

# Surgical Periodontics: Mucogingival Procedures

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[➔ Instructions for Use](#)

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## Coverage Rationale

### Tissue Graft Procedures

Pedicle soft tissue Graft, Autogenous connective tissue Graft, non-Autogenous connective tissue Graft and combined connective tissue and double pedicle Graft procedures are indicated for the following:

- Areas with less than 2 mm of attached gingiva
- Unresolved sensitivity in areas of Recession
- Progressive Recession or chronic inflammation
- Teeth with subgingival restorations where there is little or no attached gingiva to improve plaque control
- Ridge augmentation
- To increase vestibular depth for the correct fit of prosthesis
- To widen zone of attached gingiva for prosthetic abutment teeth
- To increase vestibular depth to allow proper oral hygiene techniques
- Gingival clefting

Pedicle soft tissue Graft, Autogenous connective tissue Graft, non-Autogenous connective tissue Graft and combined connective tissue and double pedicle Graft procedures are not indicated for the following:

- Roots covered with thin bony plates
- Individuals with an untreated medical condition
- Autogenous connective tissue Graft is not indicated when there is a broad, shallow palatal donor site, or excessively glandular or fatty submucosal tissue in donor site

Free soft tissue Graft procedure (including donor site surgery) is indicated for the following:

- Unresolved sensitivity in areas of Recession
- Progressive Recession or chronic inflammation
- Teeth with subgingival restorations where there is little or no attached gingiva to improve plaque control
- To increase vestibular depth for the correct fit of prosthesis
- To widen zone of attached gingiva for prosthetic abutment teeth
- To increase vestibular depth to allow proper oral hygiene techniques

- Gingival clefting
- Areas with less than 2 mm of attached gingiva
- Ridge augmentation

Free soft tissue Graft procedure is not indicated for the following:

- Broad, shallow palatal donor site
- Excessively glandular or fatty submucosal tissue in donor site
- A donor site with roots covered with thin bony plates
- Individuals with an untreated medical condition

## Biologic Materials to Aid in Soft and Osseous Tissue Regeneration

Biological Material to aid in soft and osseous tissue regeneration are not indicated for mucogingival defects due to insufficient evidence of efficacy.

## Exclusions

- Any Dental Procedure performed solely for cosmetic/aesthetic reasons
- Procedures that are considered to be Experimental, Investigational or Unproven
- Any Dental Procedure not directly associated with dental disease
- Dental Services that are not Necessary

## Definitions

**Autogenous Graft:** Taken from one part of a patient's body and transferred to another (AAP).

**Biologic Materials/Biologic Response Modifiers:** Agents that alter wound healing or host-tumor interaction. Such materials can include cytokines, growth factor, or vaccines, but do not include any actual hard or soft tissue Graft material. These agents are added to Graft material or used alone to effect acceleration of healing or regeneration in hard and soft tissue surgical procedures. (AAP)

**Experimental, Investigational or Unproven Services:** Medical, dental, surgical, diagnostic, or other health care services, technologies, supplies, treatments, procedures, drug therapies or devices that, are determined to be:

- Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the propose use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; or
- Subject to review and approval by any institutional review board for the proposed use; or
- The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight; or
- Not demonstrated through prevailing peer-reviewed professional literature to be safe and effective for treating or diagnosing the condition or illness for which its use is proposed; or
- Pharmacological regimens not accepted by the American Dental Association (ADA) Council on Dental Therapeutics

**Graft:** Defined by any of the following (AAP 2007):

- Any tissue or organ used for implantation or transplantation
- A piece of living tissue placed in contact with injured tissue to repair a defect or supply deficiency
- To induce union between normally separate tissues

**Necessary:** Dental Services and supplies which are determined through case-by-case assessments of care based on accepted dental practices to be appropriate; and

- Needed to meet your basic dental needs; and
- Rendered in the most cost-efficient manner and type of setting appropriate for the delivery of the dental service; and
- Consistent in type, frequency and duration of treatment with scientifically based guidelines of national clinical, research, or health care coverage organizations or governmental agencies that are accepted; and
- Consistent with the diagnosis of the condition; and
- Required for reasons other than the convenience of you or your dental provider; and

- Demonstrated through prevailing peer-reviewed dental literature to be either:
  - Safe and effective for treating or diagnosing the condition or sickness for which its use is proposed; or
  - Safe with promising efficacy:
    - For treating a life threatening dental disease or condition; and
    - In a clinically controlled research setting; and
    - Using a specific research protocol that meets standards equivalent to those defined by the National Institutes of Health

**Quadrant:** One of the four equal sections into which the dental arches can be divided; begins at the midline of the arch and extends distally to the last tooth (ADA).

