



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Sohonos (palovarotene) Page: 1 of 3

Effective Date: 2/11/2026 Last Review Date: 1/2026

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sohonos under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Sohonos is indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Sohonos

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Genetic test results confirming diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented activin receptor type 1 (ACVR1) variation (e.g., R206H).
- Chart notes or medical record documentation supporting signs and symptoms of FOP.

Continuation requests

- Chart notes or medical record documentation supporting benefit from therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., endocrinologist, orthopedist, rheumatologist, neurologist).

Coverage Criteria



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Fibrodysplasia ossificans progressiva (FOP)¹⁻³

Authorization of 12 months may be granted for reduction in the volume of new heterotopic ossification in fibrodysplasia ossificans progressiva (FOP) when all of the following criteria are met:

- Member has a confirmed diagnosis of FOP by genetic test indicating the patient has an activin receptor type 1 (ACVR1) variation (e.g., R206H).
- Member has signs and symptoms of FOP (e.g., malformation of the great toe, abnormal vertebral morphology, ectopic ossification in ligament or muscle tissue).
- Member meets either of the following age criteria:
 - Member is a male 10 years of age or older.
 - Member is a female 8 years of age or older.

Continuation of Therapy¹⁻³

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when both of the following criteria are met:

- Member meets either of the following age criteria:
 - Member is a male 10 years of age or older.
 - Member is a female 8 years of age or older.
- Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the volume of new heterotopic ossification).

Approval Duration and Quantity Restrictions:

Initial Approval: 12 months

Quantity Level Limit:

Medication	Quantity Level Limit	FDA-recommended dosing
Sohonos 1mg	28 capsules per 28 days	<u>Patients ≥14 years:</u> 5mg QD
Sohonos 1.5mg	56 capsules for 28 days	<u>Flare-up dose:</u> 20mg QD for 4 weeks, followed by 10mg QD x 8 wks



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Medication	Quantity Level Limit	FDA-recommended dosing
Sohonos 2.5mg	28 capsules per 28 days	<u>Patients ≤13 years:</u> 2.5mg to 5mg QD based on weight <u>Flare-up dose:</u> 10mg to 20mg QD x 4 wks, followed by 5mg to 10mg QD x 8 wks based on weight
Sohonos 5mg	28 capsules per 28 days	
Sohonos 10mg	56 capsules per 28 days	

References:

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; March 2025.
2. Kaplan FS, Al Mukaddam M, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2019;1:1-111.
3. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated July 2024. Accessed August 15, 2025. <https://rarediseases.info.nih.gov>.