**TOPICAL FLUORIDE TREATMENT**

**Policy Number:** DCP018.04  
**Effective Date:** June 1, 2019

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**COVERAGE RATIONALE**

**Topical Application of Fluoride – Excluding Varnish**

Topical fluoride treatments in the form of gel, foam, and rinses are applied in the dental office as a caries preventive agent.

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**Topical Application of Fluoride Varnish**

**Fluoride varnish is indicated for the following:**

- As the preferred caries prevention agent for children under age 6
- For members receiving head and neck radiation therapy
- Sensitivity that does not resolve with an over the counter desensitizing dentifrice
- For moderate to high caries risk members with a medical or cognitive impairment that limits cooperation with a tray or rinse delivery method
- Xerostomia
- For members in active orthodontic treatment
- For the Remineralization of incipient or white spot enamel carious lesions

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**Interim Caries Arresting Medicament (Silver Diamine Fluoride) Application**

**Interim caries arresting medicament application is indicated for the following:**

- As conservative treatment for active, non-symptomatic carious lesions
- Individuals with high caries risk
- Individuals unable to tolerate standard restorative treatment. These include, but are not limited to the following:
  - An uncooperative child
  - Frail elderly individuals
  - Individuals with cognitive or physical disability
  - Individuals in which restorative treatment requiring general anesthesia is contraindicated
- Individuals with multiple lesions that cannot be treated in one office visit
- Caries that are difficult to treat with traditional restorations (i.e., crown margins, furcations, partially erupted teeth)
- Individuals with limited or restricted access to dental care

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

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

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**Coverage Limitations (for Topical Fluoride when used as a Component of Routine Preventive Dental Care)**

- Limited to Covered Persons under the age of 16 years
- Limited to 2 times per consecutive 12 months
DEFINITIONS

**Fluoride**: A compound of fluorine with a metal, a nonmetal, or an organic radical; the anion of fluorine; inhibits enolase; found in bone and toothapatite; Fluoride has a cariostatic effect; high levels are toxic.

**Remineralization**: A process enhanced by the presence of Fluoride whereby partially decalcified enamel, dentin, and cementum become recalcified by mineral replacement.

**Silver Diamine Fluoride**: A colorless liquid that is 24.4% to 28.8% silver and 5.0% to 5.9% Fluoride. (ADA)

**Xerostomia**: Dryness of the mouth caused by cessation of normal salivary secretion. The condition is a symptom of various diseases such as diabetes, acute infections, hysteria, and Sjögren’s syndrome and can be caused by paralysis of facial nerves. It may also result from radiation treatments for cancers of the face, head, or neck. It is also caused by an adverse reaction to drugs.

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>
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<td>Topical application of fluoride varnish</td>
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<td>D1208</td>
<td>Topical application of fluoride – excluding varnish</td>
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<tr>
<td>D1354</td>
<td>Interim caries arresting medicament application – per tooth</td>
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*CDT® is a registered trademark of the American Dental Association*

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<th>CPT Code</th>
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<td>Application of topical fluoride varnish by a physician or other qualified health care professional</td>
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*CPT® is a registered trademark of the American Medical Association*

DESCRIPTION OF SERVICES

Fluoride is a naturally occurring mineral that has been well established as a caries prevention agent. Beneficial sources of fluoride include drinking water, over the counter and prescription toothpastes and rinses, and fluoride supplements, as well as topical application of professional strength products in an office setting. Combined, these provide a “halo” or “diffusion” effect of total fluoride exposure and, along with individual patient risk, should be considered when making the decision to apply in office topical fluoride treatments for caries prevention. Topical fluoride treatments are typically applied with prescription strength products in a dental setting by a licensed dental professional; however fluoride varnish may also be applied in a medical setting by licensed providers as part of preventive services for children (USPSTF).

CLINICAL EVIDENCE

In a 2018 systematic review of ten studies on different enamel remineralization therapies for post orthodontic white spot lesions, Fernández-Ferrer et al. concluded that neither fluoride mouthrinses nor phosphopeptide toothpastes with or without fluoride had any positive effect when added to oral hygiene maintenance with fluoride toothpaste. A 5% sodium fluoride varnish was the only therapy to show a statistically significant improvement compared with results in the control group.

