Topical Medicaments for Caries Prevention or Remineralization

Policy Number: DCP018.09
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Instructions for Use

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Related Dental Policy

- Medically Necessary Orthodontic Treatment

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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 may be the preferred delivery method for the following:

- Children under age 6
- individuals receiving head and neck radiation therapy
- Sensitivity that does not resolve with an over-the-counter desensitizing dentifrice
- Moderate to high caries risk individuals with a medical or cognitive impairment
- Xerostomia
- Individuals in active orthodontic treatment
- The Remineralization of incipient or white spot enamel carious lesions

Interim Caries Arresting Medicament (Silver Diamine Fluoride) Application

Interim caries arresting medicament (Silver Diamine Fluoride) application may be indicated for caries arrest in the following situations:

- 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
  - The elderly
  - 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

Caries Preventive Medicament Application (other than Fluoride)

Non- Fluoride medicaments for caries prevention and/or Remineralization are not indicated due to insufficient evidence of efficacy.

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	Application of caries arresting medicament-per tooth
D1355	caries preventive medicament application - per tooth; For primary prevention or remineralization. Medicaments applied do not include topical fluorides

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. Additional non- Fluoride medicaments may

be applied to prevent caries, and/or facilitate Remineralization. These include, but are not limited to silver nitrate, thymol chlorhexidine (CHX) varnish, topical povidone iodine, and calcium phosphate derivatives.

Clinical Evidence

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 mouth rinses 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 could 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

In 2023, Ruff et al. reported the results of the ongoing CariedAway single-blind, cluster randomized, school based clinical trial to evaluate the effectiveness and noninferiority of SDF with fluoride varnish in comparison with an established, active comparator of glass ionomer sealants and atraumatic restorative treatment with fluoride varnish for dental caries. Children received a single application of silver diamine fluoride with fluoride varnish or an active comparator of glass ionomer sealants and atraumatic restorations with fluoride varnish. A total of 2998 children with untreated dental caries were recruited and treated from September 16, 2019, to March 12, 2020, and follow-up observations were completed for 1398 children from June 7, 2021, to March 2, 2022. The mean (SE) proportion of children with arrested caries was 0.56 after experimental treatment and 0.46 after control treatment. The mean (SE) proportion of patients without new caries was 0.81 after experimental treatment and 0.82 after control treatment. There were no adverse events. The results showed silver diamine fluoride with fluoride varnish was noninferior to sealants and atraumatic restorations with fluoride varnish for caries arrest and prevention and these results may support the use of silver diamine fluoride as an arresting and preventive agent in school-based oral health programs.

In a 2021 randomized controlled trial, Mendiratta et al. compared the efficacy of caries arrest using Silver Diamine Fluoride (SDF) compared to Fluoride containing glass ionomer cement (GIC) with 5% Fluoride varnish (FV) in intellectually disabled individuals. Eighty two participants with active caries in permanent posterior teeth were randomized to each group, and caries arrest and preventive fraction was assessed at 6 month follow up. The results showed for the SDF group, a 94.5% caries arrest rate with a 45% preventive fraction rate over the GIC group. The authors concluded that SDF is at least as clinically effective as a combination of GIC and FV in arresting caries, Further research with larger numbers of participants and longer follow up are required to validate these findings.

Grandjean et al. (2021) conducted a systematic review and meta-analysis of three RCTs assessing the efficacy of SDF in arresting and preventing root surface caries in the elderly. A meta-analysis, using a fixed-effects model, was performed on the mean active root caries lesions (RCLs) present after SDF intervention compared to controls at 24 months and 30-36 months post intervention. The results showed a significant decrease in new RCLs following the application of SDF at both follow up points and demonstrates the efficacy it prevents and arrests root caries in the elderly. Further research is warranted to validate these findings.

