

| <b>Delta Dental of Michigan Clinical Criteria for Utilization Management Decisions</b> |                               |   |                                 |  |
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| Reference Number: 282.32 v3  |                               | Title: Clinical Criteria for Periodontal Regenerative Treatment |                                 |  |
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**Introduction**

This Delta Dental of Michigan (Delta Dental) clinical criteria document addresses periodontal regenerative treatment including bone replacement grafts, biologic materials to aid in tissue regeneration and guided tissue regeneration. The purpose of this document is to provide written clinical criteria to ensure that Delta Dental consistently applies sound and objective clinical evidence when determining the medical necessity and clinical appropriateness of periodontal regenerative treatment, as well as taking individual patient circumstances and the local delivery system into account.

The outcome of periodontal disease progression is the destruction of alveolar bone leading to intrabony osseous defects and furcation involvement that may shorten the life of a tooth due to critical loss of periodontal support. While resective surgical treatment may be selected to treat some patterns of bone destruction, clinical management of intrabony defects is ideally accomplished through techniques of periodontal regeneration to achieve gain of clinical attachment, reduction of probing depths and tooth retention. Regenerative procedures aimed at the formation of a new periodontium include the use of bone replacement grafts, application of biological materials to aid in periodontal tissue regeneration and the placement of guided tissue regeneration barriers. Depending on a patient's periodontal condition, clinicians may use a combination of regenerative techniques and materials:

- Bone replacement grafting for periodontal osseous defects can utilize autografts with a patient's own bone harvested from a donor site, allografts of non-autologous human bone, xenografts with bone products harvested from non-human sources and alloplastic bone substitutes. While autografts are generally considered to be the most effective bone graft material, other periodontal grafting materials are more commonly used because of the disadvantages of multiple wound sites on a patient and limited amounts of bone that can be harvested. Bone grafts can be osteogenic where new bone may develop from cells contained within a graft, osteoinductive where substances within a graft may stimulate cells near the graft to form new bone or osteoconductive where a graft provides a scaffold for nearby cells to move into a graft to form new bone.
- Guided tissue regeneration procedures utilize barrier membranes placed over treated periodontal osseous defects to prevent faster growing epithelial and connective tissue cells from entering into healing surgical wound sites, so that slower growing tissues that may create new bone and periodontal attachment to root surfaces can populate the sites and initiate regeneration. Barrier membranes for guided tissue regeneration can be resorbable or non-resorbable, however the need for a second surgery to remove non-resorbable membranes after regeneration and other disadvantages of non-resorbable membranes has led to more use of the biodegradable membranes.
- Biological materials that may enhance periodontal tissue regeneration are available that may be used alone or in combination with bone grafting and/or guided tissue regeneration. When added to a periodontal defect site, these biologics may stimulate periodontal regeneration and facilitate more predictable regenerative outcomes through the provision of growth factors, scaffolding for the cells for bone growth and/or other augmentation to a site.

Periodontal regenerative treatment generally involves performance of the following steps:

- Reflection of a full thickness mucoperiosteal flap to allow direct visualization of the involved root surfaces and the full extent of underlying deformities in the alveolar bone caused by periodontal disease
- Reshaping of underlying deformities in the alveolar bone if needed to optimize the shape of osseous defects for the placement of regenerative materials

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- Debridement of the root surfaces of the involved teeth and removal of soft tissue defects
- Application of bone grafts, biologic material and/or guided tissue regeneration membranes as appropriate for existing osseous defects
- Closure of the flap incision wound with a suture needle and suture material
- Subsequent removal of non-resorbable guided tissue regeneration membranes if used

Periodontal regenerative treatment is commonly performed by periodontists, but may also be performed by other dental specialists and general dentists in a variety of healthcare facilities.