**Recession:** The migration of the marginal soft tissue to a point apical to the cemento-enamel junction of a tooth or the platform of a dental implant (AAP). Miller’s Classification of Gingival Recession (Takei 2015):

- Class I: Marginal tissue Recession does not extend to the mucogingival junction. There is no loss of bone or soft tissue in the interdental area. This type of Recession can be narrow or wide.
- Class II: Marginal tissue Recession extends to or beyond the mucogingival junction. There is no loss of bone or soft tissue in the interdental area. This type of Recession can be subclassified into wide and narrow.
- Class III: Marginal tissue Recession extends to or beyond the mucogingival junction. There is bone and soft tissue loss interdentally or malpositioning of the tooth.
- Class IV: Marginal tissue Recession extends to or beyond the mucogingival junction. There is severe bone and soft tissue loss interdentally or severe tooth malposition.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CDT Code	Description
D4265	Biologic materials to aid in soft and osseous tissue regeneration
D4270	Pedicle soft tissue graft procedure
D4273	Autogenous connective tissue graft, per tooth
D4275	Non-autogenous connective tissue graft (including recipient site and donor material) first tooth, implant, or edentulous tooth position in graft
D4276	Combined connective tissue and double pedicle graft, per tooth
D4277	Free soft tissue graft procedure (including donor site surgery), first tooth or edentulous tooth position in graft
D4278	Free soft tissue graft procedure (including donor site surgery), each additional contiguous tooth or edentulous tooth position in same graft site
D4283	Autogenous connective tissue graft, each additional contiguous tooth
D4285	Non-autogenous connective tissue graft procedure (including recipient surgical site and donor material) - each additional contiguous tooth, implant or edentulous tooth position in same graft site
D4999	Unspecified periodontal procedure, by report

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## Description of Services

The American Academy of Periodontology (AAP) guidelines stress that periodontal health should be achieved in the least invasive and cost effective manner for each individual. Mucogingival conditions are deviations from the normal anatomic

relationship between the gingival margin and the mucogingival junction (MGJ). Surgical procedures for mucogingival conditions are designed to correct localized gingival defects and provide a functionally adequate zone of attached gingiva. Bone grafting, guided tissue regeneration and the use of biological materials to aid in tissue regeneration may enhance these surgical procedures. Success of these procedures is highly dependent on individual patient considerations such as level of oral hygiene, smoking, and overall health status. The development of various regenerative technologies in medicine and dentistry is rapidly advancing and the technologies outlined in this policy are not all inclusive. For information on guided tissue regeneration with barrier membranes, refer to the Dental Clinical Policy titled [Dental Barrier Membrane Guided Tissue Regeneration](#).

## Clinical Evidence

Discepoli et al. (2019) conducted a systematic review and meta-analysis to evaluate if enamel matrix derivatives are able to improve the quality of keratinized gingival tissue around natural teeth in patients with recession defects following periodontal surgical procedures. 12 Randomized Clinical Trials (RCT) (included medium-low quality evidence) in English evaluating root coverage procedures in combination with enamel matrix derivatives (commercially known as Emdogain®—EMD), with at least 10 subjects and a minimum duration of six months, were included. In total 639 recessions were treated (334 tests and 305 control). The recessions defects were classified according to the classification of Miller (Class I, II, III, IV). Only one trial included Miller Class III recessions (7 in total). Enamel matrix derivatives were applied in conjunction with Coronally Advanced Flap (CAF), Coronally Advanced Flap + Sub Epithelial Connective Tissue Graft (CAF + CTG), Semilunar Flap (SF). For the group CAF vs CAF + EMD the mean difference between the keratinized tissue gain in the two procedures was 0.40 mm; for the comparison CAF + CTG + EMD vs. CAF + CTG the mean difference between the two groups resulted in 0.06 mm. The authors concluded that the application of Enamel Matrix Derivatives to surgical procedures aimed to cover gingival recessions does not add robust clinical benefit to conventional surgical procedures alone.

