TOPICAL FLUORIDE TREATMENT

Policy Number: DCP018.03 **Effective Date**: May 1, 2018

Table of Contents **Page**

Related Dental Policy

- Medically Necessary Orthodontic Treatment

Related Medical Policy

- Preventive Care Services

INSTRUCTIONS FOR USE

This Dental Coverage Policy provides assistance in interpreting UnitedHealthcare dental benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Dental Coverage Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Dental Coverage Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Dental Coverage Policy. Other Clinical Policies and Coverage Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Dental Coverage Policy is provided for informational purposes. It does not constitute medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group health plans (inside and outside of Exchanges) to provide coverage for Pediatric Dental Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for Pediatric Dental EHBs. However, if such plans choose to provide coverage for benefits which are deemed Pediatric Dental EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute Pediatric Dental EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Topical Application of Fluoride – Excluding Varnish

Topical fluoride treatments in the form of gel, foam and rinses applied as a caries preventive agent in the dental office are benefitted twice per consecutive twelve months for children up to age 15. Members at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.

Topical Application of Fluoride Varnish

Fluoride varnish is indicated for the following:

- As the preferred caries prevention agent for children under age 6
- For head and neck radiation therapy patients
- 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 due to systemic disease or medication
- For members in active orthodontic treatment
- For the remineralization of incipient or white spot enamel carious lesions

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.

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

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Clinical Policies and Coverage Guidelines may apply.

CDT Code	Description
D1206	Topical application of fluoride varnish
D1208	Topical application of fluoride – excluding varnish

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

CPT® is a registered trademark of the American Medical Association

DESCRIPTION OF SERVICES

Topical fluoride treatments are applied with prescription strength products in a dental setting by a licensed dental professional. Products may be in the form of varnish, gel, foam or in office rinses and are separate from fluoridated prophylaxis paste. Fluoride varnish is also covered as a preventive service for children in a medical setting based on recommendations from the United States Preventive Services Task Force (USPSTF) and the Bright Futures/American Academy of Pediatrics Recommendations for Preventive Pediatric Health Care. There are other sources of fluoride, including drinking water, over the counter and prescription toothpastes and rinses, and fluoride supplements. 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.

CLINICAL EVIDENCE

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

participants. Further adequately powered, double-blind, randomized controlled trials are required to determine the best means of preventing DWLs in patients undergoing orthodontic treatment.

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

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

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

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

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

comparable in number. The authors concluded that both the agents showed significant reduction in sensitivity at all-time intervals compared to baseline. A comparatively significant reduction in sensitivity score was seen in patients treated with fluoride varnish and it appeared to be more effective in providing long-term relief against all the three test stimuli.

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

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.

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.

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

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).

Sjögren's Syndrome Foundation

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

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Fluoride varnish currently has FDA approval as a cavity liner and desensitizer, and the application as a caries preventive agent is considered off label use. There are extensive manufacturers of fluoride varnish. See the following website for more information and search by specific product name: http://www.fda.gov/MedicalDevices/default.htm. (Accessed March 6, 2018)

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 March 6, 2018)

REFERENCES

American Academy of Pediatric Dentistry Council on Clinical Affairs. Policy on Use of Fluoride. 2014.

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

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, Cantor A, Zakher B, et al. Prevention of Dental Caries in Children Younger Than 5 Years Old: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 May.

Deng 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.

Farlex Partner Medical Dictionary (2012). Available at: http://medical-dictionary.thefreedictionary.com/fluoride. Accessed February 16, 2017.

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

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.

Makhija SK, Gilbert GH, Funkhouser E, et al. National Dental PBRN Collaborative Group. Twenty-month follow-up of occlusal caries lesions deemed questionable at baseline: findings from the National Dental Practice-Based Research Network. J Am Dent Assoc. 2014 Nov; 145(11):1112-8.

Medical Dictionary for the Health Professions and Nursing. (2012). Available at: http://medical-dictionary.thefreedictionary.com/remineralization. Accessed February 16, 2017.

Mosby's Medical Dictionary, 8th edition. (2009). Available at: http://medical-dictionary.thefreedictionary.com/xerostomia. Accessed February 16, 2017.

National Cancer Institute. Oral Complications of Chemotherapy and Head/Neck Radiation–for health professionals 2016.

National Institute of Dental and Craniofacial Research, National Institutes of Health. Oral complications of cancer treatment: what the dental team can do, 2009. Available at: http://www.nidcr.nih.gov/oralhealth/Topics/CancerTreatment/OralComplicationsCancerOral.htm#top. Accessed January 13, 2016.

National Institute of Dental and Craniofacial Research, National Institutes of Health. Oral complications of cancer treatment: what the oncology team can do, 2009. Pandit N, Gupta R, Bansal A. Comparative evaluation of two commercially available desensitizing agents for the treatment of dentinal hypersensitivity. Indian J Dent Res. 2012 Nov-Dec; 23(6):778-83.

Petersson LG. The role of fluoride in the preventive management of dentin hypersensitivity and root caries. Clin Oral Investig. 2013 Mar;17 Suppl 1:S63-71

Sjögren's Syndrome Foundation's Clinical Practice Guidelines. Oral Management: Caries Prevention in Sjogren's Patients. 2011.

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.

Zero DT, Brennan MT, Daniels TE, et al. Sjögren's Syndrome Foundation Clinical Practice Guidelines Committee. Clinical practice guidelines for oral management of Sjögren disease: Dental caries prevention. J Am Dent Assoc. 2016 Jan 4.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
05/01/2018	• Updated coverage rationale; replaced references to "patients" with "members" • Updated supporting information to reflect the most current clinical evidence and references • Archived previous policy version DCP018.02