SURGICAL PERIODONTICS: MUCOGINGIVAL PROCEDURES

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INSTRUCTIONS FOR USE

This Dental Coverage Policy provides assistance in interpreting UnitedHealthcare dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Dental Coverage Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Dental Coverage Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Dental Coverage Policy. Other Clinical Policies and Coverage Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Dental Coverage Policy is provided for informational purposes. It does not constitute medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group health plans (inside and outside of Exchanges) to provide coverage for Pediatric Dental Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for Pediatric Dental EHBs. However, if such plans choose to provide coverage for benefits which are deemed Pediatric Dental EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute Pediatric Dental EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Pedicle Soft Tissue Graft Procedure

Pedicle soft tissue graft procedure is indicated for the following:

- Areas with less than 2 mm of attached gingiva
- Unresolved sensitivity in areas of recession
- Progressive recession or chronic inflammation
- For 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 procedure is not indicated for the following:
- Roots covered with thin bony plates
- Individuals with an untreated medical condition

Autogenous Connective Tissue Graft

Autogenous connective tissue graft is indicated for the following:
- Areas with less than 2 mm of attached gingiva
- Unresolved sensitivity in areas of recession
- Progressive recession or chronic inflammation
- For 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

Autogenous connective tissue graft 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

Non-Autogenous Connective Tissue Graft

Non-autogenous connective tissue graft is indicated for the following:
- Areas with less than 2 mm of attached gingiva
- Unresolved sensitivity in areas of recession
- Progressive recession or chronic inflammation
- For 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

Non-autogenous connective tissue graft is not indicated for the following:
- When indications for connective tissue grafting are not met
- Individuals with an untreated medical condition

Combined Connective and Double Pedicle Graft

Combined connective and double pedicle graft is indicated for the following:
- Areas with less than 2 mm of attached gingiva
- Unresolved sensitivity in areas of recession
- Progressive recession or chronic inflammation
- For 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

Combined connective and double pedicle graft is not indicated for the following:
- Roots covered with thin bony plates
- Individuals with an untreated medical condition

Free Soft Tissue Graft Procedure (Including Donor Site Surgery)

Free soft tissue graft procedure is indicated for the following:
- Unresolved sensitivity in areas of recession
- Progressive recession or chronic inflammation
- For 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

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

Biologic materials to aid in soft and osseous tissue regeneration are intended to enhance periodontal tissue regeneration and healing for mucogingival defects in conjunction with mucogingival surgeries. There is inconclusive clinical evidence demonstrating the benefit of these materials in published peer-reviewed literature and further clinical studies are needed.

Guided Tissue Regeneration – Resorbable and Non-Resorbable Barrier (Includes Membrane Removal)

Guided tissue regeneration is indicated for the following:
- For sensitivity in areas of recession
- Progressive recession or chronic inflammation
- Areas of bone dehiscence and fenestration
- Single tooth, wide and deep localized recession
- For areas associated with failed cervical restorations

Guided tissue regeneration is not indicated for the following:
- Multiple adjacent tooth sites of root coverage required
- Solely for cosmetic/aesthetic purposes

DEFINITIONS

Autogenous Graft: Tissue transferred from one position to another within the same individual.

Biologic Materials: 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. Also known as biologic response modifiers. (ADA)

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.

Guided Tissue Regeneration: A surgical procedure with the goal of achieving new bone, cementum, and PDL attachment to a periodontally diseased tooth, using barrier devices or membranes to provide space maintenance, epithelial exclusion, and wound stabilization. (AAP)

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.

Recession: Location of marginal periodontal tissues apical to the cemento-enamel junction (AAP 2007). 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.

Site: A term used to describe a single area, position, or locus. The word "site" is frequently used to indicate an area of soft tissue recession on a single tooth or an osseous defect adjacent to a single tooth; also used to indicate soft tissue defects and/or osseous defects in edentulous tooth positions.
- If two contiguous teeth have areas of soft tissue recession, each area of recession is a single site.
- If two contiguous teeth have adjacent but separate osseous defects, each defect is a single site.
- If two contiguous teeth have a communicating interproximal osseous defect, it should be considered a single site.

- All non-communicating osseous defects are single sites.
- All edentulous non-contiguous tooth positions are single sites.
- Depending on the dimensions of the defect, up to two contiguous edentulous tooth positions may be considered a single site.

