

# Topical Medicaments for Caries Prevention or Remineralization

**Policy Number:** DCP018.11  
**Effective Date:** May 1, 2025

[➔ Instructions for Use](#)

<b>Table of Contents</b>	<b>Page</b>
<a href="#">Coverage Rationale</a> .....	1
<a href="#">Definitions</a> .....	2
<a href="#">Applicable Codes</a> .....	2
<a href="#">Description of Services</a> .....	2
<a href="#">Clinical Evidence</a> .....	3
<a href="#">U.S. Food and Drug Administration</a> .....	7
<a href="#">References</a> .....	8
<a href="#">Policy History/Revision Information</a> .....	9
<a href="#">Instructions for Use</a> .....	10

## Related Dental Policy

- [Medically Necessary Orthodontic Treatment](#)
- [Sealants and Preventive Resin Restorations](#)

## Related Medical Policy

- [Preventive Care Services](#)

## 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

*CDT® is a registered trademark of the American Dental 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).

Silver Diamine Fluoride (SDF) is a silver Fluoride salt made soluble in water through the addition of ammonia. The silver component functions as an antimicrobial, Fluoride promotes Remineralization, and ammonia is a stabilizing agent. It is a non-invasive medicament that is applied to active decay and stops the progress. It is also being explored for caries prevention.

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.

### Topical Fluoride Application

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 Sjogren's 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 Sjogren's 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.

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.

## Interim Caries Arresting Medicament Application

In a 2024 Cochrane Database Systematic Review, Worthington et al. assessed the effects of silver diamine fluoride for preventing and managing caries in primary and permanent teeth (coronal and root caries) compared to any other intervention including placebo or no treatment. Included were 29 randomized controlled trials with parallel-group or split-mouth design in children and adults (with or without carious lesions) that compared SDF with placebo or no treatment, different frequencies, concentrations or duration of SDF, or any other intervention. Studies were comprised of 13036 total participants (12020 children, 1016 older adults). The five most clinically relevant comparisons were assessed and the results showed:

- SDF compared to placebo, or no treatment showed SDF may help prevent and arrest new caries in the primary and permanent dentitions. These results were very uncertain. Moderate certainty evidence shows that SDF prevents root caries.
- Studies compared different dosages and frequency of application and findings could not be combined to draw conclusions.
- SDF compared to fluoride varnish showed that SDF may result in little or no difference in preventing new caries.
- SDF versus sealants and resin infiltration results showed that due to very low certainty evidence, it cannot be determined which intervention is better for primary prevention in permanent teeth.
- SDF versus atraumatic restoration treatment (ART) with glass ionomer cement (GIC) or GI materials very low certainty evidence showed there was no ability to determine superiority of one over the other.

The authors concluded that application of SDF shows benefit for caries arrest, but the benefits for caries prevention is uncertain.

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 meta-analysis 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 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.

Oliveira et al. (2019) conducted a systematic review and meta-analysis on the efficacy of SDF in preventing caries in the primary dentition in children 0-12 years of age when compared to placebo or other active treatments. Four trials that randomized 1118 participants were included. Two compared SDF to no treatment (NT), one compared SDF to placebo and sodium fluoride varnish (FV) and one compared SDF to high viscosity glass-ionomer cement (GIC). The trials differed regarding type of tooth surfaces treated, and interval between SDF applications. The results showed when yearly application of 38% SDF is compared to quarterly application of fluoride varnish (22,600 ppm), there was a 54% reduction in new caries that favored SDF. When comparing SDF with sealing cavities using GIC, the results favor GIC over SDF after 12 months of follow-up. When comparing SDF to placebo or no treatment, with at least 24 months of follow-up SDF application significantly reduce the development of dentin caries lesions in treated and untreated primary teeth. The authors concluded that while these studies showed SDF as superior to no treatment, placebo, and other active treatments, they all had a high or unknown risk of bias. Larger well-designed studies are needed to validate these findings.

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 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 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 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 and impact on oral health-related quality of life.

In the 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. Calcium phosphate artificial saliva is recommended to alleviate xerostomia and related caries risk. These recommendations are part of the overall principles of oral/dental evaluation and management, which also includes dietary counseling, oral hygiene, and regular, frequent dental visits.

