APPLICATION OF MEDICAMENTS AND DESENSITIZING RESINS

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INSTRUCTIONS FOR USE

This Dental Coverage Guideline 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 Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Dental Coverage Guideline. 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 Guideline. 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 Guideline is provided for informational purposes. It does not constitute medical advice.

BENEFIT CONSIDERATIONS

Before using this guideline, 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 guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Application of Desensitizing Medicament or Resin

Application of desensitizing medicament or resin is indicated for the following:

- For teeth with sensitivity that does not resolve with an over the counter desensitizing dentifrice

Application of desensitizing medicament or resin is not indicated for the following:

- Placement on teeth with erosion, recession, cervical abrasion or abfraction when asymptomatic
- As a base or liner prior to restoration placement
Interim Caries Arresting Medicament Application

Interim caries arresting medicament application is indicated for the following:

- As conservative treatment for active, non-symptomatic carious lesions
- Patients with extreme risk of caries (such as xerostomia or severe early childhood caries)
- Patients that cannot tolerate standard treatment for medical or psychological reasons. These may be included but are not limited to the following:
  - An extremely uncooperative child
  - Frail elderly patients
  - Patients with severe cognitive or physical disability
  - Patients that are immunocompromised
- Patients with multiple lesions that cannot be treated in one office visit
- Recurrent caries that are difficult to treat
- Patients without access to dental care

Interim caries arresting medicament application is not indicated for the following:

- Patients with a silver allergy
- Pregnant women
- During the first six months of breast feeding

Coverage Limitations and Exclusions

- Any dental procedure performed solely for cosmetic/aesthetic reasons (cosmetic procedures are those procedures that improve physical appearance).
- Clinical situations that can be effectively treated by a less costly, dental appropriate alternative procedure will be assigned a benefit based on the least costly procedure.
- These codes are for medicaments and resins, and not for the use of lasers for desensitization.

Definitions

Medicament: Substance or combination of substances intended to be pharmacologically active, specially prepared to be prescribed, dispensed or administered by authorized personnel to prevent or treat diseases in humans or animals. (ADA)

Remineralization: A process enhanced by the presence of fluoride whereby partially decalcified enamel, dentin, and cementum become recalcified by mineral replacement. (Mosby's)

Resin, Acrylic: Resinous material of the various esters of acrylic acid, used as a denture base material, for trays or for other restorations. (ADA)

Silver Fluoride: A colorless aqueous solution containing silver ions and fluoride ions. (Shah Review Article)

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 guideline 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.

<table>
<thead>
<tr>
<th>CDT Code</th>
<th>Description</th>
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<tr>
<td>D1354</td>
<td>interim caries arresting medicament application</td>
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<tr>
<td>D9910</td>
<td>application of desensitizing medicament</td>
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<tr>
<td>D9911</td>
<td>application of desensitizing resin for cervical and/or root surface, per tooth</td>
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Description of Services

Many patients experience significant dental sensitivity. It may be localized to select teeth, or generalized involving the entire dentition. The most common cause is due to exposed dentin (layer of tooth structure under tooth enamel) or cementum (root surface). This may be caused by erosion of tooth enamel, abrasion and abfraction from toothbrushing and traumatic occlusion, as well as systemic factors including diabetes and smoking. Many cases of hypersensitivity respond favorably to the counter desensitizing products. When sensitivity persists, there is a variety of treatment options available by prescription, or in office application. One of the newest is silver diamine fluoride. This is a topical...
medicament used to treat dental caries and dentin sensitivity (The FDA cleared Diamine Silver Fluoride Dental Hypersensitivity Varnish in July of 2014, and its use as a caries arresting agent is considered “off label”). The silver acts as an antimicrobial and prevents proteins from breaking down that would otherwise cause decay on the surface. The fluoride promotes remineralization. The one drawback is the SDF medicament may darken caries lesions when applied and give patients a metallic or bitter taste in their mouth.