Benson et al. (2013) conducted a Cochrane literature review with the primary objective of evaluating the effects of fluoride in reducing the incidence of demineralized white spot lesions (DWLs) on the teeth during orthodontic treatment. The secondary objectives were to examine the effectiveness of different modes of fluoride delivery in reducing the incidence and size of DWLs. This is an update of a Cochrane review first published in 2004. Trials were included in this review if they met the following criteria: (1) parallel-group randomized clinical trials comparing the use of a fluoride-containing product versus placebo, no treatment or a different type of fluoride treatment, in which (2) the outcome of enamel demineralization was assessed at the start and at the end of orthodontic treatment. One placebo-controlled study of fluoride varnish applied every six weeks (253 participants, low risk of bias), provided moderate-quality evidence of an almost 70% reduction in DWLs. This finding is considered to provide moderate-quality
evidence for this intervention because it has not yet been replicated by further studies in orthodontic participants. The authors concluded that there is moderate evidence that fluoride varnish applied every six weeks at the time of orthodontic review during treatment is effective, but this finding is based on a single study with a high number of participants. Further adequately powered, double-blind, randomized controlled trials are required to determine the best means of preventing DWLs in patients undergoing orthodontic treatment.

Deng et al. (2015) conducted a narrative literature review regarding dental caries in HNC population from 1985 to 2014. The authors also reviewed information from National Institute of Dental and Craniofacial Research (NIDCR), American Dental Association (ADA), Healthy People 2020, National Cancer Institute (NCI), American Cancer Society (ACS), and other related healthcare professional association web sites. This literature review focuses on critical issues related to dental caries in patients with HNC: potential mechanisms and contributing factors, clinical assessment, physical sequelae, negative impact on body image and quality of life, potential preventative strategies, and recommendations for practice and research in this area. Radiation-associated dental caries may progress rapidly in HNC patients who do not follow an appropriate oral care regimen. In a literature review conducted by the Oral Care Study Group of the Multinational Association of Supportive Care in Cancer and the International Society for Oral Oncology (MASCC/ISOO) which included 37 HNC trials, the prevalence of decayed, missing or filled teeth (DMFT), a standard outcome measure of dental health, was 17.01 for HNC patients who had received radiation versus 4.4 for healthy controls. The prevalence of dental disease appears to increase significantly over time as demonstrated by a retrospective study conducted in 314 nasopharyngeal cancer patients. In this study, the prevalence of dental disease escalated from 16% the first year post-radiation to 36%, 55% and 74% at 3, 5, and 7 years post-treatment respectively. National Institute of Dental and Craniofacial Research (NIDCR) recommends oral health maintenance in HNC patients before, during and after chemoradiation. Recommendations include: pre-treatment assessment of dentition with extraction of non-viable teeth, rigorous oral hygiene, diets that minimize risk for dental caries and the use of prescription-strength fluoride to enhance enamel remineralization. The authors concluded that the routine use of prescription-strength fluoride has been shown to be an effective preventive agent in the HNC population.

Dholam et al. (2013) conducted a study to evaluate the effectiveness of three-month fluoride varnish application on radiation caries and dental sensitivity and to assess compliance to three-month fluoride varnish application. There were 190 irradiated head and neck cancer patients randomly selected and reviewed retrospectively (Oral prophylaxis, fluoride varnish application, and treatment of dental caries were done prior to radiation therapy). Decayed-missing-filling-teeth (DMFT) indices, dental sensitivity, and compliance to fluoride varnish application were noted every 3 months for fifteen months and analyzed statistically. Despite an increase in DMFT indices, the numbers were less than what was expected, and was highly dependent on site of disease and radiation dose. Sensitivity decreased and there was very high compliance with this regimen. The authors concluded that the application of fluoride varnish to the teeth of dental patients treated with radiation therapy results in lowered DMFT scores, decreased sensitivity and has high patient compliance.