In a 2018 Cochrane systematic review, Chambrone et al. sought to evaluate the efficacy of different root coverage procedures in the treatment of single and multiple recession-type defects. They included randomised controlled trials (RCTs) only of at least 6 months' duration evaluating recession areas (Miller's Class I or II  $\geq 3$  mm) and treated by means of root coverage periodontal plastic surgery (RCPPS) procedures. There were 48 RCTs in the review. Of these, the authors assessed one as at low risk of bias, 12 as at high risk of bias and 35 as at unclear risk of bias. The results indicated a greater reduction in gingival recession for subepithelial connective tissue grafts (SCTG) + coronally advanced flap (CAF) compared to guided tissue regeneration with resorbable membranes (GTR rm) + CAF. The authors concluded that the available evidence base indicates that in cases where both root coverage and gain in the width of keratinized tissue are expected, the use of subepithelial connective tissue grafts shows a slight improvement in outcome.

França-Grohmann et al. (2018) completed a clinical trial (NCT02459704) to evaluate the treatment of gingival recessions by semilunar coronally positioned flap plus enamel matrix derivative (SCPF + EMD). Thirty patients with class I localized gingival recession were included. They were randomly allocated in two groups: SCPF + EMD and SCPF. Recession height (RH), recession width (RW), width of keratinized tissue (WKT), thickness of keratinized tissue (TKT), probing depth (PD), and clinical attachment level (CAL) were measured at baseline, 6 and 12 months post-surgery. Patient/professional evaluation of esthetics and root sensitivity was also performed. The result showed that after 12 months, mean root coverage was  $1.98 \pm 0.33$  mm for SCPF + EMD and  $1.85 \pm 0.41$  mm for SCPF (the esthetic evaluation by the patient showed preference for SCPF + EMD). According to the professional evaluation (QCE), the use of EMD decreases the appearance of postoperative scar tissue line). There was a significant reduction in root hypersensitivity with no further complaints by the patients. The results showed that the addition of EMD provides significantly better esthetics to SCPF, according to patient and professional assessments. SCPF + EMD are effective but not superior to SCPF for root coverage, after 12 months.

Alexiou et al (2017) conducted a study to compare the clinical efficiency of enamel matrix derivative (EMD) placed under a coronally advanced flap (CAF; test group), to a connective tissue graft (CTG) placed under a CAF (control group), in patients with multiple recession defects. Twelve patients with multiple Miller's Class I or II gingival recessions in contralateral quadrants of the maxilla were selected. The primary outcome variable was the change in depth of the buccal recession (REC) at 6 months after surgery. The secondary outcome parameters included the clinical attachment level (CAL), the probing pocket depth (PPD), and the width of keratinized gingiva (WKT) apical to the recession. Recession defects were randomly divided to the test or control group by using a computer-generated randomization list. The results showed no statistically significant differences observed between test and control groups in regards with the depth of buccal recession with a mean REC of 1.82 mm (CTG) and 1.72 mm (EMD) respectively. Similarly the mean PPD value was 1.3 mm for both groups, while the respective value for CAL

was 1.7 mm (EMD) and 1.8 mm (CTG). Statistically significant differences were observed only for the WKT, which were 3.0 mm and 3.6 mm for the test and control groups respectively. The authors concluded that the use of EMD in conjunction with a CAF resulted in similar results as compared to the CTG plus CAF.

Moraschini et al. (2016) conducted a systematic review and meta-analysis to evaluate the effects of platelet-rich fibrin (PRF) membranes on the outcomes of clinical treatments in patients with gingival recession. The eligibility criteria comprised randomized controlled trials (RCTs) and prospective controlled trials with follow-up periods of  $\geq 6$  months that compared the performance of PRF to other biomaterials in the treatment of Miller Class I or II gingival recessions. Six RCTs and one prospective clinical trial are included in this review. The estimates of the intervention effects were expressed as the mean differences in percentages or millimeters. The results showed root coverage (RC) and clinical attachment level (CAL) did not differ significantly between the analyzed subgroups, and the keratinized mucosa width (KMW) gain was significantly greater in the subgroup that was treated with connective tissue grafts. The author's conclusion suggests that the use of PRF membranes did not improve the RC, KMW, or CAL of Miller Class I and II gingival recessions compared with the other treatment modalities.

