

## Silver Diamine Fluoride (SDF) Fact Sheet

### March 2017

#### **What is SDF?**

Silver diamine fluoride (SDF) has been used extensively outside the United States for many years for caries control.<sup>1</sup> SDF is a colorless liquid containing silver particles and 38% (44,800 ppm) fluoride ion that at pH 10 is 25% silver, 8% ammonia, 5% fluoride, and 62% water. This is referred to as 38% SDF.

#### **What is the strength of evidence for SDF?**

In clinical trials, SDF applied directly to the cavitated lesion outperformed fluoride varnish for the non-surgical arrest of caries in children and older adults. In addition, SDF demonstrated impressive caries prevention to adjoining teeth not receiving direct application of SDF.<sup>1,2</sup> At least eight published reports of randomized clinical trials consistently demonstrated very high rates of caries arrest.<sup>3,4,5,6,7,8,9,10</sup> Although a 2016 systematic review and meta-analysis of clinical trials in children that concluded that 38% SDF applied at least once per year effectively arrested more than 65% of active caries,<sup>11</sup> there is no consensus for the number and frequency of applications for optimal caries control.<sup>12</sup> A critical summary of the systematic review, published in early 2017, called for more well-designed and well-conducted clinical trials comparing the effectiveness of SDF with no treatment or other caries management approaches in populations with varying caries risk, lesion severities, and other fluoride exposures.<sup>12</sup>

#### **Does SDF have FDA Approval?**

In August 2014, SDF was approved by the Food and Drug Administration (FDA) as a desensitizing agent, similar to the off-label use of fluoride varnish 20 years-ago.<sup>13</sup> As of early 2017, there is only one SDF product on the U.S. market. The FDA granted the manufacturer “breakthrough therapy status,” facilitating clinical trials of SDF for caries arrest.

#### **What are indications for SDF use?**

SDF arrests active carious lesions painlessly and without local anesthetic, as long as the teeth are asymptomatic, avoiding or delaying traditional surgical removal of caries. This intervention can be applied to teeth as soon as caries is detected. SDF is effective in treating people who are unable to access dental treatment or tolerate conventional dental care, including very young “pre-cooperative” children, persons with intellectual/developmental disabilities, or older adults.

#### **What are contraindications for SDF therapy?**

No adverse events using silver compounds have been reported in more than 80 years of use in dentistry.<sup>1,14</sup> Silver allergy is the only known contraindication.<sup>2</sup> Teeth with evidence of pulpitis or pulpal necrosis are not appropriate for SDF treatment and require surgical treatment. Similarly, teeth with deep lesions where the carious dentin has been excavated are not candidates for SDF, due to the ammonia content and high pH which may create a pulpal reaction.

#### **Are there other considerations for SDF therapy?**

The silver particles in SDF darken active dental caries and temporarily stain unprotected soft tissues, which may be a concern with patient/parent acceptance. It does not stain sound enamel. Post-treatment application of potassium iodide solution reduces staining. Some individuals report a transient metallic taste after application of SDF. SDF will also permanently stain floors, clothing and furniture.

#### **Silver diamine fluoride clinical presentation\***



Figure 2: Arrested dental caries after silver diamine fluoride application



Figure 3: Black discoloration in anterior teeth after application of silver diamine fluoride



Figure 4: Black discoloration in pit and fissure after application of silver diamine fluoride

\* Sabadini, GD. Used with permission, granted 01/03/2017.

### ***Are there recommended protocols?***

All providers applying SDF need appropriate training. In January 2016, for example, the University of California San Francisco (UCSF) School of Dentistry published a thorough [clinical protocol](#) for the use of SDF<sup>14</sup> (watch the [application](#) of SDF on YouTube). The American Academy of Pediatric Dentistry is currently conducting a review that, depending on the evidence, may include clinical guidelines (personal communication, Norman Tinanoff, University of Maryland, 3/1/2017).

### ***Can SDF be used in addition to fluoride varnish, other professionally applied fluorides, or dental sealants?***

SDF is a new addition to professionally applied topical fluoride products available in the U.S. While there is little evidence in the literature to support additional efficacy, some practitioners apply fluoride varnish or fluoride in addition to SDF treatment, but not to the teeth already treated with SDF. For any patient with active caries, UCSF's protocol includes replacement of fluoride varnish with the application of silver diamine fluoride to active lesions only.<sup>14</sup> Dental sealants are more effective than SDF for caries prevention in non-cavitated teeth.<sup>15,16</sup> Compared to SDF, the use of dental sealants is firmly supported for long term caries prevention by the quantity and quality of evidence available.<sup>17</sup>

### ***In which states does Medicaid reimburse for SDF therapy?***

State Medicaid policy and coverage guidelines may vary by professional training, risk, age, dentition, and frequency of application. As of December 2016, at least 14 states reported using existing or implementing new policy coverage for SDF application (reported by Vermont Department of Health, informal survey of ASTDD members, December 2016). State Oral Health Programs and interested health professionals should review their individual state Medicaid program dental policy on fluoride applications to determine if and how the policy addresses coverage of SDF application.