### ***Sjögren's Foundation***

In 2016, the Sjögren's Foundation developed the first-ever U.S. Clinical Practice Guidelines for Caries Prevention in Sjögren's to ensure quality and consistency of care. The Oral Working Group had a high level of confidence that using topical fluoride represents a best clinical practice. The expert panel did not make a recommendation on fluoride type or frequency. This recommendation is part of the overall guidelines for best practices which also include salivary stimulation, non-fluoride remineralizing agents, and chlorhexidine varnish, gel, or rinse.

### ***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 5, 2025)

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 5, 2025)

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/pmnmn.cfm?ID=K102973>.

(Accessed February 5, 2025)

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](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191453.pdf).

(Accessed February 5, 2025)

## References

American Academy of Pediatric Dentistry. Policy on use of Fluoride. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2023:100-2. Available at:

[https://www.aapd.org/globalassets/media/policies\\_guidelines/p\\_fluorideuse.pdf](https://www.aapd.org/globalassets/media/policies_guidelines/p_fluorideuse.pdf). Accessed February 5, 2025.

American Academy of Pediatric Dentistry. Policy on the use of Silver Diamine Fluoride for pediatric dental patients. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2023:103-5. Available at:

[https://www.aapd.org/media/Policies\\_Guidelines/P\\_SilverDiamine.pdf](https://www.aapd.org/media/Policies_Guidelines/P_SilverDiamine.pdf). Accessed February 5, 2025.

American Academy of Pediatric Dentistry. Policy on early childhood caries (ECC): Consequences and preventive strategies. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2023:88-91. Available at: [https://www.aapd.org/globalassets/media/policies\\_guidelines/p\\_eccconsequences.pdf](https://www.aapd.org/globalassets/media/policies_guidelines/p_eccconsequences.pdf). Accessed February 5, 2025.

American Dental Association (ADA) CDT Codebook 2025.

American Dental Association (ADA) Glossary of Dental Clinical and Administrative Terms.

American Dental Association Council on Scientific Affairs. Professionally applied and Prescription-strength, Home-use Topical Fluoride Agents for Caries Prevention Clinical Practice Guideline. 2013.

American Dental Association Council on Scientific Affairs. Nonrestorative Treatments for Carious Lesions Clinical Practice Guideline. 2018.

Autio-Gold J. The role of chlorhexidine in caries prevention. *Oper Dent*. 2008 Nov-Dec;33(6):710-6.

Benson PE, Parkin N, Dyer F, et al. Fluorides for the prevention of early tooth decay (demineralized white lesions) during fixed brace treatment. *Cochrane Database Syst Rev*. 2013 Dec 12; 12:CD003809.

Chou R, Pappas M, Dana T, et al. Screening and Interventions to Prevent Dental Caries in Children Younger Than 5 Years: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA*. 2021 Dec 7;326(21):2179-2192.

Contreras V, Toro MJ, Elías-Boneta AR, et al. Effectiveness of Silver Diamine Fluoride in caries prevention and arrest: a systematic literature review. *Gen Dent*. 2017 May-Jun;65(3):22-29.

Crystal YO, Niederman R. Evidence-Based Dentistry Update on Silver Diamine Fluoride. *Dent Clin North Am*.

2019;63(1):45–68. doi:10.1016/j.cden.2018.08.011Deng J, Jackson L, Epstein JB, et al. Dental demineralization and caries in patients with head and neck cancer. *Oral Oncol*. 2015 Sep; 51(9):824-31.

Dholam KP, Somani PP, Prabhu SD, et al. Effectiveness of Fluoride varnish application as cariostatic and desensitizing agent in irradiated head and neck cancer patients. *Int J Dent*. 2013; 2013.

Fernández-Ferrer L, Vicente-Ruiz M, García-Sanz V, et al. Enamel Remineralization therapies for treating postorthodontic white-spot lesions: A systematic review. *J Am Dent Assoc*. 2018 Sep; 149(9):778-786.

Flamee S, Gizani S, Caroni C, et al. Effect of a chlorhexidine/thymol and a fluoride varnish on caries development in erupting permanent molars: a comparative study. *Eur Arch Paediatr Dent*. 2015 Dec;16(6):449-54.

Gluzman R, Katz RV, Frey BJ, et al. Prevention of Root Caries: A Literature Review of Primary and Secondary Preventive Agents. *Special care in dentistry : official publication of the American Association of Hospital Dentists, the Academy of Dentistry for the Handicapped, and the American Society for Geriatric Dentistry*. 2013; 33(3):133-140.

