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

Bone Replacement Grafts

Bone Replacement Grafts are indicated for the following:
- Infrabony/Intrabony vertical defects
- Class II furcation involvements

Bone Replacement Grafts are not indicated for the following:
- Class I furcation involvement
- Class III or higher furcation involvement
- Non-vertical defects
- Patients with an uncontrolled underlying medical condition
- Patients who have been non-compliant with previous periodontal therapies
- Patients with poor oral hygiene
• Teeth with a hopeless prognosis (more than 75% bone loss and Class 3 or higher mobility).

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

Biologic Materials to Aid in Soft and Osseous Tissue Regeneration are indicated for the following:
• Intrabony/Infrabony vertical defects
• Class II furcation involvements

Biologic Materials to Aid in Soft and Osseous Tissue Regeneration are not indicated for the following:
• Class I and Class III or higher furcation involvement
• Non-vertical defects
• Patients with an uncontrolled underlying medical condition
• Patients who have been non-compliant with previous periodontal therapies
• Patients with poor oral hygiene
• Teeth with a hopeless prognosis (more than 75% bone loss and Class 3 or higher mobility).

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

Guided Tissue Regeneration is indicated for the following:
• Intrabony/infrabony vertical defects
• Class II furcation involvements

Guided Tissue Regeneration is not indicated for the following:
• Teeth with a hopeless prognosis (more than 75% bone loss and Class 3 or higher mobility)
• Class I furcation involvement
• Class III or higher furcation involvement
• Horizontal bone loss
• Non-vertical defects
• Patients with an uncontrolled underlying medical condition
• Patients who have been non-compliant with previous periodontal therapies
• Patients with poor oral hygiene
• Crater defects

**Surgical Revision Procedure (per Tooth)**

Surgical Revision Procedure is indicated to correct an abnormal healing response that interferes with the therapeutic goals of the original regenerative surgical procedure.

Surgical Revision Procedure is not indicated solely for cosmetic/aesthetic purposes.

**DEFINITIONS**

**Anatomical Crown:** That portion of tooth normally covered by, and including, enamel. (ADA 2016).

**Flap:** A loosened section of tissue separated from the surrounding tissues except at its base. (ADA 2016)

**Furcation:** The anatomic area of a multirooted tooth where the roots diverge. A furcation involvement refers to loss of periodontal support in a furcation (ADA, 2016). The Glickman Classification of Tooth Furcation Grading (Sims, 2015):
• Grade I
  o Incipient
  o Just barely detectable with examination hand instruments
  o No horizontal component of the furcation is evident on probing
• Grade II
  o Early bone loss
  o Examination hand instrument goes partially into the furcation, but not all the way through
  o Furcation may be grade II on both sides of the tooth, but are not connected
• Grade III
  o Advanced bone loss
  o Examination hand instrument goes all the way through furcation, to other side of tooth
  o Furcation is through-and-through
• Grade IV
  o Through-and-through, plus furcation is clinically visible due to gingival recession

**Gingival Flap:** A flap that does not extend apical to the mucogingival junction. (ADA 2016)
Intrabony Defect (Intrabony D): A periodontal defect surrounded by two or three bony walls or a combination of these.

McGuire Classification of Tooth Prognosis (Levi 2016)

- Good: Teeth with adequate periodontal support where the etiologic factors can be controlled, including systemic factors.
- Fair: No more than 25% attachment loss with Grade 1 furcation invasion which can be maintained. Plaque control and systemic factors can be maintained.
- Poor: As much as 50% bone loss with Grade II furcation invasions, poor crown: root ratio; mobility greater than Miller Class I; systemic factors; poor patient participation in treatment.
- Questionable: Teeth with greater than 50% attachment loss; Grade II or III furcation involvements; the tooth is not easily maintained either with professional hygiene or by the patient.
- Hopeless: Inadequate attachment to support the tooth; Class III or IV furcation involvement; Miller Class III mobility; the tooth cannot be maintained with adequate plaque control by the clinician or by the patient.