### Applicable Dental Procedure Codes

The following dental procedure codes defined in the current version of the American Dental Association’s Code on Dental Procedures and Nomenclature (the CDT® Code) are applicable to this document and are the appropriate codes to use when documenting the performance of periodontal regenerative treatment. Inclusion of these codes here is for informational purposes only and does not imply benefit coverage or noncoverage of a procedure by a member’s dental plan. A determination that a dental procedure is medically necessary and clinically appropriate does not guarantee that the procedure is a covered benefit of a member’s dental plan. To determine if periodontal regenerative treatment is a covered benefit of an individual member’s dental plan, please refer to the plan documents in effect on the date of service.

| CDT® Procedure Code | Procedure Code Nomenclature  |
|---------------------|--|
| D4263               | bone replacement graft – retained natural tooth – first site in quadrant           |
| D4264               | bone replacement graft – retained natural tooth – each additional site in quadrant |
| D4265               | biologic materials to aid in soft and osseous tissue regeneration, per site        |
| D4266               | guided tissue regeneration, natural – resorbable barrier, per site                 |
| D4267               | guided tissue regeneration, natural – non-resorbable barrier, per site             |

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### Clinical Criteria<sup>1</sup>

When approval of benefit payment for periodontal regenerative treatment by a member’s dental plan requires a determination by Delta Dental that a procedure is medically necessary and clinically appropriate, the patient’s dental record must document a generally accepted indication for performing periodontal regenerative treatment. The following conditions are generally considered to be indications for performing periodontal regenerative treatment:

- 2-wall and 3-wall vertical intrabony osseous defects (defects surrounded by 2 or 3 walls of bone that generally present a higher potential for regeneration)
- Grade I-II furcation involvement (furcation involvement where bone loss has not progressed to a through-and-through defect and the bony architecture presents a potential for regeneration)

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<sup>1</sup> Government regulations or the provisions of a member’s dental plan that define when a dental procedure may be considered medically necessary and clinically appropriate with respect to benefit coverage may take precedence over these clinical criteria.

- Class I-II tooth mobility where presurgical splinting has been performed (evidence supports controlling mobility through presplinting of mobile teeth prior to regenerative treatment)

For patients who do not meet the published qualifying criteria for periodontal regenerative treatment, Delta Dental will consider documentation from relevant clinicians that explains the necessity of covering periodontal regenerative treatment for conditions not included in the criteria.

Depending on the clinical circumstances, the performance of periodontal regenerative treatment under the following conditions may be considered not medically necessary, inadvisable or deficient in clinical quality and may result in disapproval of benefits based on a professional determination that treatment is not medically necessary or not clinically appropriate:

- Absence of bone loss
- 0-wall and 1-wall intrabony defects, wide crater-type defects, horizontal bone loss (defects where the bony architecture generally presents a lower potential for regeneration)
- Grade III furcation involvement (through-and-through furcation defects that generally present a lower potential for regeneration)
- Class I-II tooth mobility where presurgical splinting has not been performed
- Class III tooth mobility
- Periodontal regenerative treatment performed on a tooth that has a hopeless periodontal, endodontic or structural prognosis
- Patients with medical conditions and/or treatment history where periodontal surgery is inadvisable, including, but not limited to, a history of bisphosphonate treatment or chemotherapeutic or radiation therapy of the head and neck
- Patient non-compliance with oral hygiene procedures and supportive care
- Lifestyle-associated risk factors that may have negative effect on bone regeneration (e.g., heavy smoking)
- Strategic extraction and placement of an implant is more appropriate for a patient's condition or circumstance based on accepted standards of care

Depending on an individual patient's condition and circumstances, the following additional criteria for periodontal regenerative treatment may be applied for coverage determinations:

- Unless otherwise established by a dental benefit program, periodontal regeneration treatment is eligible for benefit coverage for the treatment of natural teeth only.
- Additional criteria specific to the use of biologic materials in periodontal regeneration treatment include:
  - Some type of access flap must be performed in conjunction with application of a biologic material for the biologic material procedure to be considered for benefit payment.
  - Based on the American Academy of Periodontology 2022 best evidence consensus statement, conditions where the use of biologics may be beneficial in periodontal regeneration treatment include patients with compromised wound healing, defects with a lower potential for regeneration, situations that require a shortened healing time and patients who have had poor results with conventional treatment approaches.
  - Biologic materials currently considered eligible for benefit consideration are limited to the products Emdogain (enamel matrix derivative protein) and GEM-21S (growth factor derived enhanced matrix). Other biologics are currently considered as having investigational status.

