INDIAN HEALTH SERVICE
National Pharmacy and Therapeutics Committee
Formulary Brief: *Oral Health Update (Fluoride)*
-April 2026-

Summary:
In April 2026, the Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) received an oral health update which focused on prescription fluoride products for prevention of dental caries. Medications currently listed on the National Core Formulary relevant to this topic include(s) any oral fluoride supplement (e.g., fluoride gels, chewable tablets, lozenges, pediatric drops). Current guidance for ingestible fluoride products supports the use of these products in children aged 3 years and older who are at high caries risk and whose primary drinking water is fluoride deficient. Following clinical review and analysis, the NPTC **no modifications** to the National Core Formulary.

Background/Discussion:
Dental decay remains the most common chronic disease of childhood and continues to disproportionately affect American Indian and Alaska Native (AI/AN) children. Among AI/AN dental clinic patients aged 1 to 5 years, 42 percent had untreated tooth decay in 2024-2025, and by age 5 more than 80 percent had early childhood caries.[1] Among AI/AN school children aged 6 to 9 years, 90 percent had decay experience and 46 percent had untreated decay in 2023.[2] These findings support the continued use of evidence-based fluoride strategies across the caries prevention spectrum. Topical fluoride remains foundational because it acts directly on the tooth surface and can be delivered broadly through fluoride toothpaste, professionally applied fluoride varnish, and other topical products. Systemic fluoride exposure from optimally fluoridated drinking water also contributes to caries prevention, while prescription ingestible fluoride should be reserved for more selective use when the expected benefit is most likely to outweigh risk.[3-6]

The 2025 FDA review of ingestible fluoride drug products concluded that they should not be given to children younger than 3 years or to older children at low or moderate risk for tooth decay. The FDA recommends limiting use to children aged 3 years and older who are at high risk for tooth decay, such as those with a history of dental caries and inadequate access to fluoridated drinking water.[7,8] In keeping with that recommendation, the dosing approach below removes supplementation for children younger than 3 years. For children aged 3 years and older, the milligram dosages reflect the longstanding supplement schedule used in pediatric dental guidance and historical fluoride supplement products, while retaining the central role of drinking water fluoride concentration in decision-making.[3,5,7]

Age	Fluoride in Drinking Water **<0.3 ppm (mg/L)**	Fluoride in Drinking Water **0.3-0.6 ppm (mg/L)**	Fluoride in Drinking Water **>0.6 ppm (mg/L)**
Birth to <3 years	None	None	None
3 to <6 years	0.50 mg/day	0.25 mg/day	None
6 to 16 years	1.0 mg/day	0.50 mg/day	None

Table. FDA-aligned approach to prescription ingestible fluoride supplementation. Children younger than 3 years: no supplement recommended. For children aged 3 years and older, any decision to prescribe should consider high caries risk, the fluoride content of the child's primary drinking water, and other dietary fluoride sources.[3,5,7]

The potential benefit of ingestible fluoride products is narrow but clinically meaningful in selected settings: children 3 years of age and older at high caries risk who primarily drink fluoride-deficient water may receive additional protection against caries when topical fluoride exposure and oral hygiene alone are insufficient.[3,5,7] At the same time, the FDA's recent evaluation identified several reasons to avoid broad or routine use. Namely, these products are unapproved - the FDA concluded that proven benefit on primary teeth is lacking, and fluoride overexposure is associated with dental fluorosis. The FDA also identified emerging safety concerns including altered gut microbiome development and epidemiologic signals involving thyroid function, weight gain, and possible effects on IQ.[7,8] For these reasons, ingestible fluoride products are best viewed as a targeted adjunct, not a default strategy. Topical fluoride, fluoridated toothpaste, fluoride varnish beginning at tooth eruption, and community water fluoridation remain the primary prevention framework.[3-6]

Findings:
Dental decay remains highly prevalent among AI/AN children. Efforts to reduce decay should include education about dental hygiene, improved dietary practices, routine use of fluoridated toothpaste, and application of topical fluoride varnish by an appropriately trained dental or allied health professional beginning at tooth eruption and repeated every 3 to 6 months thereafter.[1-4] The need for fluoride supplementation depends on the amount of fluoride available in the child's primary drinking water supply, which may vary substantially by water source and should be verified locally.[3,5,6] Based on

the NPTC review and discussion, in concert with IHS procurement and utilization trends, the NPTC retained prescription fluoride products on the National Core Formulary while recognizing that ingestible fluoride products should not be dispensed to children younger than 3 years of age. For children aged 3 years and older, use should be limited to those at high caries risk whose primary drinking water is fluoride deficient.[7,8] The decision regarding which oral fluoride product is optimal for a given facility remains at the discretion of the local facility Pharmacy and Therapeutics Committee.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the NPTC website.

References:

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