Mobility: The movement of a tooth in its socket resulting from an applied force. (AAP)

Miller Index of Tooth Mobility (Harpenau 2013):

- Class 0: Normal physiologic tooth movement
- Class I: First distinguishable signs of movement beyond normal
- Class II: Tooth movement up to 1mm in any direction
- Class III: Tooth can be moved more than 1mm in any direction and/or the tooth can be depressed into the socket.

Moderate Chronic Periodontal Disease: Characterized by 3-4 mm clinical attachment loss. (CAL) (AAP 2007)

Osseous Surgery: Procedures to modify bone support altered by periodontal disease, either by reshaping the alveolar process to achieve physiologic form without the removal of alveolar supporting bone, or by the removal of some alveolar bone, thus changing the position of the crestal bone relative to the tooth root. (See: Ostectomy; Osteoplasty)

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.

Severe Chronic Periodontal Disease: Characterized by more than 5 mm of loss. (CAL) (AAP 2007)

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.

Tooth Bounded Space: A space created by one or more missing teeth that has a tooth on each side. (ADA 2016)

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.

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<tr>
<th>CDT Code</th>
<th>Description</th>
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<tr>
<td>D4263</td>
<td>bone replacement graft – retained natural tooth – first site in quadrant</td>
</tr>
<tr>
<td>D4264</td>
<td>bone replacement graft – retained natural tooth – each additional site in quadrant</td>
</tr>
<tr>
<td>D4265</td>
<td>biologic materials to aid in soft and osseous tissue regeneration</td>
</tr>
<tr>
<td>D4266</td>
<td>guided tissue regeneration – resorbable barrier, per site</td>
</tr>
<tr>
<td>D4267</td>
<td>guided tissue regeneration – nonresorbable barrier, per site (includes membrane removal)</td>
</tr>
</tbody>
</table>
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 patients 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. Regenerative procedures involve bone grafting, which is the clinical restoration of bone tissue in a treated periodontal defect, and guided tissue regeneration which attempt to regenerate lost periodontal structures, as well as the use of biological materials to aid in these processes. 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

Avila-Ortiz et al. (2015) conducted a systematic review from the American Academy of Periodontology Regeneration Workshop based on predetermined eligibility criteria to identify human original studies and systematic reviews on the topic of periodontal regeneration of furcation defects. The final selection consisted of 150 articles, of which six were systematic reviews, 109 were clinical trials, 27 were case series, and eight were case reports. A summary of the main findings of previously published systematic reviews and the available evidence regarding regenerative approaches for furcation defects compared with conventional surgical therapy were reviewed. On the basis of the reviewed evidence, the authors concluded that periodontal regeneration has been demonstrated histologically and clinically for the treatment of maxillary facial or interproximal and mandibular facial or lingual Class II furcation defects. For Class I defects, the majority can be successfully treated with non-regenerative treatment, and for Class III lesions, the evidence is lacking and limited to case reports.

Cortellini et al. (2016) conducted a 20 year follow up review to compare the long-term outcomes and costs of three treatment modalities in intra-bony defects. Forty-five intra-bony defects in 45 patients had been randomly allocated to receive: modified papilla preservation technique with titanium-reinforced expanded-polytetrafluoroethylene (ePTFE) membranes; access flap with expanded-PTFE membranes and access flap alone. Supportive periodontal care (SPC) was provided monthly for 1 year, then every 3 months for 20 years. Periodontal therapy was delivered to sites showing recurrences. The results showed clinical attachment-level differences between 1 and 20 years were −0.1 ± 0.3 mm in the MPPT Tit; −0.5 ± 0.1 mm in the Flap-ePTFE and −1.7 ± 0.4 mm in the Flap. At 20 years, sites treated with Flap showed greater attachment loss compared to MPPT Tit and to Flap-ePTFE. Flap group lost two treated teeth. Five episodes of recurrences occurred in the MPPT Tit, six in the Flap-ePTFE and fifteen in the Flap group. Residual pocket depth at 1-year was significantly correlated with the number of recurrences. Sites treated with flap had greater OR for recurrences and higher costs of re-intervention than regenerated sites over a 20-year follow-up period with SPC. The authors concluded that regeneration provided better long-term benefits than Flap with no tooth loss, less periodontitis progression and less expense from re-intervention over a 20-year period. However, these benefits need to be interpreted in the context of higher immediate costs associated with regenerative treatment, as well as patient compliance, and recommended these initial observations be extended to larger groups and broader clinical settings.

