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). 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.</p> <p>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).</p>
Policy:	<p>DDVA Guidelines:</p> <ol style="list-style-type: none"> 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. A periodontal charting must be provided documenting the presence of pocket depths to 5mm. 4. The use of biological materials will not be considered in conjunction with soft tissue grafting or when utilized with other regenerative materials.
Code(8):	D4265
References:	<ol style="list-style-type: none"> 1. American Academy of Periodontology. AAP Position Paper. Periodontal regeneration. J Perio 2005;76:1621-1622. 2. American Academy of Periodontology. AAP Commissioned Review. Bone augmentation techniques. J Perio 2007;78:377-396. 3. Parodi R, Liuzzo G, et al. Use of Emdogain in the treatment of deep intrabony defects: 12-month clinical results. Histologic and radiographic evaluation. Int J Perio Rest Dent 2000;19:93. 4. Yukna RA and Mellonig JT. Histologic evaluation of periodontal healing in humans following regenerative therapy with enamel matrix derivative. A 10-case series. J Perio 2000;71:752-759. 5. Sculean A, Windisch P and Chiantella GC. Human Histologic evaluation of an intrabony defect treated with enamel matrix derivative, xenografts, and GTR. Int J Perio Rest Dent 2004;24:326-333 6. Giannobile W, Somerman M. Growth and amelogenin-like factors in periodontal wound healing. A systematic review. Ann Periodontol 2003;8:193-204.

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