Dental Barrier Membrane Guided Tissue Regeneration

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➲ Instructions for Use

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Coverage Rationale

Guided Tissue Regeneration – Resorbable and Non-Resorbable Barriers

Guided Tissue Regeneration is indicated for the following:

- Intrabony/infrabony vertical defects
- Class II Furcation involvements
- In conjunction with bone grafting for:
  - Ridge Preservation
  - Ridge augmentation or reconstruction
  - Implant placement
  - Treatment of peri implant defects
  - To enhance periodontal tissue regeneration and healing for mucogingival defects in conjunction with mucogingival surgeries

Guided Tissue Regeneration is not indicated for the following:

- Teeth with a poor or hopeless prognosis
- Individuals with an uncontrolled underlying medical condition
- Individuals who have been non-compliant with previous therapies
- Individuals with poor oral hygiene
- Osseous defects with less than two walls
- Crater defects
- Periapical lesions that are endodontic in origin

Definitions

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

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). The Glickman Classification of Tooth Furcation Grading (Sims, 2015):
- Grade I:
  - Incipient
  - Just barely detectable with examination hand instruments
  - No horizontal component of the Furcation is evident on probing
- Grade II:
  - Early bone loss
  - Examination hand instrument goes partially into the Furcation, but not all the way through
  - Furcation may be grade II on both sides of the tooth, but are not connected
- Grade III:
  - Advanced bone loss
  - Examination hand instrument goes all the way through Furcation, to other side of tooth
  - Furcation is through-and-through
- Grade IV:
  - Through-and-through, plus Furcation is clinically visible due to gingival recession

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)

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

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

Ridge Preservation: A surgical procedure aimed at preventing ridge collapse and preserving ridge dimension after tooth extraction, typically done for purposes of implant site development. Involves the use of hard and/or soft tissue biomaterials and/or membranes. (AAP)

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
D6106	Guided tissue regeneration - resorbable barrier, per implant
D6107	Guided tissue regeneration - non-resorbable barrier, per implant
D3432	Guided tissue regeneration, resorbable barrier, per site, in conjunction with periradicular surgery
D4266	Guided tissue regeneration, natural teeth - resorbable barrier, per site
D4267	Guided tissue regeneration, natural teeth - non-resorbable barrier, per site
D4286	Removal of non-resorbable barrier
D7956	Guided tissue regeneration, edentulous area - resorbable barrier, per site
D7957	Guided tissue regeneration, edentulous area - non-resorbable barrier, per site

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Description of Services

A barrier membrane is used in oral and periodontal surgeries to prevent epithelial tissue from growing into an area in which bone is desired or when regeneration of periodontal tissues is the goal, to prevent epithelial and connective gingival tissue from forming on the surface of the root and bone (Siali et al. 2018) These include augmentation and reconstruction of alveolar ridge defects, improving bone healing around or to treat failing dental implants and improve bone grafting results. Membranes may be resorbable or non-resorbable. Resorbable membranes include natural membranes such as collagen; and synthetic membrane such as aliphatic polyesters. Non- resorbable membranes include expanded polytetrafuoroethylene (e-PTFE), and alginate.

Clinical Evidence

In a 2021 controlled clinical trial, Jung et al. reported on the clinical and radiographic outcomes of implants placed with resorbable and non-resorbable guided bone regeneration (GBR) membranes after 22-24 years. The original patient cohort included 72 patients with 265 individual implants, 39 patients and 147 implants were included in this study with a median time period of 23.5 years. Dehiscence defects were treated with GBR by either using resorbable collagen membranes or nonresorbable ePTFE membranes. Implants placed in pristine bone served as a control. Clinical parameters, marginal bone levels, and technical outcomes were evaluated following restoration placement and at this follow-up. A 3D radiographic analysis was conducted in order to assess buccal and oral bone dimensions, and implant survival was assessed. The results showed favorable implant survival rates ranging from 89.3% to 93.8% for augmented and nonaugmented sites with comparable bone levels between site with or without regeneration technique. Smoking was a factor that significantly had a negative effect on healing, bone loss, and long term implant survival rates. The authors concluded that implant treatment with and without GBR led to favorable long term implant survival rates, with smoking having the greatest impact on negative outcomes.