Galav et al (2016) conducted a randomized controlled trial to compare the clinical efficacy of platelet-rich fibrin (PRF) with autogenous bone grafting (ABG) for the treatment of intra bony defects (IBD’s) in chronic periodontitis. Twenty chronic periodontitis patients with IBDs were randomly treated by PRF or ABG. Probing pocket depth (PPD), relative attachment level (RAL), surgical reentry bone fills, and radiographic bone fill (RBF) were recorded at baseline, 3, 6, and 9 months postsurgery, respectively. Both PRF and ABG sites produced a significant improvement from baseline to 9 months for all the parameters. However, there was no significant difference between the two treatment modalities in the reduction of PPD and RAL gain at 9 months. In addition, ABG showed significantly greater RBF (30.34%) as compared to PRF (20.22%). Similar findings were supported by surgical reentry, where a surgical reentry of 65.31% at ABG sites and 43.64% at PRF sites was seen. The authors concluded that both ABG and PRF can be used predictably to reconstruct lost periodontal structures as indicated by PPD reduction and RAL gain. However, in terms of osseous defect fill, ABG yields more definitive outcome than PRF.

Ge et al. (2016) conducted a randomized controlled trial aimed to evaluate the effect of autogenous bone grafting in situ for regeneration of periodontal osseous defect distal to the second molar (M2) compared with non-grafting after impacted third molar (M3) removal. A total of 60 sites in adult patients were enrolled and randomly assigned to the control group or the test group. In both groups, the M3 was extracted using a piezo surgical device, and the distal root surface of M2 was scaled and root planed. In addition, the removed alveolar bone was ground to particles and...
grafted to the distal osseous defect of M2 in the test group. The primary outcome variable was the osseous defect depth (ODD), the secondary outcome variables were probing pocket depth (PD) and clinical attachment level (CAL) on the disto-buccal aspect of the M2 during a 12-month follow-up period. The patient characteristics were homogeneous between the 2 groups. Six and 12 months after surgery, there were statistically significant bone fill in both groups. Moreover, the ODD and CAL in the test group were significantly lower than the control group at every postoperative re-entry. The result of this study demonstrated that scaling and root planing is beneficial to periodontal healing of M2 after impacted M3 extraction. Addition of autogenous bone grafting for the treatment of osseous defects distal to M2 was safe and more effective than periodontal treatment alone.

Kao and Nares (2015) conducted this review to update the last published systematic review on periodontal regeneration from 2002 by reviewing approaches developed for the correction of intrabony defects with the focus on patient-, tooth-, and site-centered factors, surgical approaches, surgical determinants, and biologics. This review focused on clinically available regenerative approaches with histologic evidence of periodontal regeneration in humans. (For topics in which the literature is lacking, non-randomized observational and experimental animal model studies were used). Therapeutic endpoints examined were: changes in clinical attachment level, changes in bone level/fill (For purposes of analysis, change in bone fill was used as the primary outcome measure, except in cases in which this information was not available), and probing depth. There were fifty-eight studies in the treatment of intrabony defects, and forty-five on the use of biologics for the treatment of intrabony defects. The authors concluded that biologics (enamel matrix derivative and recombinant human platelet-derived growth factor-BB plus β-tricalcium phosphate) are generally comparable with demineralized freeze-dried bone allograft and guided tissue regeneration (GTR), and superior to open flap debridement procedures alone in improving clinical parameters in the treatment of intrabony defects. Clinical outcomes appear most influenced by patient behaviors and surgical approach rather than by tooth and defect characteristics. The long-term studies reviewed indicate that improvements in clinical parameters are maintainable up to 10 years, even in severely compromised teeth, resulting in a favorable long-term prognosis.