Atieh et al (2016) Several clinical trials describe the effectiveness of xenogeneic collagen matrix (XCM) as an alternative option to surgical mucogingival procedures for the treatment of marginal tissue recession and augmentation of insufficient zones of keratinized tissue (KT). The aim of this systematic review and meta-analysis was to evaluate the clinical and patient-centered outcomes of XCM compared to other mucogingival procedures. Applying guidelines of the Preferred Reporting Items for Systematic Reviews and Meta analyses statement, randomized controlled trials were searched for in electronic databases and complemented by hand searching. The risk of bias was assessed using the Cochrane Collaboration's Risk of Bias tool and data were analyzed using statistical software. A total of 645 studies were identified, of which, six trials were included with 487 mucogingival defects in 170 participants. Overall meta-analysis showed that connective tissue graft (CTG) in conjunction with the coronally advanced flap (CAF) had a significantly higher percentage of complete/mean root coverage and mean recession reduction than XCM. Insufficient evidence was found to determine any significant differences in width of KT between XCM and CTG. The XCM had a significantly higher mean root coverage, recession reduction and gain in KT compared to CAF alone. No significant differences in patient's aesthetic satisfaction were found between XCM and CTG, except for postoperative morbidity in favor of XCM. Operating time was significantly reduced with the use of XCM compared with CTG but not with CAF alone. There is no evidence to demonstrate the effectiveness of XCM in achieving greater root coverage, recession reduction and gain in KT compared to CTG plus CAF. Superior short-term results in treating root coverage compared with CAF alone are possible. The authors concluded that there is limited evidence that XCM may improve aesthetic satisfaction, reduce postoperative morbidity and shorten the operating time. Further long-term randomized controlled trials are required to endorse the supposed advantages of XCM.

Keceli et al. (2016) Platelet-rich fibrin (PRF) is an autologous preparation that has encouraging effects in healing and regeneration. The aim of this randomized, parallel-group controlled trial was to evaluate the effectiveness of coronally advanced flap (CAF) + connective tissue graft (CTG) + PRF in Miller Class I and II recession treatment compared to CAF + CTG. Forty patients were treated surgically with either CAF + CTG + PRF (test group) or CAF + CTG (control group). Clinical parameters of plaque index, gingival index, vertical recession (VR), probing depth, clinical attachment level (CAL), keratinized tissue width (KTW), horizontal recession (HR), mucogingival junction localization, and tissue thickness (TT) were recorded at baseline and 3 and 6 months after surgery. Root coverage (RC), complete RC (CRC), attachment gain (AG), and keratinized tissue change (KTC) were also calculated. All individuals completed the entire study period. At baseline, mean VR, HR, CAL, KTW, and TT values were similar. In both groups, all parameters showed significant improvement after treatment except TT. No intergroup difference was observed at 6 months after surgery. The amount of RC and AG, but not KTC and CRC, was higher in the PRF-applied group. According to the results, the addition of PRF did not further develop the outcomes of CAF + CTG treatment except increasing the TT. However, this single trial is not sufficient to advocate the true clinical effect of PRF on recession treatment with CAF + CTG, and additional trials are needed.

In a 2016 systematic review, Kaur et al. reviewed the clinical data currently available on the use of bone morphogenetic proteins (BMPs) in various periodontal applications. BMPs have been shown in preclinical and clinical studies to enhance periodontal regeneration. BMPs have demonstrated beyond doubt their role as a superior alternative of autogenous bone graft. However, much of the data in BMP research has been derived from animal studies which are important as far as providing base line data for further clinical studies. The available data on use of rhBMP-2 and 7 in humans are promising in showing an osteoinductive potential in periodontal regeneration, but not conclusive in the predictability and consistency results to allow clinical use at this stage, other than in well-designed clinical trials. Since many other factors including smoking, age, steroid use, malnutrition, and disease severity play a role in determining the physiology of periodontal regeneration in humans, the true efficacy and safety of



these agents for different scenarios must be established in carefully designed prospective randomized clinical trials before they are approved for use. Research should continue to focus on improving the use of BMPs in the current clinical applications.

McGuire et al. (2014) conducted a study to compare the clinical parameters 5 years post operatively, of a previously reported split-mouth, randomized controlled trial. In that study, Miller Class II gingival recession defects were treated with either a connective tissue graft (CTG) (control) or recombinant human platelet-derived growth factor-BB +  $\beta$ -tricalcium phosphate (test), both in combination with a coronally advanced flap (CAF). Twenty of the original 30 patients were available for follow-up 5 years after the original surgery. Outcomes examined were recession depth, probing depth, clinical attachment level (CAL), height of keratinized tissue (wKT), and percentage of root coverage. Group results at 6 months and 5 years were compared with original baseline values. At 5 years, all parameters for both treatment protocols showed statistically significant improvements over baseline. The primary outcome parameter, change in recession depth at 5 years, demonstrated statistically significant improvements in recession over baseline, although intergroup comparisons favored the control group at both 6 months and 5 years. At 5 years, intergroup comparisons also favored the test group for percentage root coverage and change in wKT, whereas no statistically significant intergroup differences were seen for 100% root coverage and changes to CAL. The authors concluded that treatment with either test or control treatments for Miller Class II recession defects appear to lead to stable, clinically effective results, although CTG + CAF resulted in greater reductions in recession, greater percentage of root coverage, and increased wKT.