Nibali et al. (2021) conducted a systematic review on defect morphology and healing of infrabony defects following regenerative periodontal procedures. The main outcomes assessed were clinical attachment level (CAL) gain, periodontal pocket depth (PPD) reduction and radiographic bone gain. A total of fourteen studies were included. The results showed that deeper, narrower defects and defects with more walls are associated with improved CAL and radiographic outcomes 12 months post-regenerative surgery, and this appears to be irrespective of which type of Guided Tissue Regeneration is used. The authors concluded that more data and research is needed on other aspects of defect morphology, including when the defect extends to the buccal and/or lingual surfaces.

In a 2021 systematic review and meta-analysis, Swami et al. aimed to evaluate the efficacy of bone replacement graft (BRG) with Guided Tissue Regeneration (GTR) over BRG or open flap debridement (OFD) alone for the treatment of grade II Furcation defects. Outcome parameters included clinical attachment level (CAL) gain, changes in gingival marginal level (GML), vertical defect fill (VDF), horizontal defect fill (HDF) and reduction in defect volume. There were 9 randomized controlled trials (RCTs) comparing BRG + GTR vs BRG, while 3 compared BRG + GTR vs OFD. The results showed In the BRG + GTR vs BRG comparison group, 6 studies showed standardized mean difference (SMD) of 0.513 for VDF, 9 RCTs showed SMD of 0.83 for HDF and 2 RCTs showed SMD of 0.651 for CAL gain, and only 2 studies in the same group reported reduction in defect volume. Three studies of the BRG + GTR vs OFD group exhibited significant VDF and CAL gain with SMD of 2.002 and 1.161 respectively. No significant change was recorded for GML in both groups. The authors concluded that this systematic review indicates supplemental benefits of combination therapy of BRG + GTR over monotherapy in resolving grade II Furcation defects, and clinical situations warranting near-complete regeneration of the tissues in such defects are better suited for combination therapies.

Avila-Ortiz et al. (2019) conducted a systematic review of randomized clinical trials (RCTs) to critically analyze the available evidence on the effect of different modalities of alveolar Ridge Preservation (ARP) as compared to tooth extraction alone in function of relevant clinical, radiographic and patient-centered outcomes. Endpoints of interest included clinical, radiographic, and patient-reported outcome measures (PROMs). Interventions reported in the selected studies were clustered into ARP treatment modalities. All these different ARP modalities were compared to the control therapy (i.e. spontaneous socket healing) in each individual study after a 3- to 6-month healing period. Random effects meta-analyses were conducted if at least two studies within the same ARP treatment modality reported on the same outcome of interest. 22 RCTs were included in the final selection, from which 9 different ARP treatment modalities were identified:

- Bovine bone particles (BBP) + Socket sealing (SS)
- Construct made of 90% bovine bone granules and 10% porcine collagen (BBG/PC) + SS
- Cortico-cancellous porcine bone particles (CPBP) + SS
- Allograft particles (AG) + SS
- Alloplastic material (AP) with or without SS
- Autologous blood-derived products (ABDP)
- Cell therapy (CTh)
- Recombinant morphogenic protein-2 (rh-BMP2)
- SS alone

Quantitative analyses for different ARP modalities, all of which involved socket grafting with a bone substitute, were feasible for a subset of clinical and radiographic outcomes. The results of a pooled quantitative analysis revealed that ARP via socket grafting (ARP-SG), as compared to tooth extraction alone, prevents horizontal, vertical mid-buccal and vertical mid-lingual bone resorption. Whether there is a superior ARP or SS approach could not be determined on the basis of the selected evidence. However, the application of particulate xenogenic or allogenic materials covered with an absorbable collagen membrane, or a rapidly-absorbable collagen sponge was associated with the most favorable outcomes in terms of horizontal Ridge Preservation. A specific quantitative analysis showed that sites presenting a buccal bone thickness > 1.0 mm exhibited more favorable Ridge Preservation outcomes (difference between ARP [AG + SS] and control = 3.2 mm), as compared to sites with a thinner buccal wall (difference between ARP [AG + SS] and control = 1.29 mm). The authors concluded that ARP is an effective therapy to attenuate the dimensional reduction of the alveolar ridge that normally takes place after tooth extraction. Trobos et al. (2018) conducted a study to evaluate biofilm formation and barrier function against Streptococcus oralis of nonresorbable polytetrafluoroethylene (PTFE) guided bone regeneration membranes having expanded (e-PTFE) and dense (d-PTFE) microstructure. Three e-PTFE membranes of varying openness, one d-PTFE membrane, and commercially pure titanium discs were evaluated. All e-PTFE membranes consisted of PTFE nodes interconnected by fibrils. The d-PTFE membrane was fibril-free, with large evenly spaced indentations. The surfaces were challenged with S. oralis and incubated statically for 2-48h. bacterial colonization, viability, and penetration were evaluated.

