

Dental Clinical Policy

Subject: Biological Materials to Aid in Soft and Osseous Tissue Regeneration	
Guidelines #: 04-203	Publish Date: 01/01/2024
Status: Revised	Last Review Date: 10/04/2023

Description			
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This document addresses the biological materials to aid in soft and osseous tissue regeneration whether used alone or in conjunction with other procedures. The field of tissue engineering or regenerative medicine is a process by which damaged tissues are regenerated rather than using grafts (autografts, allografts) by developing biological substitutes that restore, maintain, or improve tissue function. In dentistry, adjunctive regenerative therapy utilizing biological materials can be used for the treatment of periodontal disease defects of natural teeth and dental implants.

The plan performs review of Biological Materials to Aid in Soft and Osseous Tissue Regeneration due to contractual requirements that necessitate benefits for dental services meet specific contract requirements. For example, plan contract(s) may require the provision of benefits for services that meet generally accepted standards of dental care at the lowest cost that properly addresses the patient's condition. The conclusion that a particular service is medically or dentally necessary and/or appropriate does not constitute an indication and/or warranty that the service requested is a covered benefit payable by the dental plan.

Clinical Indications

Dental review as it applies to accepted standards of care means dental services that a Dentist, exercising prudent clinical judgment, provides to a patient for the purpose of evaluating, diagnosing or treating a dental injury or disease or its symptoms, and that are: in accordance with the generally accepted standards of dental practice; , in terms of type, frequency and extent and is considered effective for the patient's dental injury or disease; and is not primarily performed for the convenience of the patient or Dentist, is not cosmetic and is not more costly than an alternative service.

For dental purposes, "generally accepted standards of dental practice" means:

- standards that are based on credible scientific evidence published in peer-reviewed, dental literature generally recognized by the practicing dental community
- specialty society recommendations/criteria
- the views of recognized dentists practicing in the relevant clinical area
- any other relevant factors from credible sources

Criteria

When covered by specific group contract, indications for the use of biologic materials must be documented by:

- 1. Pretreatment periapical radiographic images that are of diagnostic quality, properly oriented, and identified, and dated current (within 12 months).
- 2. Current, dated periodontal charting (6-point periodontal charting) indicating a minimum of 5mm pocket depths.
- 3. Rationale in support of the regeneration procedure and the type of material being used may be requested. For example, platelet rich plasma (PRP), Emdogain®, recombinant human bone morphogenic protein (rhBMP), GEM 21S®, etc.
- 4. The use of biological materials may not be considered when used in conjunction with soft tissue grafting, bone grafts, guided tissue regeneration, ridge augmentation, periradicular surgery, placed within extraction sites, or when utilized with other regenerative materials regardless of specific group plan coverage.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CDT	Including, but not limited to, the following:
D3431	Biological materials to aid in soft and osseous tissue regeneration in conjunction with periradicular surgery
D4265 D4266	Biologic materials to aid in soft and osseous tissue regeneration, per site Guided tissue regeneration – resorbable barrier per site

ICD-10 CM Diagnoses for Dental Diseases and Conditions: See the current CDT code book for details

References

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- 9. Meyle J, Hoffman T, et al. A multi-center randomized controlled clinical trial on the treatment of intra-bony defects with enamel matrix derivatives/synthetic bone graft or enamel matrix derivatives alone. J Clin Periodontol 2011;38:652-660.
- 10. 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
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- 13. Markous N, Pepelassi E, et al. The use of platelet--rich plasma combined with demineralized freeze-dried bone allograft in the treatment of periodontal endosseous defects. J Amer Dent Assoc 2010; 141:967-978.

History				
Revision History	Version	Date	Nature of Change	SME
	initial	2/8/17	creation	Rosen
	Revision	2/6/18	Related dental policies, appropriateness and medical necessity	M Kahn
	Revision	10/01/2020	Annual Review	Committee
	Revised	12/4/2020	Annual Review	Committee
	Revised	10/06/2021	Annual Review	Committee
	Revised	10/26/2022	Annual Review	Committee
	Revised	10/04/2023	Annual Review	Committee

Federal and State law, as well as contract language, takes precedence over Dental Clinical Policy. Dental Clinical Policy provides guidance in interpreting dental benefit application. The Plan reserves the right to modify its Dental Clinical Polices and guidelines periodically and as necessary. Dental Clinical Policy is provided for informational purposes and does not constitute medical advice. These Policies are available for general adoption by any lines of business for consistent review of the medical or dental necessity and/or appropriateness of care of dental services. To determine if a review is required, please contact the customer service number on the member's card.

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