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- Repetition of periodontal regenerative procedures following the recurrence of periodontal breakdown is currently considered investigational based on a lack of documentation of effectiveness from scientifically conducted studies.
- Dental benefit programs may establish benefit limitations for biologics when used in conjunction with other periodontal, endodontic or oral surgery procedures such as periodontal soft tissue grafts, periradicular surgery procedures, implants, tooth extraction, sinus augmentation or ridge preservation procedures.
- For the purpose of benefit review, a communicating osseous defect between two adjacent teeth is considered to be a single site.
- When dental benefit programs have established program-specific criteria that define when periodontal regenerative treatment is considered medically necessary and eligible for benefit coverage or that place other limitations on periodontal regenerative treatment coverage, Delta Dental will apply that criteria when there is a need to evaluate periodontal regenerative treatment for medical necessity.

### **Other Considerations**

When the payment of benefits for a dental procedure by a member's dental plan depends on the application of clinical criteria to determine whether the procedure is medically necessary or clinically appropriate, the following additional information will be taken into consideration, if applicable:

- Individual patient characteristics including age, comorbidities, complications, progress of treatment, psychosocial situation and home environment
- Available services in the local dental delivery system and their ability to meet the member's specific dental care needs when clinical criteria are applied

### **Required Documentation**

The decision to perform periodontal regenerative treatment on a patient should be based on a thorough clinical and radiographic examination that facilitates the formulation of an appropriate treatment plan. When the payment of benefits for a periodontal regenerative treatment by a member's dental plan depends on a review of the procedure's medical necessity and clinical appropriateness, the treating practitioner should submit with the claim the following information as applicable from the patient's dental record. If the practitioner is unable to provide this information, benefit payment may be disapproved.

- Preoperative diagnostic quality radiographs including bitewing images showing the teeth in the areas where a periodontal regeneration procedure is planned
- Intraoral photographs of the involved areas when radiographs do not adequately demonstrate the need for the submitted services
- Preoperative six-point periodontal pocket depth charting performed within 12 months of treatment that includes documentation of clinical attachment loss, tooth mobility, bleeding on probing and furcation involvement
- Documentation consistent with the patient record that explains the diagnostic rationale for performing a periodontal regeneration procedure, including any supporting information from the patient's dental and medical histories

When determining coverage based on medical necessity or clinical appropriateness, Delta Dental may request other clinical information relevant to a patient's care if needed to make coverage decisions.

### **Additional Information**

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The provision of dental advice and clinical treatment of patients is the sole responsibility of treating dentists, and these clinical criteria are not intended to restrict dentists from carrying out that responsibility or recommend treatment to their patients.

Delta Dental's clinical criteria are developed and annually updated by a panel of licensed dental general practitioners and specialists serving on Delta Dental's Utilization Management (UM) Committee, including the Dental Director and Utilization Management Director. The criteria are developed in alignment with evidence-based clinical recommendations, guidelines and parameters of care of leading nationally recognized dental public health organizations, health research agencies and professional organizations, credible scientific evidence published in peer-reviewed medical and dental literature, the curriculum of accredited dental schools, the regulatory status of relevant dental technologies, the rules and requirements of the Centers for Medicare and Medicaid Services, Delta Dental national processing policies and input from practicing dentists. New and revised clinical criteria must be approved by the Dental Director and adopted by the UM Committee prior to release.

Federal or state statutes or regulations, dental plan contract provisions, local or national claim processing policies or other mandated requirements may take precedence over these clinical criteria.

Delta Dental reserves the right to modify or replace this document at any time as appropriate to ensure the soundness, accuracy and objectivity of Delta Dental's clinical criteria.

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