The results showed S. oralis numbers increased over time on all surfaces, as observed using scanning electron microscopy, while cell viability decreased, as measured by colony forming unit (CFU) counting. At 24h and 48h, biofilms on d-PTFE were more mature and thicker (tower formations) than on e-PTFE, where fewer layers of cells were distributed mainly horizontally. Biofilms accumulated preferentially within d-PTFE membrane indentations. At 48h, greater biofilm biomass and number of viable S. oralis were found on d-PTFE compared to e-PTFE membranes. All membranes were impermeable to S. oralis cells. The authors concluded that all PTFE membranes were effective barriers against bacterial passage in vitro.

Bassir et al. (2018) conducted a systematic review and meta-analysis aimed to assess the efficacy of alveolar Ridge Preservation procedures in terms of hard tissue dimensional changes and to determine clinical factors affecting outcomes of these procedures. Studies comparing alveolar Ridge Preservation procedures with tooth extraction alone that reported quantitative outcomes for hard tissue dimensional changes were included. The primary outcome variable was horizontal dimensional changes of alveolar bone. Subgroup analyses evaluated effects of wound closure, flap elevation, type of grafting materials, use of barrier membranes, use of growth factors, socket morphology, and the position of teeth on outcomes of alveolar Ridge Preservation procedures. Twenty-one studies were included, and quantitative analyses were performed for seven outcome variables. Significant differences between alveolar Ridge Preservation and control sites were found for six outcome variables, all favoring alveolar Ridge Preservation procedures. The magnitude of effect for the primary outcome variable (horizontal dimensional changes of alveolar bone) was 1.86 mm. This magnitude of effect for the primary variable (as determined by subgroup analysis) was also significantly affected by type of wound closure ,type of grafting materials , use of barrier membranes , use of growth factors ,and socket morphology. Alveolar Ridge Preservation procedures are effective in minimizing postextraction hard tissue dimensional loss. The outcomes of these procedures are affected by morphology of extraction sockets, type of wound closure, type of grafting materials, use of barrier membranes, and use of growth factors.

In a 2018 meta-analysis, Wessing et al. sought to evaluate different methods for guided bone regeneration using collagen membranes and particulate grafting materials in implant dentistry. An electronic database and hand search were performed for all relevant articles dealing with guided bone regeneration in implant dentistry published between 1980 and 2014. Only randomized clinical trials and prospective controlled studies were included. The primary outcomes of interest were survival rates, membrane exposure rates, bone gain/defect reduction, and vertical bone loss at follow-up. A meta-analysis was performed to determine the effects of presence of membrane cross-linking, timing of implant placement, membrane fixation, and decortication. Twenty studies met the inclusion criteria. Implant survival rates were similar between simultaneous and subsequent implant placement. The membrane exposure rate of cross-linked membranes was approximately 30% higher than that of non-cross-linked membranes. The use of anorganic bovine bone mineral led to sufficient newly regenerated bone and high implant survival rates. Membrane fixation was weakly associated with increased vertical bone gain, and decortication led to higher horizontal bone gain (defect depth). The authors concluded that guided bone regeneration with particulate graft materials and resorbable collagen membranes is an effective technique for lateral alveolar ridge augmentation.