**CLINICAL EVIDENCE**

**Application of Desensitizing Medicament or Resin**

Castillo et al. (2011) conducted a multi-center, randomized clinical trial to assess the effectiveness and safety of topical diammine silver fluoride on tooth sensitivity. From two sites, 126 adults with at least one tooth sensitive to compressed air were randomly assigned to either the topical silver diamine fluoride or sterile water, and pain was assessed by means of a 100-mm visual analogue scale at 24 hours and 7 days. The diammine silver fluoride reduced pain at 7 days at both sites. No tissue ulceration, white changes, or argyria was observed. A small number of participants in the silver fluoride group experienced a mild but transient increase in erythema in the gingiva near the tooth. No changes were observed in the Gingival Index. The authors concluded that diammine silver fluoride is a clinically effective and safe tooth desensitizer.

Craig et al. (2013) conducted a double-blind, randomized clinical trial. A total of 19 subjects with dentine hypersensitivity on both sides of their upper arch were selected. The most sensitive tooth in each quadrant was identified and received a cold stimulus. The response was recorded on a visual analogue scale (VAS). The tooth selected was treated with one of the treatment agents. One week later the level of dentine sensitivity was assessed. Participants were also asked for their subjective assessment of treatment effects. The mean difference between VAS at baseline and seven days for teeth treated with diamine silver fluoride/potassium iodide was greater than that for teeth treated with the oxalic acid-based preparation. The subjects' subjective assessment of changes in dentine hypersensitivity indicated that more obtained relief with the diamine silver fluoride/potassium iodide treatment. The authors concluded that a diamine silver fluoride/potassium iodide product has potential as a treatment for dentine hypersensitivity.

Ding et al. (2014) This short-term (4-week) randomized, double-blind, placebo-controlled, split-mouth study evaluated the effect of Clinpro XT Varnish (VXT) paste-liquid, resin-modified glass-ionomer and the resinous dentin desensitizing varnish and Gluma Dentin Desensitizer (Gluma) in treating dentin hypersensitivity (DH). A total of 119 teeth from 31 individuals were randomized into three groups: VXT, Gluma, and placebo (warm water). Dentin sensitivity was evaluated by subjects' perception of DH determined by pretreatment tooth sensitivity score (TSS) measured on a 0-10 visual analogue scale (VAS) after tactile (probe) or thermal/evaporative (blast of air) stimuli. TSS was scored at baseline, immediately after treatment (Day 0), after 1 week and after 4 weeks. For both stimuli, mean TSS was significantly decreased in the VXT and Gluma groups at all time points compared with baseline. Regarding comparisons of TSS between treatment groups, the VXT group had significantly lower mean TSS compared with the Gluma group and placebo control group at all time points after treatment regardless of stimuli.

Pandit et al. (2012) conducted a randomized clinical trial was designed to compare the efficacy of two commercially available desensitizing agents (fluoride varnish containing 6% sodium fluoride and 6% calcium fluoride and a gel containing 6% potassium nitrate and 0.11% fluoride ions) in the treatment of dentinal hypersensitivity. Twenty-one patients were selected. Subjects were evaluated using three different stimuli, i.e., tactile test, air blast test and cold water test. They were then randomly divided into two groups. Patients in group I were treated with fluoride varnish and group II patients were treated with gel containing 6% potassium nitrate and 0.11% fluoride ions. The patients were examined at baseline, immediately after application of the agent, at 1 week, 1 month and 3 month intervals. The results showed that patients treated in group I showed significantly better results compared to group II patients at 1 month and 3 months interval. Teeth which required repeat dose and those which did not require repeat dose were comparable in number. The authors concluded that both the agents showed significant reduction in sensitivity at all-time intervals compared to baseline. A comparatively significant reduction in sensitivity score was seen in patients treated with fluoride varnish and it appeared to be more effective in providing long-term relief against all the three test stimuli.

Petersson, Lars G (2013) conducted a literature review of original scientific papers from clinical trials listed in PubMed and Medline from 2000 to October 2011 for studies using fluoride to control dentin hypersensitivity (DHS) and prevent root caries. The results showed that fluoride toothpaste shows a fair effect on sensitive teeth when combined with dentin fluid-obstructing agents such as different metal ions, potassium, and oxalates. Fluoride in solution, gel, and varnish give an instant and long term relief of dentin and bleaching hypersensitivity. Most fluoride preparations in combination with dentin fluid obstruction agents are beneficial to reduce DHS, while prevention of root caries is favorable with higher fluoride concentrations. The authors concluded that fluoride is an effective agent to control DHS and to prevent root caries particularly when used in higher concentrations.
**Interim Caries Arresting Medicament Application**

Horst et al. (2016) authored a manuscript on rationale, indications and consent for using silver diamine fluoride. Nine published randomized clinical trials were reviewed each involving hundreds of children age 3-9 or adults aged 60-89 with at least one year duration of the study. The findings showed silver diamine fluoride outperformed standard fluoride varnish and was equivalent or better than glass ionomer cement. Direct application to healthy surfaces of children’s teeth also prevented caries. These studies show that 38% silver diamine fluoride is effective in preventing carious lesions.