Nevins et al. (2013) provided results from a 36-month extension study of a multicenter, randomized, controlled clinical trial evaluating the effect and long-term stability of homodimer platelet derived growth factor (PDGF-BB) treatment in patients with localized severe periodontal osseous defects. A total of 135 participants were enrolled from six clinical centers for this trial, and eighty-three individuals completed the study at 36 months and were included in the analysis. The study investigated the local application of β-tricalcium phosphate scaffold matrix with or without two different dose levels of PDGF (0.3 or 1.0 mg/mL PDGF-BB) in patients possessing one localized periodontal osseous defect. Clinical and radiographic evidence of treatment success was defined as percentage of cases with clinical attachment level (CAL) ≥2.7 mm and linear bone growth (LBG) ≥1.1 mm. Although there were no significant increases in CAL and LBG at 36 months among all groups, there were continued increases in CAL gain, LBG, and percentage bone fill over time, suggesting overall stability of the regenerative response. The authors concluded that PDGF-BB in a synthetic scaffold matrix promotes long-term stable clinical and radiographic improvements in patients with localized severe periodontal osseous defects.

Nickles et al. (2009) conducted an evaluation of the 10-year results after open flap debridement (OFD) and guided tissue regeneration (GTR) therapy using bioabsorbable barriers of intrabony defects in a randomized controlled clinical trial. In the randomized control trial, there were 16 periodontitis patients treated with OFD or GTR assigned randomly to 44 intrabony defects. In a subgroup of 10 patients exhibiting 2 contra-lateral defects each, OFD and GTR was assigned to either side (split-mouth). Clinical parameters were obtained at baseline, 12, and 120 (+/- 12) months after surgery. For this evaluation, 15 of the original 16 were available. Based on the results 10 years later, the authors concluded that the vertical attachment gains achieved either by OFD and GTR therapy using bioabsorbable barriers could be maintained stable up to 10 years after surgery in 32 of 41 (78%) deep two- and three-wall intrabony defects.

Pradeep et al. (2012) completed a randomized controlled clinical trial to explore the clinical and radiographic effectiveness of autologous platelet rich fibrin (PRF) and platelet rich plasma (PRP) in the treatment of 3 walled intrabony periodontal defects. Ninety intrabony defects were selected and treated with open flap debridement and PRF, open flap debridement and PRP and open flap debridement alone as the control group. Clinical and radiologic parameters, of probing depth (PD), clinical attachment level (CAL), intrabony defect depth, and percentage of defect fill were all recorded at baseline and 9 months postoperatively. This study showed improvements in all parameters with the most significant being the decreased depth of the defect. The authors concluded that both PRF and PRP in conjunction with open flap debridement show improvements in all clinical and radiographic parameters measured and that PRF is less time consuming and less technique sensitive, and may be a better treatment option than PRP. However, long-term, multicenter randomized, controlled clinical trials will be required to know their clinical and radiographic effects on bone regeneration.

Shah et al. (2014) conducted a systematic review and meta-analysis to determine the clinical and radiographic outcomes of using platelet-rich fibrin (PRF) for the treatment of periodontal intra-bony defect (IBD) compared with open flap debridement (OFD). Studies investigating the effect of platelet concentrate in surgical procedure for the
treatment of periodontal intra osseous defects compared with the control group in which platelet concentrate was not used were included. A total of 298 sites were treated using PRF either in combination with graft or as a monotherapy in comparison to traditional OFD procedure. The meta-analysis showed a standard mean difference of 0.95 mm in clinical attachment level (CAL) and 2.33 mm in IBD after treatment of IBD with PRF compared with OFD. The authors concluded that clinically significant improvements in periodontal parameters such as CAL, IBD, and reduction in probing depth were achieved when IBDs were treated with PRF alone when compared to OFD.