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 Clinical Policies and Coverage Guidelines may apply.

CDT Code	Description
D4265	Biologic materials to aid in soft and osseous tissue regeneration
D4266	Guided tissue regeneration – resorbable barrier, per site
D4267	Guided tissue regeneration – nonresorbable barrier, per site (includes membrane removal)
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

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. Using non-surgical periodontal therapy, many individuals can be treated and maintained without the need for surgical intervention. However, surgical procedures may be required when periodontal health cannot be achieved or maintained non-surgically. 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 through grafting and guided tissue regeneration. Bone grafting, guided tissue regeneration and the use of biological materials to aid in tissue regeneration have applications in different areas of dentistry, and each has its own coverage rationale and indications. Please see the procedure specific documents for details.

CLINICAL EVIDENCE

Jenabian et al. (2017) conducted a randomized, triple-blinded, split-mouth study to compare the additive effect of combined guided tissue regeneration (GTR) and platelet-rich growth factor (PRGF) on the treatment of furcation bony defects. Eight patients with moderate to severe chronic periodontitis with bilateral Grade II furcation involvement of first or second mandibular molars were selected. Each side of mouth was randomly allocated for the treatment with either Bio-Gide GTR or a PRGF or PRGF by itself. Plaque index, gingival index, vertical clinical attachment level, vertical probing depth, recession depth (REC), horizontal probing depth, fornix to alveolar crest (FAC), fornix to base of defect (FBD), furcation vertical component and furcation horizontal component (FHC) were recorded. The results showed that general and specific clinical and furcation parameters were improved except REC that was deteriorated insignificantly and FAC improved not significantly. Intergroup comparison revealed better improvement of FHC in GTR/PRGF group. The authors concluded there was a significant improvement in the Grade II furcation defects treated with either GTR or PRGF/GTR and further large-scale trials are needed to reveal differences of mentioned treatment in more details.

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 ≥ 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.

Troiano et al. (2017) conducted a systematic review, meta-analysis and trial sequential analysis to assess the effects of a combination of enamel matrix derivatives (EMD) to bone substitutes (BS) on the clinical improvement of intrabony defects, and compare the treatment with BS alone. The following outcomes were assessed: clinical attachment level (CAL) gain, probing depth (PD) reduction and recession (REC). Electronic databases were searched for randomized controlled trials in humans addressing the use of a combination of BS and EMD versus a control group with BS alone for the treatment of intrabony defects, with a minimum of 6 months of follow-up; meta-analysis and trial sequential analysis were then performed. From a total of 1,197 records screened by title and abstract, nine studies were read full-text and five out of them included in the meta-analysis. The authors concluded that for the treatment of intrabony defects, the addition of EMD to BS seems to be not beneficial in terms of CAL gain, PD reduction and REC changes. However, such results should be considered with caution because of the small number of studies included in the meta-analysis and their heterogeneity.

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 analysed 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 favour 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

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.

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.

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.

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 + β-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.

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.

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 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.

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 (≥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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Products used for bone grafting 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 December 2017)

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 December 2017)

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. (Accessed December 2017)
- Emdogain™ (Straumann)
  - See the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P930021. (Accessed December 2017)

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/pmn.cfm.
(Accessed December 21, 2017)

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/pmn.cfm?ID=K030555.
(Accessed December 21, 2017)

REFERENCES

American Academy of Periodontology Glossary of Periodontal Terms, 2001.

Atieh MA, Alsabeeha N, Tawse-Smith A, et al. Xenogeneic collagen matrix for periodontal plastic surgery procedures: a systematic review and meta-analysis. J Periodontal Res. 2016 Aug; 51(4):438-52.

Cohen, Edward S, DMD. Atlas of Cosmetic and Reconstructive Periodontal Surgery, 3rd ed. Shelton, CT: Peoples Medical Publishing House c2007. Chapter 6, Advanced Periodontal Procedures; p. 288.

Jankovic S, Aleksic Z, Klokkevold P, et al. Use of platelet-rich fibrin membrane following treatment of gingival recession: a randomized clinical trial. Int J Periodontics Restorative Dent. 2012 Apr; 32(2):e41-50.

