

### Silver Diamine Fluoride (SDF) Fact Sheet

## March 2017 Updated October 2023

#### What is SDF, what does SDF do, and what are indications for its use?

Silver diamine fluoride (SDF), a clear liquid that combines the antibacterial effects of silver and the remineralizing effects of fluoride, is a therapeutic agent for managing caries lesions and that is also effective in preventing cavities. Silver diamine fluoride (SDF) contains silver particles and 38% (44,800 ppm) fluoride ion that at pH 10 is 25% silver, 8% ammonia, 5% fluoride, and 62% water.<sup>1</sup>

SDF arrests active carious lesions painlessly and without local anesthetic, avoiding or delaying traditional surgical removal of caries. SDF is particularly indicated in treating cavities in people who are unable to access dental treatment or tolerate conventional dental care, including very young pre-cooperative children, persons with physical/intellectual/developmental disabilities, or older adults.<sup>2,3</sup> Its use for adolescents and working age adults may also be indicated for individuals without regular access to preventive dental care.<sup>4,5</sup>

#### What is the strength of evidence for its use?

In clinical trials, SDF applied directly to cavitated lesions 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.¹ SDF has been used extensively outside the United States for many years for caries control.⁴ Published reports of randomized clinical trials consistently demonstrated high rates of caries arrest.<sup>6,7,8</sup> A-systematic review and meta-analysis of clinical trials in children concluded that 38% SDF applied at least once per year effectively arrested more than 65% of active caries.<sup>9</sup> The preventive effect appears to be immediate and maintains at the same fraction over time. Direct comparisons of SDF applied once per year with alternative treatments show that SDF is more effective than other topical fluorides placed two to four times per year.¹¹0

#### Does SDF have FDA Approval?

In August 2014, SDF was cleared by the Food and Drug Administration (FDA) as a medical device for use in treating dental sensitivity, similar to fluoride varnish 20 years before. In 2016, the FDA granted the manufacturer "breakthrough therapy status," facilitating clinical trials of SDF for caries arrest. This designation indicates that a therapy has the potential to address a currently unmet medical need facilitating its use off-label for caries prevention and arrest.

#### What are contraindications for SDF therapy?

Silver allergy is the only known contraindication for use of silver diamine fluoride.<sup>13</sup>

#### Are there other considerations for the acceptance of SDF therapy?

The silver particles in SDF permanently darken active dental caries, and if touched, 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 on the carious lesion. Some individuals report a transient metallic taste after application of SDF. SDF will also permanently stain floors, clothing, and furniture.<sup>6</sup>

#### Are there recommended protocols?

All providers who apply 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 issued a "Chairside Guide" in 2017. The American Dental Association

published its clinical practice guideline in 2018. The CareQuest Institute for Oral Health published The

Non-Invasive Caries Therapy Guide in April 2023. Use of SDF should be followed by patient monitoring and follow-up, including definitive treatment if needed. 13

Caries-Before SDF

After SDF

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

Some practitioners apply fluoride varnish or fluoride in addition to SDF treatment. For any patient with active caries, UCSF's protocol includes replacement of fluoride varnish with the application of SDF to active lesions. <sup>14 Error! Bookmark not defined.</sup> In a cluster randomized noninferiority trial published in 2023, the proportion of children with arrested caries after two years was 0.56 among those receiving silver diamine fluoride and 0.46 among those receiving glass ionomer sealants. The proportion of children who remained free from caries was 0.81 among those receiving silver diamine fluoride and 0.82 among those receiving sealants. In other words, this study found that silver diamine fluoride was noninferior to traditional sealants when used in a school-based program. <sup>17</sup>

#### In how many 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 2022, at least 46 states reported using existing or implementing new policy coverage for SDF application (MSDA). State and Territorial 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. In October 2022, a billing code for medical providers was established by the American Medical Association, effective July 1, 2023.

#### 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 where Medicaid programs cover SDF application may be permitted to apply SDF under the same authorization or restrictions as other topical fluorides.<sup>20</sup>

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See also State Specific Information on Silver Diamine Fluoride (revised March 2021).