### ***Who can apply SDF?***

According to the rules and as governed by their state medical and/or dental practice acts, dentists, dental hygienists, physicians, nurses, and their assistants may be permitted to apply fluorides and SDF. Dental hygienists in most states whose Medicaid programs cover SDF application are permitted to apply SDF under the same authorization or restrictions as other topical fluorides (personal communication, Ann Lynch, American Dental Hygienists' Association, 11/21/2016).

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<sup>1</sup> Rosenblatt A, Stamford TC, Niederman R. Silver diamine fluoride: a caries "silver-fluoride bullet." J Dent Res. 2009;88(2):116–125.

<sup>2</sup> Mei ML, Lo EC, Chu CH. [Clinical use of silver diamine fluoride in dental treatment](#). Compend Contin Educ Dent. 2016;37(2):93–98.

<sup>3</sup> Yee RC, Holmgren C, Mulder J, Lama D, Walker D, Helderman W. Efficacy of silver diamine fluoride for arresting caries treatment. J Dent Res. 2009;88(7):644–647

<sup>4</sup> Zhang W, McGrath C, Lo EC, Li JY. [Silver diamine fluoride and education to prevent and arrest root caries among community-dwelling elders](#). Caries Res. 2013;47(4):284–290.

<sup>5</sup> Santos Dos VE, de Vasconcelos FMN, Ribeiro AG, Rosenblatt A. [Paradigm shift in the effective treatment of caries in schoolchildren at risk](#). Int Dent J 2012;62(1):47–51

<sup>6</sup> Chu CH, Lo ECM, Lin HC. [Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children](#). J Dent Res. 2002;81(11):767–770.

<sup>7</sup> Llodra JC, Rodriguez A, Ferrer B, Menardia V, Ramos T, Morato M. [Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial](#). J Dent Res. 2005;84(8):721–724.

<sup>8</sup> Lo EC, Chu CH, Lin HC. [A community-based caries control program for pre-school children using topical fluorides: 18-month results](#). J Dent Res. 2001; 80(12):2071–2074.

<sup>9</sup> Zhi QH, Lo EC, Lin HC. Randomized clinical trial on effectiveness of silver diamine fluoride and glass ionomer in arresting dentine caries in preschool children. J Dent. 2012;40(11):962–967.

<sup>10</sup> Li R, Lo EC, Liu BY, Wong MC, Chu CH. [Randomized clinical trial on arresting dental root caries through silver diamine fluoride applications in community-dwelling elders](#). J Dent. 2016 Aug;51:15-20. doi: 10.1016/j.jdent.2016.05.005. Epub 2016 May 18.

<sup>11</sup> Gao SS, Zhang S, Mei ML, Lo EC, Chu CH. [Caries remineralisation and arresting effect in children by professionally applied fluoride treatment - a systematic review](#). BMC Oral Health. 2016;16:12.

<sup>12</sup> Cheng LL. [Limited evidence suggesting silver diamine fluoride may arrest dental caries in children](#) J Am Dent Assoc. 148(2) February 2017.

<sup>13</sup> Wittach CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. Mayo Clin Proc. 2012;87(10):982–990.

<sup>14</sup> Horst JA, Ellenikiotis H, Milgrom PL. [UCSF protocol for caries arrest using silver diamine fluoride: rationale, indications and consent](#). J Calif Dent Assoc. 2016;44(1):16-28.

<sup>15</sup> Liu BY, Lo ECM, Chu CH, Lin HC. [Randomized trial on fluorides and sealants for fissure caries prevention](#). J Dent Res. 2012;91(8):753-758.

<sup>16</sup> Monse B, Heinrich-Weltzien R, Mulder J, Holmgren C, van Palenstein, Helderman WH. [Caries preventive efficacy of silver diamine fluoride \(SDF\) and ART sealants in a school-based daily fluoride toothbrushing program in the Philippines](#). BMC Oral Health. 2012 Nov 21;12:52.

<sup>17</sup> Twetman S. [The evidence base for professional and self-care prevention--caries, erosion and sensitivity](#). BMC Oral Health. 2015;15 Suppl 1:S4. doi: 10.1186/1472-6831-15-S1-S4. Epub 2015 Sep 15.