Jenabian N, Haghanifar S, Ehsani H, et al. Guided tissue regeneration and platelet rich growth factor for the treatment of Grade II furcation defects: A randomized double-blinded clinical trial - A pilot study. Dent Res J (Isfahan). 2017 Nov-Dec; 14(6):363-369.

Keceli HG, Kamak G, Erdemir EO, et al. The Adjunctive Effect of Platelet-Rich Fibrin to Connective Tissue Graft in the Treatment of Buccal Recession Defects: Results of a Randomized, Parallel-Group Controlled Trial. J

Kuis D, Sciran I, Lajnert V, et al. Coronally advanced flap alone or with connective tissue graft in the treatment of single gingival recession defects: a long-term randomized clinical trial. JPeriodontol. 2013 Nov; 84(11):1576-85.

McGuire MK, Scheyer ET, Snyder MB. Evaluation of recession defects treated with coronally advanced flaps and either recombinant human platelet-derived growth factor-BB plus β-tricalcium phosphate or connective tissue: comparison of clinical parameters at 5 years. J Periodontol. 2014 Oct; 85(10):1361-70.

Moraschini V, Barboza Edos S. Use of Platelet-Rich Fibrin Membrane in the Treatment of Gingival Recession: A Systematic Review and Meta-Analysis. J Periodontol. 2016 Mar; 87(3):281-90.

Moslemi N, Mousavi Jazi M, Haghighati F, et al. Acellular dermal matrix allograft versus subepithelial connective tissue graft in treatment of gingival recessions: a 5-year randomized clinical study. J Clin Periodontol.2011 Dec; 38(12):1122-9.

Periodontol. 2015 Nov;86(11):1221-30.

Reddy, Shantipriya, BDS MDS. Essentials of Clinical Periodontology and Periodontics, 2nd ed. Maryland Heights, MD: Jaypee Brothers Medical Publishers c2008. Chapter 43, Mucogingival Surgery; p. 360.

Rosetti EP, Marcantonio E Jr, Zuza EP, et al. Root coverage stability of the subepithelial connective tissue graft and guided tissue regeneration: a 30-month follow-up clinical trial. J Dent. 2013 Feb; 41(2):114-20.

Takei H, Scheyer E, Azzi R et al. Carranza's Clinical Periodontology, 12th ed. St. Louis: Saunders c2015. Chapter 63, Periodontal Plastic and Esthetic Surgery; p. 628-631.

Trivedi SR, Bhavsar NV, Dulani K, et al. Clinical evaluation of subepithelial connective tissue graft and guided tissue regeneration for treatment of Miller's class 1 gingival recession (comparative, split mouth, six months study). J Clin Exp Dent. 2014 Jul 1;6(3):e218-24.

Troiano G, Laino L, Zhurakivska K, et al. Addition of enamel matrix derivatives to bone substitutes for the treatment of intrabony defects: A systematic review, meta-analysis and trial sequential analysis. J Clin Periodontol. 2017 Jul; 44(7):729-738.

Zucchelli G, Mounssif I, Mazzotti C, et al. Coronally advanced flap with and without connective tissue graft for the treatment of multiple gingival recessions: a comparative short- and long-term controlled randomized clinical trial. J Clin Periodontol. 2014 Apr;41(4):396-403.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

04/01/2018	• Updated coverage rationale:
	  ○ Replaced references to "patients" with "individuals"
	  ○ Modified language pertaining to clinical evidence/study findings for **biologic materials to aid in soft and osseous tissue regeneration**:
	  ▪ Replaced language indicating:
	  - "Biologic materials to aid in soft and osseous tissue regeneration are *indicated* to enhance periodontal tissue regeneration and healing for mucogingival defects in conjunction with mucogingival surgeries *with or without guided tissue regeneration*" with "biologic materials to aid in soft and osseous tissue regeneration are *intended* to enhance periodontal tissue regeneration and healing for mucogingival defects in conjunction with mucogingival surgeries"
	  ▪ Added language to indicate:
	  - There is inconclusive clinical evidence demonstrating the benefit of these materials in published peer-reviewed literature and further clinical studies are needed
	• Added definition of:
	  ○ Biologic Materials
	  ○ Guided Tissue Regeneration
	• Updated list of applicable CDT codes; revised description for D4275 and D4285
	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references
	• Archived previous policy version DCP015.02