<sup>&</sup>lt;sup>1</sup> Crystal YO, Niederman Richard. Evidence-based dentistry update on silver diamine fluoride. Dent Clin North Am. 2019 Jan; 63(1): 45–68. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500430/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500430/</a>

<sup>&</sup>lt;sup>2</sup> Slayton RL, Urquhart O, Araujo, MWB, et al. Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions. JADA 2018:149(10):837-849 <a href="https://doi.org/10.1016/j.adaj.2018.07.002">https://doi.org/10.1016/j.adaj.2018.07.002</a>

<sup>&</sup>lt;sup>3</sup> Zhang W, McGrath C, Lo EC et al. Silver diamine fluoride and education to prevent and arrest root caries among community-dwelling elders. Caries Res. 2013;47(4):284–290.

<sup>&</sup>lt;sup>4</sup> Oliveira BH, Rajendra A, Veitz-Keenan A, Niederman R. 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. doi: 10.1159/000488686. Epub 2018 Jun 6. PMID: 29874642; PMCID: PMC6292783.

<sup>&</sup>lt;sup>5</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>&</sup>lt;sup>6</sup> Santos Dos VE, de Vasconcelos FMN, Ribeiro AG, et al. Paradigm shift in the effective treatment of caries in schoolchildren at risk. Int Dent J 2012;62(1):47–51.

<sup>&</sup>lt;sup>7</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>&</sup>lt;sup>8</sup> Li R, Lo EC, Liu BY, et al. 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.

<sup>&</sup>lt;sup>9</sup> Gao SS, Zhang S, Mei ML, et al. Caries remineralisation and arresting effect in children by professionally applied fluoride treatment - a systematic review. BMC Oral Health. 2016;16:12.

<sup>&</sup>lt;sup>10</sup> Horst JA, Heima M. prevention of dental caries by silver diamine fluoride. Compend Contin Educ Dent. 2019 Mar;40(3):158-163; quiz 164. PMID: 30829497.

<sup>&</sup>lt;sup>11</sup> American Dental Association. Silver diamine fluoride. <a href="https://www.ada.org/en/resources/research/science-and-research-institute/oral-health-topics/silver-diamine-fluoride">https://www.ada.org/en/resources/research/science-and-research-institute/oral-health-topics/silver-diamine-fluoride</a> [Resource page and video]

<sup>&</sup>lt;sup>12</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>&</sup>lt;sup>13</sup> Rosenblatt A, Stamford TC, Niederman R. Silver diamine fluoride: a caries "silver-fluoride bullet." J Dent Res. 2009;88(2):116—125.

<sup>&</sup>lt;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>&</sup>lt;sup>15</sup> American Academy of Pediatric Dentistry. <a href="https://www.aapd.org/research/oral-health-policies---">https://www.aapd.org/research/oral-health-policies---</a>
recommendations/chairside-guide-silver-diamine-fluoride-in-the-management-of-dental-caries-lesions/

<sup>&</sup>lt;sup>16</sup> The Non-Invasive Caries Therapy Guide. CareQuest Institute for Oral Health. Boston, MA: April 2023. https://www.carequest.org/content/non-invasive-caries-therapy-guide

<sup>&</sup>lt;sup>17</sup> 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;6(2):e2255458. doi:10.1001/jamanetworkopen.2022.55458/

<sup>&</sup>lt;sup>18</sup> Medicaid | Medicare | CHIP Services Dental Association. Medicaid Policy on SDF by State, 12.7.22.

 <sup>&</sup>lt;sup>19</sup> CareQuest Institute. The CPT Code for the Application of Silver Diamine Fluoride, Explained.
 <a href="https://www.carequest.org/about/blog-post/cpt-code-application-silver-diamine-fluoride-explained">https://www.carequest.org/about/blog-post/cpt-code-application-silver-diamine-fluoride-explained</a>
 <sup>20</sup> American Dental Hygienists Association. <a href="https://www.carequest.org/about/blog-post/cpt-code-application-silver-diamine-fluoride-explained">Dental Hygiene Practice Act Overview: Permitted Functions and Supervision Levels by State.</a> Rev. August 2022. <a href="https://www.adha.org">www.adha.org</a>. Accessed 7.30.2023.