Gao et al. (2016) performed a systemic review of 2,177 papers including 17 randomized trials from 1948 to 2014. Data of the selected studies were divided into two groups. Group one had ten studies, which investigated the use of professional fluoride application to remineralise early enamel caries or white spot lesions. Group two comprised studies investigating the arresting effect of fluoride in dentine caries. Meta-analysis using the random-effects model was used to evaluate the overall percentage of remineralised early enamel caries and to show the effective weight of each study in this review according to the sample size and calculated percentage of remineralised early enamel caries. For studies investigating dentine caries, the total number of active dentine caries surfaces at baseline and the total numbers of arrested dentine caries surfaces after intervention were used to calculate the caries arresting rates. The conclusion showed silver diamine solution at 38% is effective in arresting active dentine caries and the capability to remineralise early enamel caries in children.

Zhi et al. (2012) conducted a randomized clinical trial with 212 children that had a total of 719 active dentine caries lesions. After 24 months, 181 children remained in the study. This study addressed annual application of silver diamine fluoride solution or high fluoride-releasing glass ionomer. Both topical applications arrest active dentine caries. Increasing the frequency application of silver diamine fluoride to every 6 months can increase the caries arrest rate.

Gluzman et al. (2012) conducted a literature review of 31 studies. The goal of this literature review was to conduct a systematic review on the effectiveness of the seven leading preventive agents for root caries and to provide recommendations for use to the general population of healthy older adults as well as specific recommendations for vulnerable older adults. Results showed the recommended choice for primary prevention of root caries is a 38% Silver Diamine Fluoride solution professionally applied annually; the recommended secondary prevention of root caries, is fluoride varnish professionally applied every 3 months.

Mei et al. (2014) conducted an ex vivo study in association with a 24 month randomized clinical trial approved for the University of Hong Kong. The clinical trial compares the effectiveness of biannual silver diamine fluoride (SDF) application on arresting caries treatment. Ninety-eight four year old children with active caries on primary teeth were recruited. Their carious teeth were dried and cleaned and then application of 38% SDF solution was applied. At the end of the 24 month study, six 6 year old children were chosen for extraction of their primary upper central incisors with arrested cavitated dentinal lesions treated with biannual SDF in addition to 6 incisors with cavitated dentinal lesions with no topical fluoride application were collected. The study concluded a highly remineralised zone rich in calcium and phosphate was found on the arrested cavitated dentinal lesion of primary teeth with an SDF application. Clinical SDF application positively influences dentine remineralization.

Rosenblatt et al. (2009) performed a systemic review asking if silver diamine fluoride (SDF) would more effectively prevent caries than fluoride varnish. 99 human clinical trials were identified between 1966 and 2006 with only 2 meeting the inclusion criteria. The results suggest that SDF is more effective than fluoride varnish, and may be a valuable caries-preventive intervention.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Fluoride varnish currently has FDA approval as a cavity liner and desensitizer, and the application as a caries preventive agent is considered off label use. There are extensive manufacturers of fluoride varnish. See the following website for more information and search by specific product name: [http://www.fda.gov/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm) (Accessed June 29, 2016)

The FDA cleared Diamine Silver Fluoride Dental Hypersensitivity Varnish in July of 2014. Application as a caries arresting agent is considered off label use. The varnish is a Class II device intended to block dentinal tubules for the purpose of reducing tooth sensitivity. For additional information, please see the following: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K102973](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K102973) (Accessed June 29, 2016)

There are extensive products for in office application that have FDA clearance for reducing dental hypersensitivity. Please refer to the following website and search for product specific name: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) (Accessed June 29, 2016)
REFERENCES


GUIDELINE HISTORY/REVISION INFORMATION

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