Crystal 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 dentin caries arrest capabilities of Silver Diamine Fluoride (SDF) and sodium Fluoride (NaF). Four articles were considered for meta-analysis. When comparing the caries arrest lesions of SDF and NaF, SDF was found to be statistically more effective in dentin 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. The authors concluded that SDF is a more effective caries management reagent than NaF. Though the quality of evidence and meta-analyses are strong, the findings were based on a small number of studies, and further research is needed to evaluate the minimal necessary concentration and frequency of application to arrest dentin 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 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 results showed 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. 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. 7 studies 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.

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.

Non-Fluoride Caries Prevention Medicaments

Singal et al. (2022) conducted a systematic review and meta-analysis of 26 randomized controlled trials on the caries preventive and tooth remineralizing effect of various calcium phosphate (CaP) derivative agents compared to no-intervention/placebo or fluoride (F) use alone among children. The meta-analysis of 10 studies showed complete white spot lesions (WSLs) regression, post intervention active WSLs and post intervention salivary S. mutans count significantly favored the CaP + F combined therapy as compared to F alone. No significant differences in the lesion area, Delta F, and DIAGNOdent values were observed between the 2 groups. The authors concluded that there was a low certainty of the evidence due to the high/unclear risk of bias, imprecision, and indirectness of included trials, and more high quality research is needed before providing definitive recommendations for the use of CaP.

In a 2020 systematic review and meta-analysis, Gupta et al. compared the effectiveness of topical fluorides and povidone iodine combined, and topical fluoride alone to reduce bacterial load and caries incidence among 1-12 year old children. Based on the results of very low quality, limited published literature, the results showed that overall, in the primary and permanent dentitions, caries incidence was significantly lower in the combined treatment group compared to fluoride alone, but no significant difference in bacterial load. The authors concluded that povidone iodine may have an added benefit for caries prevention, but more research with robust methodologies are needed to validate these findings.

Walsh et al. (2015) conducted a Cochrane database systematic review on the effects of CHX containing products (toothpastes, mouth rinses, varnishes, gels, gums and sprays) with each other, placebo or no intervention on the prevention of caries in children and adolescents. Included were eight RCTs that evaluated the effects of chlorhexidine varnishes (1%, 10% or 40% concentration) and chlorhexidine gel (0.12%) on primary or permanent teeth, or both, of children from birth to 15 years. The studies randomized a total of 2876 participants, of whom 2276 (79%) were evaluated. The results showed that six studies were at high risk of bias overall and two studies as being at unclear risk of bias overall. Follow-up assessment ranged from 6 to 36 months. Six trials compared chlorhexidine varnish with placebo or no treatment. Only one trial (10% concentration chlorhexidine varnish) provided usable data for elevated mutans streptococci levels > 4 with RR 0.93 (95% CI 0.80 to 1.07, 496 participants; very low quality evidence). One trial measured adverse effects (for example, ulcers or tooth staining) and reported that there were none; another trial reported that no side effects of the treatment were noted. No trials reported on pain, quality of life, patient satisfaction or costs. Two trials compared chlorhexidine gel (0.12% concentration) with no treatment in the primary dentition. Data for the effects of chlorhexidine gel on the prevalence of mutans streptococci were inconclusive. Both trials measured adverse effects and did not observe any. The authors concluded that there is limited evidence to either support or refute the assertion that chlorhexidine is more effective than placebo or no treatment in the prevention of caries or the reduction of mutans streptococci levels in children and adolescents. Further high quality research is needed, specifically research that evaluates the effects on both the primary and permanent dentition and using other chlorhexidine-containing oral products.

In a 2015 comparative study, Flamee et al compared the caries preventive effect of a CHX/thymol antibacterial varnish with fluoride varnish when applied during the eruption of permanent molars in 189 patients. The primary endpoint was caries incidence (primary and cavitated), and the secondary outcome was salivary mutans streptococci (MS) counts. The results showed the caries incidence after two years was low in both groups and there was no significant difference between the two groups with respect to occlusal caries development in the erupting molars, however, there were significantly lower levels of salivary MS. The authors concluded both medicaments are effective in preventing caries in erupting permanent molars.

