

# **Policy and Fact Summary**

Silver Diamine Fluoride (**SDF**) has been shown to help stop cavities from getting worse and is a valuable additional tool to manage tooth decay. Its effective use requires a professional diagnosis of cavities, a plan of use specific to the treatment of an individual patient, and monitoring by a dentist.

### What is silver diamine fluoride (SDF)?

SDF is a clear liquid that combines the antibacterial effects of silver with the remineralizing power of fluoride.<sup>1</sup> According to the 2017 clinical practice guidelines of the American Academy of Pediatric Dentistry (AAPD), SDF may be used in certain circumstances as a non-restorative management technique for the arrest of progression of small cavities and cavity-susceptible areas on primary (baby) teeth<sup>1</sup> and permanent teeth.<sup>2</sup> SDF is painted on the caries-affected areas of teeth in a quick, painless procedure. After application, the treated decay is permanently stained black.



Primary front teeth before SDF



Primary front teeth after SDF







Primary molar teeth before SDF

Primary molar teeth after SDF

### Does it work?

Yes, in as many as four out of five teeth if used properly. Systematic reviews of clinical trials confirm that when SDF is applied twice a year, its effectiveness in arresting tooth decay in baby teeth can be as high as 80 percent. The tooth decay arrest rates in clinical studies ranged from one in two teeth (54 percent) to nine in 10 teeth (90 percent), depending on the location of the tooth, size of the cavity, and presence of plaque (a film of saliva, food and bacteria that forms and can harden on the teeth).<sup>2,3,4</sup>

While application of SDF can arrest the progression of tooth decay for an average of six months, it does not repair the damage already done to teeth. Teeth harmed by decay often need to be restored with such treatments as root canals, fillings or crowns. Equally important, SDF does not offer a permanent "cure" for the dental disease of caries, or tooth decay. A dentist needs to monitor the health of SDF-treated teeth to determine when to re-apply SDF and/or provide necessary restorative treatment.

### Is it safe?

Yes. Scientific reviews and clinical trials report no adverse events or serious side effects in either children or adults.<sup>5,6</sup> However, a small number of patients have experienced minor side effects such as short-term gum irritation or a metallic taste.<sup>7</sup>

SDF is approved by the U.S. Food and Drug Administration **(FDA)** as a "topical antimicrobial and remineralizing agent" to treat tooth sensitivity. In addition, the FDA has designated SDF as a breakthrough therapy, thus encouraging further clinical trials of SDF as a way to arrest tooth decay.<sup>8</sup>

# What are the advantages of SDF?

SDF can offer an alternative to restoration for the management of some forms of tooth decay. It can be especially valuable for vulnerable populations who are unable to receive traditional oral health care.<sup>6</sup> Even when conventional restorative dental services are accessible, they can be difficult to deliver to very young children and patients with special management considerations.<sup>6</sup> For example, a pediatric dentist might recommend SDF to postpone restorative treatment for a very young patient with extensive decay. When the patient is older, damaged teeth could be restored in an office setting instead of under general anesthesia in a hospital.

The advantages of SDF are:

- Since no decay is removed, the treatment is painless, with no need for even a local anesthetic.
- It can be applied in one visit as soon as decay is diagnosed.
- The treatment requires little preparation, is easily performed, and takes only a few minutes.
- It is affordable and often covered by both public and private dental insurance plans.

To receive the full measure of these advantages, SDF should be used as an integral part of a total program of decay management, after consideration of the medical and dental needs of the individual patient and the informed consent of the parent or guardian.<sup>7</sup>

## What are the disadvantages of SDF?

The main disadvantage of SDF – besides not offering a restoration of tooth damage or a long-term remedy for tooth decay – is the way it looks. SDF stains decay and affected tooth structures black. The stain is permanent, lasting the life of the tooth.

Many parents are justifiably concerned about the esthetic effects of SDF on their child's smile, especially on the front teeth. In a 2019 study to identify parents' specific concerns about the esthetic effects of SDF, parents were strongly influenced in their decisions about SDF by the location of the cavities and visibility of staining. Parents were more likely to accept SDF if staining was on the back teeth and thus less noticeable. Although staining on the front teeth was judged undesirable, most parents preferred this option to such advanced management procedures as sedation or general anesthesia. In other words, many parents were willing to compromise on the esthetics of SDF to avoid treatments they considered risky or invasive.<sup>9</sup>

#### Does SDF make dental care more affordable?

It depends upon the patient's situation. Consider these examples:

- Emma, age four, had a small cavity in her lower front baby tooth. By applying SDF every six months, the decay was arrested until the tooth came out on its own, so the treatment expense was for application of SDF and thus less costly than more traditional treatment.
- Noah, age three, had severe decay in his front teeth and could not tolerate the treatment length and sensations of the necessary placement of five crowns without general anesthesia. After 24 months of SDF treatments, he matured enough to manage the treatment in an office setting, saving the high cost of hospitalization and general anesthesia.
- Isabella, age seven, had moderate decay in four primary molars. Unfortunately, her dad had lost his job. Her parents, faced with financial pressures, chose SDF to stop the decay and prevent potential pain and infection. A year later, the family finances rebounded, and Isabella received the needed fillings, and her situation hadn't worsened or resulted in greater costs.
- Jaydon, age three, had advanced decay in many primary teeth. His age and pre-cooperative behavior precluded office treatment. Getting operating room access was difficult with a long delay expected. Jaydon's teeth were treated with SDF to prevent a worsening situation while he waited for more definitive care, avoiding pain and possible visits to a hospital emergency room. The benefit of SDF was a reduction of risk and human suffering in this situation.