Lenzi et al. (2016) conducted a systematic review and meta-analysis of the literature to determine the effectiveness of professional topical fluoride application (gels or varnishes) on the reversal treatment of incipient enamel carious lesions in primary or permanent dentition. The statistical analysis was performed only for studies assessing fluoride varnish; there were insufficient data to perform it for fluoride gel studies. The therapeutic methods ranged considerably regarding the fluoride application protocols, and there was a significant trend of effectiveness of fluoride varnish on the reversal of incipient enamel carious lesions, and further clinical trials concerning efficacy of topical fluorides for treating lesions are still required, mainly regarding the fluoride gel. The authors concluded that dentists can use fluoride varnishes as an adjuvant for the treatment of active white-spot lesions in primary or permanent dentition.

Makhija et al. (2014) conducted a twenty-month follow-up of occlusal carious lesions deemed questionable at baseline. A questionable occlusal caries (QOC) lesion can be defined as an occlusal surface with no radiographic evidence of caries, but caries is suspected because of clinical appearance. Fifty-three clinicians from The National Dental Practice-Based Research Network participated in this study, recording lesion characteristics at baseline and lesion status at 20 months. At baseline, 1,341 QOC lesions were examined; the treatment that was planned for 1,033 of those at baseline was monitoring (oral hygiene instruction, applying or prescribing fluoride or varnish, or both), and the remaining 308 received a sealant (n=192) or invasive therapy (n=116). At the 20-month visit, clinicians continued to monitor 927 (90 percent) of the 1,033 lesions identified for monitoring. The result of this study demonstrates the effectiveness of non-invasive management of these types of lesions.

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 dental 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.

Zero et al. (2016) conducted a systematic search of the literature to develop caries prevention strategies in Sjögren disease to improve quality and consistency of care. A national panel of experts devised clinical questions in a Population, Intervention, Comparison, Outcomes format and included use of fluoride, salivary stimulants, antimicrobial agents, and non-fluoride remineralizing agents, and rated the strength of the recommendations by using a variation of grading of recommendations, assessment, development, and evaluation. After a Delphi consensus panel was conducted, the experts finalized the recommendations, with a minimum of 75% agreement required. Topical fluoride was the only recommendation assigned a recommendation of “strong”. Regarding the other recommendations, there were no study results link improved salivary flow to caries prevention, however the oral health community generally accepts that increasing saliva may contribute to decreased caries incidence, so increasing saliva through gustatory, masticatory, or pharmaceutical stimulation may be considered (weak). Chlorhexidine administered as varnish, gel, or rinse may be considered (weak); and non-fluoride remineralizing agents may be considered as an adjunct therapy (moderate). The authors concluded that the incidence of caries in patients with Sjögren disease can be reduced with the use of topical fluoride and other preventive strategies, with topical fluoride the only strategy given a strong recommendation based on current published literature.

**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.

In a systematic review with meta-analysis, Oliveira et al. (2018) assessed the effect of silver diamine fluoride (SDF) in preventing and arresting caries in exposed root surfaces of adults. The authors found 2,356 unique records and included 3 trials in which the investigators randomly assigned 895 older adults. Investigators in all studies compared SDF with a placebo; investigators in one also compared 38% SDF with chlorhexidine and sodium fluoride varnishes. The studies had low risk of bias in most domains. SDF applications had a significantly better preventive effect in comparison with the placebo, and they were as effective as either chlorhexidine or sodium fluoride varnish in preventing new root carious lesions. SDF also provided a significantly higher caries arrest effect than did the placebo. Complaints about black staining of the carious lesions by SDF were rare among older adults. The authors concluded yearly 38% SDF applications to exposed root surfaces of older adults are a simple, inexpensive, and effective way of preventing caries initiation and progression.