Autio-Gold (2008) reviewed the published literature on the effectiveness of different modes of CHX delivery for caries prevention and management. It was concluded that based on the published reviews, that chlorhexidine rinses, gels and varnishes or combinations of these items with fluoride have variable effects, and due to the current lack of evidence on long-term clinical outcomes and reported side effects, chlorhexidine rinse should not be recommended for caries prevention. For the treatment and prevention of dental caries, there are alternative evidence-based methods available, such as fluoride applications, diet modifications and good oral hygiene practices.

Clinical Practice Guidelines

American Dental Association (ADA)

The ADA Council on Scientific Affairs 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 mouth rinse 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 evidence based clinical practice guideline on nonrestorative treatments for carious lesions (Slayton et al.), the ADA recommends the following:

- 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
- To arrest or reverse noncavitated carious lesions on approximal surfaces of primary and permanent teeth, the use of 5% NaF varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% NaF varnish (application every 3-6 months), or sealants alone
- To arrest or reverse noncavitated carious lesions on facial or lingual surfaces of primary and permanent teeth, the use of 1.23% APF gel (application every 3-6 months) or 5% NaF varnish (application every 3-6 months)

American Academy of Pediatric Dentistry (AAPD)

In the 2018 policy on the use of fluoride, the AAPD encourages the application of professional fluoride treatments for all individuals at risk for dental caries. Professional fluoride products should only be applied by or under the direction of a dentist or physician who is familiar with the child's oral health and has completed a caries risk assessment.

The 2018 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 encourages more practice-based research to be conducted on SDF to evaluate its efficacy.

In the 2020 policy on Early Childhood Caries (ECC): Consequences and Preventive Strategies, the AAPD states that professionally-applied topical fluoride treatments are efficacious in reducing prevalence of ECC. The recommended professionally-applied fluoride treatment for children at risk for ECC who are younger than six years is five percent sodium fluoride varnish (NaFV; 22,500 parts per million F). Additionally, the use of 38 percent silver diamine fluoride (SDF) is effective for the arrest of cavitated caries lesions in primary teeth.

National Comprehensive Cancer Network (NCCN)

The NCCN clinical practice guidelines for head and neck cancers, advises fluoride varnish application three times per year for dental caries prevention for patients before and for the long term 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.

United States Preventive Services Task Force (USPSTF)

In a 2021 recommendation statement, the USPSTF states there is inadequate evidence to assess the benefits and harms of oral screening (including risk assessment) by a primary care clinicians, and make the following recommendations (moderate certainty) regarding Fluoride and primary care clinicians for asymptomatic children younger than age 5:

- Prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in Fluoride
- Apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (Chou et al.)

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 There are extensive manufacturers of fluoride varnish. Refer to the following website for more information and search by specific product name: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.
(Accessed February 23, 2023)

Fluoride gel, foams and rinses have FDA approval as caries preventive agents. There are extensive manufacturers of Fluoride products. Refer to the following website for more information and search by specific product name: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.
(Accessed February 23, 2023)

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, refer to the following: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K102973.
(Accessed February 23, 2023)

On February 11, 2020, the FDA cleared Cervitec® Plus (Ivoclar) a chlorhexidine varnish under the 501(k) process as a Class II device for the treatment of dentinal hypersensitivity secondary to exposed dentin and root cervical surfaces. For additional information, refer to the following: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191453.pdf.
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Policy History/Revision Information

Date	Summary of Changes
06/01/2023	**Title Change** • Previously titled *Topical Fluoride Treatment* **Coverage Rationale** • Added language to indicate non-fluoride medicaments for caries prevention and/or remineralization are not indicated due to insufficient evidence of efficacy • Replaced language indicating "interim caries arresting medicament application may be indicated *for the* [listed situations]" with "interim caries arresting medicament *(Silver Diamine Fluoride)* application may be indicated for *caries arrest in the* [listed] *situations*" • Removed content addressing coverage limitations **Applicable Codes** • Added CDT code D1355 • Removed CPT code 99188 **Supporting Information** • Archived previous policy version DCP018.08

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.