#### **Care System Savings May Result from SDF Use**

Patient situations will determine the human and financial implications for patient families – and for health systems. That's why studies vary in their results of the cost savings of SDF. Analyses of dental benefit claims in Oregon found that SDF did not change dental costs per patient compared to children receiving traditional treatment.<sup>10</sup> Similarly, an analysis of Medicaid claims showed no change in the amount of dental treatment of children under general anesthesia after the implementation of SDF.<sup>11</sup>

In contrast, a simulation study with Medicaid-enrolled children under age five estimated that use of SDF could prevent decay-related treatments, reducing costs by \$100 to \$350 per visit.<sup>12</sup> Another study comparing children with newly diagnosed tooth decay who did or did not receive SDF showed SDF offered some reduction in overall costs to families, especially for children with mild and moderate levels of decay who did not require general anesthesia to complete dental treatment. The authors noted, "Stronger clinical guidelines are needed to determine the necessity and timing of restoring teeth following SDF treatment. If the potential cost savings to public programs and third-party payers are to be realized, more descriptive guidelines are needed for the interim versus definitive use of SDF, especially in relationship to general anesthesia utilization."<sup>13</sup>

The benefit of SDF at the individual and systems levels comes down to wise use within a thoughtful approach to managing dental decay taking into consideration health, social, and financial considerations for each child.

Pros of SDF	Cons of SDF
Quick, easy, painless for the patient	Not a cure for caries
Simple to apply in a variety of clinical settings	Outcome depends on oral hygiene and regular dental visits
Inexpensive	Must be reapplied to cavities if left unrestored
Relieves sensitivity	Does not restore the form or function of decayed teeth
Remineralizes natural tooth structure	Deeply decayed teeth, especially with nerve involvement, are not candidates for SDF
Arrests up to 80 percent of cavities when applied at least twice a year	Does not arrest decay in an estimated 20 percent of affected teeth
Avoids or delays more surgical interventions	Permanently stains areas of decay black
May reduce cost of dental care for some families	Not viable for all patients due to such conditions as silver allergies

#### How should SDF be used?

In effect, the question is not *how* to apply SDF – the procedure is simple – but *when, where*, and most importantly, *why*. The answers to these questions can only be gained through a careful diagnosis by a dentist.

SDF fits into the middle of a three-tiered approach to dental caries as a management strategy. It falls between prevention of the disease and definitive traditional restorative and surgical care. The AAPD's 2018 Policy on the Use of Silver Diamine Fluoride for Pediatric Dental Patients supports the use of SDF as part of an ongoing decay-management plan with the aim of optimizing individualized patient care consistent with the goals of a dental home.<sup>14</sup> The use of SDF to arrest tooth decay requires:

- Professional diagnosis of tooth decay by a dentist (in keeping with regulations in most states)
- Development of a patient-specific treatment plan
- Monitoring of the patient's oral health status by a dentist after SDF application

The application of SDF must be grounded in an evidence-based approach with an understanding of its implications for the child's overall and long-term dental health. As such, it should be selected as a treatment on a case-by-case basis in the context of an overall oral health treatment plan. These criteria should be met:

- The arrest of active dental caries
- The management of access and/or treatment obstacles such as a patient's ability to cooperate with treatment
- A clear role in the comprehensive care strategy of elimination of disease, restoration of health and function, and patient satisfaction and well-being

The AAPD is strongly opposed to the use – or misuse – of SDF when it is not medically necessary or fails to meet the professionally recognized standards for quality dental care, as it is of any material or procedure within pediatric dentistry.<sup>15</sup>

Equally important to the application of SDF is informed consent. To provide ethical and compassionate care for children, parents or lawful guardians must be informed of all available treatment options, possible side effects, and the need for follow-up monitoring when choosing SDF treatment.<sup>14</sup>

The American Dental Association (ADA) 2020 Statement on the Use of Silver Diamine Fluoride to Arrest Carious Lesions supports the requirement of diagnosis and monitoring by a dentist in the use of SDF to arrest tooth decay and calls for dentists who use SDF to develop a treatment-specific plan for patients. The Statement also directs dentists to inform patients and/or guardians of all available treatment options, possible side effects and the need for follow-up monitoring when giving informed consent.<sup>16</sup>

## Who is a good candidate for SDF?

SDF may be a treatment choice in a broad range of clinical situations when conventional treatment is not possible. (It is considered an alternate rather than equivalent approach to traditional treatment like fillings and crowns.)