Contreras et al. (2017) evaluated the scientific evidence regarding the effectiveness of silver diamine fluoride (SDF) in preventing and arresting caries in the primary dentition and permanent first molars. A systematic literature review was performed using PubMed, ScienceDirect, and Scopus. Articles from 2005 to January 2016 were searched and 7 publications were included. These included 1 study assessing the effectiveness of SDF at different concentrations; 3 studies comparing SDF with other interventions; 2 investigations comparing SDF at different application frequencies and with other interventions; and 1 study comparing semiannual SDF applications versus a control group. The study indicated at concentrations of 30% and 38%, SDF shows potential as an alternative treatment for caries arrest in the primary dentition and permanent first molars. To establish guidelines, more studies are needed to fully assess the effectiveness of SDF and to determine the appropriate application frequency.

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.

**Professional Societies**

**American Dental Association (ADA)**
The ADA recommends the following for people at risk of developing dental caries:
- 2.26% fluoride varnish or 1.23% fluoride (APF) gel, applied every 3-6 months or a prescription-strength, home-use 0.5% fluoride gel or paste or 0.09% fluoride mouthrinse for 6 years or older.
- Only 2.26% fluoride varnish is recommended for children younger than 6 years.
- As part of the evidence-based approach to care, these clinical recommendations should be integrated with the practitioner’s professional judgment and the patient’s needs and preferences. Patients at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.

In a 2018 report, the ADA recommends clinicians prioritize the use of 38% SDF solution (biannual application) over 5% NaF varnish (application once per week for 3 weeks to arrest advanced cavitated carious lesions on any coronal surface of primary and permanent teeth.

**American Academy of Pediatric Dentistry (AAPD)**
The AAPD encourages the application of professional fluoride treatments for all children at risk for dental caries at least every six months.
- Risk category may change over time, and the type and frequency of preventive interventions should be adjusted.
- Decisions concerning the administration of fluoride are based on the unique needs of each patient, including the risks and benefits.

**American Academy of Pediatric Dentistry (AAPD)**
The AAPD Council of Clinical Affairs policy on the use of silver diamine fluoride (SDF) for pediatric dental patients states the following:
- The AAPD supports the use of SDF as part of an ongoing caries management plan for the patient with the aim of optimizing individualized patient care.
- The AAPD supports third party reimbursement for fees associated with SDF.
- The AAPD encourages more practice-based research to be conducted on SDF to evaluate its efficacy.

**International Society of Oral Oncology**
The panel recommends the use of fluoride to prevent dental caries in patients who are post-radiotherapy. Studies indicated fluoride works regardless of the type of delivery method (level of evidence II, recommendation grade B).
**National Comprehensive Cancer Network (NCCN)**

In the 2018 clinical practice guideline, the NCCN advises fluoride varnish application three times per year as dental caries prevention for patients before and after radiation therapy.

**Sjögren’s Syndrome Foundation**

The Oral Working Group had a high level of confidence that using topical fluoride represents a best clinical practice. Topical fluoride should be used in Sjögren’s patients with dry mouth. This recommendation was rated as strong. The expert panel did not make a recommendation on fluoride type or frequency.

**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 January 31, 2019)

Fluoride gel, foams and rinses have FDA approval as caries preventive agents. There are extensive manufacturers of fluoride products. See the following website for more information and search by specific product name: [http://www.fda.gov/Drugs/default.htm](http://www.fda.gov/Drugs/default.htm). (Accessed January 31, 2019)

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 March 6, 2019)

**REFERENCES**


International Society of Oral Oncology. Summary of Evidence-Based Oral Care Study Group, Multinational Association for Supportive Care in Cancer/International Society of Oral Oncology Clinical Practice Guidelines for Care of Patients with Other Oral Complications 2011.


POLICY HISTORY/REVISION INFORMATION

<table>
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| 06/01/2019 | - Revised coverage rationale:  
|          |  o Simplified content  
|          |  o Added language pertaining to **interim caries arresting medicament (silver diamine fluoride) application** (previously located in policy titled Application of Medicaments and Desensitizing Resins)  
|          |  - Added definition of “Silver Diamine Fluoride”  
|          |  - Updated list of applicable CDT codes; added D1354  
|          |  - Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references  
|          |  - Archived previous policy version DCP018.03 |
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.