Trivedi et al. (2014) conducted a comparative, split mouth, six month study to clinically compare and evaluate subepithelial connective tissue graft and GTR based root coverage in treatment of Miller's Class I gingival recession. 30 patients with at least one pair of Miller's Class I gingival recession were treated either with subepithelial connective tissue graft (Group A) or Guided tissue regeneration (Group B). Clinical parameters monitored included recession, width of keratinized gingiva, probing depth, clinical attachment level, attached gingiva, residual probing depth and percent of root coverage. Measurements were taken at baseline, three months and six months. At end of six months both treatments resulted in statistically significant improvement in clinical parameters measured. When compared, no statistically significant difference was found between both groups except in residual probing depths, where it was significantly greater in the group treated with subepithelial connective tissue grafting procedure. Percent of root coverage was similar. The authors concluded that GTR technique has advantages over subepithelial connective tissue graft for shallow Miller's Class I defects and this procedure can be used to avoid patient discomfort and reduce treatment time.

Zucchelli et al (2014) conducted a comparative short- and long-term controlled randomized clinical trial to compare short- and long-term root coverage and aesthetic outcomes of the coronally advanced flap (CAF) alone or in combination with a connective tissue graft (CTG) for the treatment of multiple gingival recessions. Fifty patients with multiple adjacent gingival recessions ( $\geq 2$  mm) in the maxillary arch were enrolled. Twenty-five patients were randomly assigned to the control group (CAF), and the other 25 patients to the test group (CAF + CTG). Clinical outcomes were evaluated at 6 months, 1 and 5 years. The aesthetic evaluations were made 1 and 5 years after the surgery. No statistically significant difference was demonstrated between the two groups in terms of recession reduction and complete root coverage (CRC) at 6 months and 1 year. At 5 years, statistically greater recession reduction and probability of CRC, greater increase in buccal keratinized tissue height (KTH) and better contour evaluation made by an independent periodontist were observed in the CAF + CTG group. The authors concluded that despite no significant differences at 6 month and 1 year evaluations, CAF + CTG provided better CRC after 5 years than CAF alone.

Kuis et al. (2013) conducted a 5-year, split mouth-design randomized clinical trial, to evaluate the effectiveness of coronally advanced flap (CAF) alone versus CAF with connective tissue graft (CAF+CTG) in the treatment of single Miller Class I and II GR defects. Thirty-seven patients with 114 bilateral, single Miller Class I and II GR defects were treated with CAF on one side of the mouth and CAF+CTG on the other side. Clinical measurements (GR length [REC], keratinized tissue width [KT], complete root coverage [CRC], and percentage of root coverage [PRC]) were evaluated before surgery and after 6, 12, 24, and 60 months. There was a significant reduction of REC and increase of KT after surgery in both groups. CAF+CTG showed significantly better results for all evaluated clinical parameters in all observed follow-up periods. The authors concluded that both surgical procedures were effective in the treatment of single Miller Class I and II GR defects. The CAF+CTG procedure provided better long-term outcomes (60 months postoperatively) than CAF alone. Long-term stability of the gingival margin is less predictable for Miller Class II GR defects compared to those of Class I.

Rosetti et al. (2013) completed a 30-month follow-up clinical trial to assess the long term stability of the root coverage of subepithelial connective tissue graft (SCTG) and guided tissue regeneration combined with demineralized freeze-dried bone

allograft (GTR-DFDBA). Twenty-four defects were treated in 12 patients who presented with canine or pre-molar Miller class I and/or II bilateral gingival recessions. GTR-DFDBA and SCTG treatments were performed in a randomized selection in a split-mouth design. The following clinical parameters were assessed at 6, 18 and 30 months post-surgery: root coverage (RC), gingival recession (GR), probing depth (PD), clinical attachment level (CAL) and keratinized tissue width (KTW). The authors concluded that there were not significant differences in RC, GR, PD and CAL for both procedures, but the increase in KTW was significantly higher in the SCTG group than in the GTR-DFDBA group. The authors concluded that both procedures provide adequate root coverage over the long term, with the connective tissue graft procedure promoting a more favorable increase in keratinized tissue.