Slotte et al. (2012) conducted a randomized study to evaluate healing after open-flap debridement (OF) of intrabony periodontal defects alone or with adjunct treatment with bovine bone material grafts (BBM). There were 32 patients with 32 intrabony periodontal defects selected. After initial periodontal scaling and root planing, full-thickness flaps were raised and root surfaces and defects were debrided. Patients were then randomly assigned to treatment groups, either OF alone or combined with defect fill with BBM, and followed in a strict postoperative maintenance care program for 12 months. Upon assessment of results at 12 month point, none of the following parameters showed significant intergroup differences: gingival recession, probing depth, gain in clinical attachment level and probing bone level. However, radiographically, there were significant changes in the infrabony defect. The authors concluded that both procedures had similar outcomes of improved periodontal conditions, and that the addition of BBM provided the greatest improvement in the radiographic appearance of intrabony defects.

Sohrabi et al. (2012) conducted a meta-analysis of randomized controlled clinical trials to evaluate bioactive glass in the treatment of intrabony and furcation defects. Criteria included publication in English, follow-up duration of ≥6 months, baseline and follow-up measures of probing depth (PD) and clinical attachment levels (CAL) with 95% confidence intervals (CIs), and an appropriate control arm. Twenty-five citations were identified, 15 of which were included in the final analysis. Pooled analyses showed that BG was superior to control for both measures. CAL heterogeneity appeared secondary to active controls versus open flap debridement (OFD) alone and to defect-type modifying BG treatment success. Per subgroup analyses, the benefit of BG over control treatment was highly significant only in studies comparing BG to OFD. The authors concluded that treatment of intrabony defects with BG imparts a significant improvement in both PD and CAL compared to both active controls and OFD.

Stavropoulos and Karrig (2010) published the 6-year results of a randomized-controlled clinical trial evaluating guided tissue regeneration (GTR) combined with or without deproteinized bovine bone mineral (DBBM) in intrabony defects. In 45 patients, one defect was treated with GTR combined with DBBM hydrated in saline (DBBM-) or gentamicin sulphate (DBBM+) or with GTR alone. Thirty-six patients (33 teeth) were available for the entire 6-year control. Clinical parameters of clinical attachment level (CAL) and probing depths (PDs) were recorded pre-surgery, and at 1 and 6 years postsurgery. These results showed statistically significant clinical improvements for all treatments, and periodontal conditions obtained after GTR treatment with or without the adjunct use of DBBM can be preserved on a long-term basis.

Suárez-López Del Amo et al. (2015) conducted a comprehensive review to describe the origin and rationale, evidence, and the most current understanding of the following biologic agents in the tissues of the periodontium for periodontal regeneration procedures: Recombinant Human Platelet-Derived Growth Factor-BB (rhPDGF-BB), Enamel Matrix Derivate (EMD), Platelet-Rich Plasma (PRP) and Platelet-Rich Fibrin (PRF), Recombinant Human Fibroblast Growth Factor-2 (rhFGF-2), Bone Morphogenic Proteins (BMPs, BMP-2 and BMP-7), Teriparatide PTH, and Growth Differential Factor-5 (GDF-5). The authors concluded that some agents are still on their infancy, others have obtained FDA approval for different clinical procedures (rhPDGF-BB, EMD). They also concluded that while biologics proved to be beneficial in a variety of aspects of periodontal regeneration and bone augmentation procedures, of great importance are basic principles of surgery, proper patient, and/or site selection as essentials for predictable clinical outcomes. More investigation is required to further understand these biologic agents, providing more information with regard to long term effects, proper carrier, and ideal concentration/dosage, among other confounding factors.

**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 websites for more information and search by product name in device name section: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm) (Accessed December 2016)

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 is available at [http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm](http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm) (Accessed December 2016)

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

American Dental Association CDT Codebook 2017.
American Dental Association Glossary of Clinical and Administrative Terms.


**POLICY HISTORY/REVISION INFORMATION**

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