MacBeth et al. (2017) conducted a systematic review to answer two focused questions: 1) What is the effect of alveolar Ridge Preservation (ARP) on linear and volumetric alveolar site dimensions, keratinized measurements, histological characteristics and patient-based outcomes when compared to unassisted socket healing? 2) What is the size effect of these outcomes in three different types of intervention (guided bone regeneration, socket grafting and socket seal). An electronic and hand-search was conducted up to June 2015. Randomized controlled trials (RCT) and controlled clinical trials (CCT); with unassisted socket healing as controls were eligible in the analysis for Q1. RCTs, CCTs and large prospective case series with or without an unassisted socket healing as control group were eligible in the analysis for Q2. The results showed for Q1: the standardized mean difference (SMD) in vertical mid-buccal bone height between ARP and a non-treated site was 0.739 mm. The SMD when proximal vertical bone height and horizontal bone width was compared was 0.796mm and 1.198 mm . Examination of ARP sites revealed significant variation in vital and trabecular bone percentages and keratinized tissue width and thickness. Adverse events were routinely reported, with three papers reporting a high level of complications in the test and control groups and two papers reporting greater risks associated with ARP. For Q2: A pooled effect reduction (PER) in mid-buccal alveolar ridge height of -0.467 mm was recorded for GBR procedures and -0.157 mm for socket grafting. A proximal vertical bone height reduction of -0.356 mm was recorded for GBR, with a horizontal dimensional reduction of -1.45 mm measured following GBR and -1.613 mm for socket grafting procedures. Five papers reported on histological findings after ARP. Two papers indicated an increase in the width of the keratinized tissue following GBR, with two papers reporting a reduction in the thickness of the keratinized tissue following GBR. Histological examination revealed extensive variations in the treatment protocols and biomaterials materials used to evaluate extraction socket healing. GBR studies reported a variation in total bone formation of 47.9 ±9.1% to 24.67 ±15.92%. Post-operative complications were reported by 29 papers, with the most common findings soft tissue inflammation and infection. The authors concluded that ARP results in a significant reduction in the vertical bone dimensional change following tooth extraction when compared to unassisted socket healing. The reduction in horizontal alveolar bone dimensional change was found to be variable. No evidence was identified to clearly indicate the superior impact of a type of ARP intervention (GBR, socket filler and socket seal) on bone dimensional preservation, bone formation, keratinized tissue dimensions and patient complications.

In 2017, Soldatos et al. conducted a study to summarize the knowledge on different types of membranes available and currently used in GBR procedures in a staged approach or with simultaneous implant placement. The primary role of the membranes is to exclude epithelial and connective tissue cells from the wound area to be regenerated, and to create and maintain the space into which pluripotential and osteogenic cells are free to migrate. A selected number of studies were chosen in order to provide a review of the main characteristics, applications, and outcomes of the different types of membranes. Resorbable membranes are made of natural or synthetic polymers like collagen and aliphatic polyesters. Collagens are the most common type used. They have similar collagen composition to the periodontal connective tissue. Other materials available include human, porcine, and bovine pericardium membranes, human amnion and chorion tissue, and human acellular freeze-dried dermal matrix. Nonresorbable membranes used in GBR include dense-polytetrafluoroethylene (d-PTFE), expanded-polytetrafluoroethylene (e-PTFE), titanium mesh, and titanium-reinforced polytetrafluoroethylene. The authors concluded that the most common complication of nonresorbable membranes is exposure, which has detrimental effect on the final outcome with both types of membranes. For vertical bone augmentation procedures, the most appropriate membranes are the nonresorbable. For combination defects, both types result in a successful outcome.

In a 2017 systematic review, Troiano et al. sought to analyze evidence regarding potential benefits of alveolar Ridge Preservation (ARP) procedures performed with allogenic/xenogenic grafts in combination with resorbable membrane coverage in comparison to a spontaneous healing. Electronic databases were screened independently by two authors in order to select studies suitable for inclusion in this revision. Horizontal Ridge Width Reduction (HRWR) and Vertical Ridge Height Reduction (VRHR) were investigated as primary outcomes and Volume Changes (VC) as secondary outcome. Meta-analysis was performed using the inverse of variance test with a random effect model. Adjustment for type I and II errors and analysis of the power of evidence was performed with Trial Sequential analysis (TSA). 7 studies met the inclusion criteria and were included in the quantitative synthesis. Meta-analysis revealed that the combination therapy resulted in a lower rate of resorption for both HRWR and VRHR. For VC no meta-analysis was performed due to insufficient data. Analysis of the power of the evidence performed with TSA, showed that the number of both studies and sockets analyzed is sufficient to validate such findings, despite the high rate of heterogeneity. The authors concluded that the use of bone graft covered by a resorbable membrane is able to decrease the rate of alveolar ridge horizontal and vertical resorption after tooth extraction.