Gupta A, Nishant, Sharda S, Kumar A, et al. Comparing the effectiveness of topical fluoride and povidone iodine with topical fluoride alone for the prevention of dental caries among children: a systematic review and meta-analysis. *Int J Clin Pediatr Dent*. 2020 Sep-Oct;13(5):559-565.

Lenzi TL, Montagner AF, Soares FZ, et al. Are topical Fluorides effective for treating incipient carious lesions? A systematic review and meta-analysis. *J Am Dent Assoc*. 2016 Feb; 147(2):84-91.

Manchanda S, Sardana D, Liu P, et al. Topical fluoride to prevent early childhood caries: Systematic review with network meta-analysis. *J Dent*. 2022 Jan;116:103885.

Mendiratta M, B C M, Kumar A, et al. Effectiveness of Silver Diamine Fluoride and glass ionomer cement combined with Fluoride varnish in arresting dental caries among intellectually disabled individuals: A randomized controlled trial. *Spec Care Dentist*. 2021 Sep;41(5):544-552.

National Cancer Institute. Oral Complications of Chemotherapy and Head/Neck Radiation—for health professionals 2016. Updated October 2022. Available at: <https://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq> – NCI (cancer.gov). Accessed February 5, 2025.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Head and Neck Cancers. Principles of Oral/ Dental Evaluation and Management. Version 2.2025 – January 17, 2025.

National Institute of Dental and Craniofacial Research, National Institutes of Health. Cancer treatments and Oral Health. 2018. Updated 2024. Available at: <http://www.nidcr.nih.gov/oralhealth/Topics/CancerTreatment/OralComplicationsCancerOral.htm#top>. Accessed February 5, 2025.

Oliveira BH, Rajendra A, Veitz-Keenan A, et al. The effect of silver diamine fluoride in preventing caries in the primary dentition: a systematic review and meta-analysis. *Caries Res*. 2019;53(1):24-32.

Oliveira BH, Cunha-Cruz J, Rajendra A, Niederman R. Controlling caries in exposed root surfaces with Silver Diamine Fluoride: A systematic review with meta-analysis. *J Am Dent Assoc*. 2018 Aug;149(8):671-679.

Ruff RR, Barry-Godín T, Niederman R. Effect of silver diamine fluoride on caries arrest and prevention: The CariedAway School-Based Randomized Clinical Trial. *JAMA Netw Open*. 2023 Feb 1;6(2):e2255458. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9912124/?report=printable>. Accessed February 5, 2025.

Singal K, Sharda S, Gupta A, et al. Effectiveness-of Calcium Phosphate derivative agents on the prevention and remineralization of caries among children- A systematic review & meta-analysis of randomized controlled trials. *J Evid Based Dent Pract*. 2022 Sep;22(3):101746.

Sjögren's Foundation's Clinical Practice Guidelines. Oral Management: Caries Prevention in Sjogren's Patients. 2015.

Trieu A, Mohamed A, Lynch E. Silver diamine Fluoride versus sodium Fluoride for arresting dentine caries in children: a systematic review and meta-analysis. *Sci Rep*. 2019;9(1):2115. Published 2019 Feb 14. doi:10.1038/s41598-019-38569-9.

United States Preventive Services Task Force (USPSTF). Prevention of Dental Caries in Children Younger Than 5 Years: Screening and Interventions. December 2021.

Walsh T, Oliveira-Neto JM, Moore D. Chlorhexidine treatment for the prevention of dental caries in children and adolescents. *Cochrane Database Syst Rev*. 2015 Apr 13;(4):CD008457.

Weyant RJ, Tracy SL, Anselmo TT et al; American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents. Topical Fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review. *J Am Dent Assoc*. 2013 Nov; 144(11):1279-91.

Worthington HV, Lewis SR, Glenny AM, et al. Topical silver diamine fluoride (SDF) for preventing and managing dental caries in children and adults. *Cochrane Database Syst Rev*. 2024 Nov 7;11(11):CD012718. doi: 10.1002/14651858.CD012718.pub2. PMID: 39508296; PMCID: PMC11542151.

## Policy History/Revision Information

Date	Summary of Changes
05/01/2025	<p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>

Date	Summary of Changes
	<ul style="list-style-type: none"> <li>Archived previous policy version DCP018.10</li> </ul>

## Instructions for Use

This Dental Clinical Policy provides assistance in interpreting UnitedHealthcare standard and Medicare Advantage dental 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.