

# Topical Fluoride Treatment

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[Instructions for Use](#)

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<b>Related Medical Policy</b>
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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.

### 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

### 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

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

## 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 tooth apatite; 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:** Decreased salivary secretion that produces a dry and sometimes burning sensation of the oral mucosa and/or cervical caries. (ADA)

## 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
D1206	Topical application of fluoride varnish
D1208	Topical application of fluoride – excluding varnish
D1354	Interim caries arresting medicament application – per tooth

*CDT® is a registered trademark of the American Dental Association*

CPT Code	Description
99188	Application of topical fluoride varnish by a physician or other qualified health care professional

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## 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). Silver Diamine fluoride (SDF) is a silver fluoride salt made soluble in water through the addition of ammonia. It is a non-invasive medicament that is applied to active decay and stops its progress through remineralizing and antibacterial activity.

Li et al. (2020) conducted a systematic review and meta-analysis of the literature to compare between fissure sealant and fluoride varnish on caries prevention for first permanent molars. Current guidelines recommend a preference of fissure sealant (FS) over fluoride varnish (FV) based on two recent systematic reviews. However, evidences of these two studies are weak because of scarce data and some limitations. Besides, an up-to-date large scale randomized controlled trial (RCT) reported commensurate effectiveness of these two techniques. Thus, in order to more accurately compare the clinical efficacy between FS and FV on caries prevention for first permanent molars (FPMs), a systematic review and meta-analysis was carried out. A total of 8 RCTs involving 3289 participants and 6878 FPMs fulfilled the inclusion criteria. For the first time the meta-analysis showed that there was no statistical difference on caries incidence or occlusal decayed missing filled surface (DMFS) increment between sealant group and fluoride varnish group at 2~3 years' follow-up. In that sense, the authors concluded biannual applications of FV or FS may be equally effective on caries prevention for FPMs. The authors found these results do not support routine recommendation of FS over FV, thus shedding light on current conceptions.

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.

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.

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.

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.

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.

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.

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.

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.

## **Interim Caries Arresting Medicament Application**

Crystal and Niederman, et al, (2019) conducted a systematic review on the effectiveness of silver diamine fluoride (SDF) as a caries arresting and preventive agent. It provides clinical recommendations around SDF's appropriate use as part of a

comprehensive caries management program. These systematic reviews confirm that SDF is effective for caries arrest on cavitated lesions in primary teeth and root caries in the elderly. It may also prevent new lesions and no caries removal is necessary to arrest the caries process. Therefore, the use of silver diamine fluoride is appropriate when other forms of caries control are not available or feasible. Application is easy, noninvasive, affordable, and safe. Although it stains the lesions dark as it arrests them, it provides clinicians with an additional tool for caries management when esthetics is not a primary concern. Some limitations include, most of the systematic reviews and metaanalysis included for this article face the obstacles of having to compile data from clinical trials that have substantial differences in treatment protocols (1 application, yearly, or twice a year applications), concentration of SDF used, dentition studied, follow-up time, outcome measured (arrest or prevention), and the way they report their findings. Their reported figures differ depending on the number of studies included and how they group the studies to make their comparisons, which may affect the generalizability of their results.

Trieu, et al. (2019) conducted a systematic review and meta-analysis on dentine caries arrest capabilities of silver diamine fluoride (SDF) and sodium fluoride (NaF). A comprehensive search strategy was developed to identify the relevant publications in electronic databases and hand searched journals and reviews (to March 2018). By applying strict inclusion and exclusion criteria, only six papers (two randomized controlled trials, two follow-up articles and two secondary statistical analysis studies) were considered for full text qualitative and quantitative assessment. The included studies were critically appraised and statistically evaluated. Only four articles were considered for meta-analysis, as the other two were secondary analyses of included studies. When comparing the caries arrest lesions of SDF and NaF, SDF was found to be statistically more effective in dentine caries arrest of primary teeth during the 18 and 30 month clinical examinations. The weighted total effect size of the differences between SDF and NaF regarding arrested caries surfaces was calculated and showed nearly double the effectiveness of SDF to NaF at 30 months. Therefore, the authors concluded SDF is a more effective caries management reagent than NaF. Though the quality of evidence and meta-analyses are strong, the findings were only based on 2 studies. Further studies are needed to evaluate the minimal necessary concentration and frequency of application to arrest dentine caries of primary and permanent teeth.

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.

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.

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.

## **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 (Slayton et al).

### ***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 2020 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)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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>. (Accessed February 17, 2021)

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>. (Accessed February 17, 2021)

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>. (Accessed February 17, 2021)

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## Policy History/Revision Information

Date	Summary of Changes
05/01/2021	<b>Supporting Information</b> <ul style="list-style-type: none"><li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li><li>Archived previous policy version DCP018.05</li></ul>

## 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.