Merli et al. (2016) completed a systematic review to evaluate the efficacy of the bone augmentation procedure at dehiscence or fenestration defects in one-stage implant insertion and to evaluate which is the most effective procedure. Only randomized controlled trials (RCTs) were included. Outcome variables considered were implant failure, complications, aesthetic and functional satisfaction, complete fill of the defect, clinical and radiological bone level variation, and vestibular peri-implant recession. Independent data extraction by two authors using predefined data fields, including study quality indicators, was completed. All pooled analyses were based on random effects models. A total of 65 full-text articles were examined in detail. Forty-six of the 65 articles did not meet the inclusion criteria. Nineteen articles involving 15 trials were identified for inclusion in the review. Only one study was considered to be at a low risk of bias. The included studies involved 396 patients and 535 implants. Comparing the test group using membranes with the control without membranes, a statistically significant difference was obtained for vertical variation of the peri-implant defect; the difference was 1.64 mm favoring the use of a membrane. Non-resorbable polytetrafluoroethylene (ePTFE) membranes obtained a complete clinical fill of defects more frequently than resorbable polylactide/polyglycolide (PLGA) membranes. The odds ratio was 0.04 to 0.64 mm, favoring the use of ePTFE membranes. No differences were observed comparing nonresorbable ePTFE membranes and resorbable collagen membranes. The authors concluded that overall, the evidence is not sufficiently robust to determine if any treatment is needed and which is the best treatment for dehiscence or fenestration defects at one-stage implant placement. Only 15 trials were included and the most are of limited sample size, have short follow-ups as well as having a high risk of bias. The use of a membrane can contribute to the regeneration of the hard tissue in horizontal one-stage augmentation. The complete fill of the defect was obtained more frequently when a non-resorbable ePTFE membrane was used compared to a resorbable PLGA membrane. No differences were observed comparing non-resorbable ePTFE membranes and resorbable collagen membranes.

No substantial differences were obtained using different non-resorbable membranes and grafts, and the results were positive for the variables examined. A high result of heterogeneity was observed in studies dealing with cross-linked membranes.

In a 2016 systematic review of randomized controlled trials, Jonker et al. sought to determine the clinical value of membranes in bone augmentation procedures such as ridge augmentation with simultaneous (one-stage) and delayed (two-stage) implant placement, sinus augmentation surgery, Ridge Preservation and immediate implant placement. Randomized controlled trials that reported membranes in bone augmentation procedures with a minimum follow-up period of 6 months after implant loading or that described geometrical changes of the bone graft at re-entry were included. Membrane placement had to be the only variable in the procedure. Outcomes were implant failure, complications, horizontal bone gain and resorption, graft resorption, defect height reduction, marginal bone loss around implants, aesthetic results and patient satisfaction. The results were pooled using fixed-effect models with mean differences (MDs) for continuous outcomes and odds ratios (ORs) for dichotomous outcomes. Seventeen articles involving 10 trials were included in this review. These studies presented outcome data for 355 patients. Seven trials were considered to be at a high risk of bias, two at a low risk of bias and one at an unclear risk of bias. Insufficient evidence was found to determine whether there were differences in implant failure rates, marginal bone level changes, aesthetic results or patient satisfaction. For one-stage ridge augmentation (two trials; N = 52), there was evidence of more horizontal bone gain (MD: 0.84 mm, 95% CI: 0.46 to 1.21, P < 0.00001; two trials), defect height reduction (MD: 18.36%, 95% CI: 10.23 to 26.50, P < 0.00001; two trials), and prevention of graft resorption (P = 0.004; one trial) in favor of the membrane-covered group, although substantial heterogeneity was found for horizontal bone gain (Chi2; P = 0.05, I2 = 74%). There was insufficient evidence to determine whether any differences exist in two-stage ridge augmentation (three trials; N = 81), sinus augmentation (one trial; N = 104) and Ridge Preservation (one trial; N = 20). For immediate implant placement (three trials; N = 98), there was evidence of an increased defect height reduction in favor of the membrane-covered groups (MD: 6.25%, 95% CI: 1.67 to 10.82, P = 0.007; two trials), although with substantial heterogeneity (Chi2; P = 0.03, I2 = 79%). More complications were observed when a membrane was used (OR: 2.52, 95% CI: 1.07 to 5.93, P = 0.03; three trials). The authors concluded there is insufficient evidence regarding the effects of membranes on bone augmentation procedures to support any definitive conclusions. Only 10 studies were included; they had limited sample sizes and short follow-up periods, and the majority were at a high risk of bias. However, no difference in implant failure was found, and the possible clinical value is still unknown, as long-term clinical parameters such as marginal bone loss, aesthetic results and patient satisfaction have been insufficiently studied.