Jankovic et al. (2012) conducted a 6-month randomized controlled clinical study to compare the results achieved by the use of a platelet-rich fibrin (PRF) membrane or connective tissue graft (CTG) in the treatment of gingival recession and to evaluate the clinical impact of PRF on early wound healing and subjective patient discomfort. Use of a PRF membrane in gingival recession treatment provided acceptable clinical results, followed by enhanced wound healing and decreased subjective patient discomfort compared to CTG-treated gingival recessions. No difference could be found between PRF and CTG procedures in gingival recession therapy, except for a greater gain in keratinized tissue width obtained in the CTG group and enhanced wound healing associated with the PRF group.

Sasikumar et al. (2012) conducted a literature review regarding the application of bone morphogenetic proteins to periodontal and peri-implant tissue regeneration. Several studies showed significant regeneration of the periodontal tissues and it is important to understand the biologic processes of periodontal wound healing and the effects of these biologic processes on BMP activity. Further studies are needed for the development of delivery systems that have mechanical and surgical properties appropriate for controlled release of bone morphogenetic proteins and identifying optimal condition for the use of BMPs for periodontal regeneration.

Moslemi et al. (2011) conducted a randomized clinical trial to compare the long-term results of subepithelial connective tissue graft (SCTG) versus acellular dermal matrix allograft (ADMA) in treatment of gingival recessions. There were 16 patients with bilateral Miller Class I/II gingival recessions selected. One side was treated with SCTG and the other side with ADMA. Clinical parameters of complete root coverage (CRC), reduction of recession depth (RD) and reduction of recession width (RW) were measured at baseline, 6 months, and at 5 years post-surgery. At 5 years, significant relapses were detected in CRC and reduction of RD and RW in both groups, with no statistically significant differences. Compared with baseline, the gingival width (GW) did not increase in ADMA-treated sites. The five-year results of SCTG and ADMA were similar in terms of CRC and reduction of RD and RW. (Both techniques showed a significant relapse associated with returning to horizontal toothbrushing habit). Increase of GW was stable in SCTG-treated sites, but reached to pre-surgical values in ADMA-treated cases.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Products used for bone grafting, bone growth and resorbable and non-resorbable membranes for guided tissue regeneration use in periodontal applications are extensive. See the following website for more information and search by product name in device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed January 5, 2021)

Connective tissue grafting products from donated human skin are regulated by the (FDA) as human tissue for transplantation. They are processed and marketed in accordance with the FDA's requirements for banked human tissue (21 CFR, Part 1270 and Part 1271) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). Information can be found here: <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>. (Accessed January 5, 2021)

Currently, there are two biologic products approved by the FDA for regenerative periodontal therapy:

- GEM 21S™ (BioMimetic Pharmaceuticals, Inc.); see the following website for more information: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf4/P040013b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040013b.pdf). (Accessed January 7, 2020)
- Emdogain™ (Straumann); see the following website for more information: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P930021>. (Accessed January 5, 2021)

There are several devices cleared for marketing by FDA for point-of-care preparation of platelet-rich plasma (PRP) from a sample of a patient's blood (see listings under product code JQC for additional devices). See the following website for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed January 5, 2021)

In April 2003, the FDA approved the use of the GPS™ Platelet Separation Kit. The GPS™ separation kit aids separation of the patient's own blood components by density through the use of the GPS™-Thermo International Equipment Company (IEC) centrifuge. The GPS separation kit permits platelet rich plasma to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment. The GPS Platelet Separation Kit is designed for use in the clinical laboratory or intraoperatively at point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60 ml) of whole blood. See the following website for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K030555>. (Accessed January 5, 2021)

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## Policy History/Revision Information

Date	Summary of Changes
04/01/2021	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"><li>Removed language addressing coverage limitations; refer to the member specific benefit plan document(s)</li></ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"><li>Updated <i>Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li><li>Archived previous policy version DCP015.06</li></ul>

## Instructions for Use

This Dental Clinical Policy provides assistance in interpreting UnitedHealthcare standard dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard dental plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Dental Clinical Policy is provided for informational purposes. It does not constitute medical advice.