



Dental Clinical Policy

**Subject: Biological Materials to Aid in Soft Tissue
and Osseous Tissue Regeneration (Endodontic)**
Guidelines #: 03-401
Status: Revised

Publish Date: 01/01/2022
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Description

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 recently 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 does not constitute an indication 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 as described by AAP and ADA) indicating a minimum of 5mm pocket depths.
3. A letter of rationale explaining the necessity 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:

D3431 Biologic materials to aid in soft and osseous tissue regeneration in conjunction with periradicular surgery

IDC-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.
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11. 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.
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History				
Revision History	Version	Date	Nature of Change	SME
	initial	2/8/17	creation	L Rosen
	Revision	2/6/18	Related policies, Appropriateness/Medical Necessity, criteria	M Kahn
	Revision	10/07/2020	Annual Review	Committee
	Revised	12/4/2020	Annual Review	Committee
	Revised	10/30/2021	Annual Review	Committee

Federal and State law, as well as contract language, and Dental Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Clinical Policy Committee are available for general adoption by plans or lines of business for consistent review of the medical or dental necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical or dental necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical or dental necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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