Examples of suitable situations for the application of SDF to primary teeth include:<sup>1</sup>

- When restorative care under local or general anesthesia is best postponed
- When there are long waitlists for general anesthesia in nearby treatment facilities
- When a patient is not able to cooperate with restorative treatment, such as young children with severe disease and those with special management considerations
- When it is necessary to offer a less costly or less invasive alternative to conventional restorative or surgical care
- When minimal intervention is desired by the patient or parent/guardian
- When a patient's family faces poor access to care or financial barriers to care
- When its use does not cause further exacerbation of infection and pain
- When special needs of the patient or special situations do not allow for traditional treatment of permanent teeth, SDF may be a suitable option as long as parents/guardians understand its limitations and patients are monitored

Examples of dental conditions that might make a patient a good candidate for SDF include:<sup>1</sup>

- Tooth hypersensitivity
- Large number of cavities requiring restoration, but not yet affecting the vitality of the pulp
- Difficult-to-treat cavities
- Teeth with recurrent tooth decay
- Decayed baby teeth that will be lost soon and replaced with permanent teeth

# Who should apply SDF?

According to the AAPD and the ADA, SDF may be applied by a dentist or delegated to qualified allied dental personnel with training and supervision in accordance with state laws.<sup>14,16</sup> Unlike fluoride varnish, the treatment choice of SDF requires more than a general oral health screening by a non-dental health professional. Instead, it calls for advanced diagnostic training, in-depth knowledge of oral symptomology, and may require radiographs to determine extent of decay and tooth status. SDF requires the same diagnostic considerations as traditional treatment of dental caries. For example, if SDF is

applied to a tooth with decay that is more extensive than is readily apparent – or has involved the nerve – the situation may not be mitigated, and the patient may experience severe pain and infection, requiring immediate treatment to restore or extract the tooth.

#### How should providers be reimbursed for SDF application?

SDF should be a covered benefit by both public and private dental insurers.14,16 To be more specific, SDF should be reimbursed as a per-tooth procedure so the effectiveness of SDF can be more accurately measured in terms of both patient health outcomes and fiscal impact. In addition, SDF should be covered as a non-definitive therapeutic agent for arresting dental caries rather than a definitive restorative procedure. That means dental insurance programs should commit to cover treatment when a patient requires a future restoration or extraction for a tooth previously treated with SDF. Dental professionals are expected to provide complete and clear documentation in records and dental benefit claims about SDF treatment provided to patients.

# How often should SDF be covered by a dental benefits plan?

The frequency of SDF application must be based upon patient characteristics, current and future risk assessment, and medical and dental health status. (One size does *not* fit all.) Unfortunately, some public and private insurance require multiple SDF applications to have a specific time frame between applications, such as three to six months, based on decay risk. Addi-

tionally, if a tooth is restored within a certain time period after SDF application, some insurance carriers lower the restorative/ surgical reimbursement by the amount of the SDF reimbursement – or deny coverage altogether.

These types of coverage policies are not justified by existing science, patient well-being or budget considerations. At the very least, insurance payers should reimburse SDF without any limitation of restorative needs in the future. In addition, lifetime limits per tooth should be determined by an individual patient's oral and general health needs and status. Further research will provide for clear and fair reimbursement policies as understanding of SDF's effects are better understood.

#### If SDF is to be used to treat tooth decay, and not as a preventive measure, why is there a new SDF insurance code (D1355) for caries prevention?

The CDT-2021 Dental Coding Manual contains the approved code D1355 (caries preventive medicament application, per tooth) effective Jan. 1, 2021. SDF is included in this code, along with a number of preventive medicaments. SDF has proven effectiveness as a *secondary* preventive agent (stopping the progress of existing tooth decay) in numerous clinical studies. However, the evidence of its efficacy as a *primary* preventive agent (applied to teeth without decay) is insufficient. Therefore, without solid scientific evidence, the AAPD does not support the use of the code D1355 for use of SDF as a primary preventive agent in children. Accordingly, the AAPD recommends D1354 as the appropriate code for SDF for the arrest of progression of small cavities.



Primary front teeth before SDF

Primary front teeth after SDF

# Conclusion

SDF offers promise as another tool in the management of dental caries. Because the scientific research is constantly growing and changing, and SDF is a fruitful area of current research efforts, scientific knowledge is expanding. Clinical indications for SDF and its optimal use may change over time as new evidence emerges. Dental professionals are urged to stay abreast of the latest science and clinical guidelines on SDF, investigate the benefits of SDF in the care of children, yet also preserve conventional proven approaches to caries prevention and management.

For more information, please contact the AAPD Research and Policy Center at *rwright@aapd.org*.

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