Lesions of Endodontic Origin

Parmar et al. (2019) conducted a randomized controlled trial to evaluate the effect of a resorbable collagen membrane on the healing of through and through lesions of endodontic origin. Thirty-two patients with periapical radiolucencies measuring at least 10 mm and with confirmed loss of buccal and lingual cortical plates were randomly divided into GTR and control groups. Periapical surgery was performed in both groups, using a resorbable collagen membrane in the GTR group only. Thirty patients were evaluated at 12 month follow- up, and the results showed both groups had a significant reduction in lesion size with no significant difference between the groups. The authors concluded that periapical surgery with or without GTR was a predictable and viable solution for through-and-through lesions of endodontic origin and there was no benefit in using a collagen membrane with regard to the outcome of periapical surgery.

Corbella et al (2016) conducted a comprehensive review of the published scientific literature of experimental and clinical studies to assess the efficacy and effectiveness of Guided Tissue Regeneration (GTR) in enhancing hard and soft tissue healing after endodontic surgery. The included articles are classified considering the anatomical characteristics of the lesion. Fourteen articles were included in the review after abstract and title selection. Eight articles were on studies on lesions affecting only the periapical region (three about through-and-through lesions) while six were about the treatment of apico-marginal lesions. On the basis of the currently available literature, there is a low scientific evidence of a benefit related to the use of guided bone regeneration procedure in endodontic surgery.

Tsesis et al. (2011) conducted a systematic review and meta-analysis to evaluate the influence of Guided Tissue Regeneration (GTR) on the outcome of surgical endodontic treatment. This systematic review included clinical studies that reported the use of Guided Tissue Regeneration in surgical endodontic treatment in patients with apical periodontitis in endodontically treated teeth. Search engines MEDLINE and EMBASE and MESH were utilized, and the methodologic quality of the selected studies was evaluated independently and in duplicate by two reviewers. The full texts of the studies were obtained and reviewed for suitability based on the inclusion and exclusion criteria. There were five articles included in the final meta-analysis and were subject to data extraction, methodologic quality assessment, and data synthesis and analysis. The review concluded that while there was a trend of better outcome when GTR was used compared to control cases and that GTR techniques may improve the outcome of bone regeneration after surgical endodontic treatments of teeth with certain lesions. Additional large-scale prospective clinical studies are needed to further evaluate possible benefits of GTR techniques in endodontic surgery.

Clinical Practice Guidelines

American Academy of Periodontology (AAP)

In a 2011 position statement on comprehensive periodontal therapy, the AAP states that periodontal regenerative procedures including bone replacement grafts, use of biologics, root biomodification, Guided Tissue Regeneration, and combinations of these procedures are appropriate for osseous, furcation, and gingival recession defects.

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.

The FDA considers barrier membranes to be Class II devices and exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) or the 21st Century Cures Act of 2016 (Cures Act).

501(k) Premarket notification regarding individual products can be found using product code NPL at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
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Policy History/Revision Information

Date	Summary of Changes
06/01/2023	**Coverage Rationale** • Removed content addressing coverage limitations and exclusions **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information • Archived previous policy version DCP045.06

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.