AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Sohonos (palovarotene)	Page:	1 of 3
Effective Date:	3/6/2025	Last Review Date:	2/2025

Applies to:	☒Illinois ☐Maryland ☐Michigan	☐Florida ☒Florida Kids ☒Virginia	☒New Jersey ☒Pennsylvania Kids

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:

Criteria for Initial Approval:

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

A. Initial requests:

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

II. Fibrodysplasia ossificans progressiva (FOP)

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

A. Sohonos is prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., orthopedist, rheumatologist).

B. Member has a genetically confirmed diagnosis of FOP with genetic testing indicating the patient has an *activin receptor type 1 (ACVR1)* mutation (e.g., R206H).

C. Member has signs and symptoms of FOP (e.g., malformation of the great toe, abnormal vertebral morphology, ectopic ossification in ligament or muscle tissue).
D. Member meets EITHER of the following age criteria:
    1. Member is a male 10 years of age or older.
    2. Member is a female 8 years of age or older

Criteria for Continuation of Therapy

III. Submission of the following information is necessary for continuation of therapy:

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

IV. Authorization may be granted for continuation of therapy when ALL the following criteria are met:

A. Member meets EITHER of the following age criteria:
    1. Member is a male 10 years of age or older.
    2. Member is a female 8 years of age or older
B. Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the volume of new heterotopic ossification).
C. Sohonos is prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., orthopedist, rheumatologist).

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	Patients ≥14 years: 5mg QD Flare-up dose: 20mg QD for 4 weeks, followed by 10mg QD x 8 wks Patients ≤13 years: 2.5mg to 5mg QD based on weight Flare-up dose: 10mg to 20mg QD x 4 wks, followed by 5mg to 10mg QD x 8 wks based on weight
Sohonos 1.5mg	56 capsules for 28 days	
Sohonos 2.5mg	28 capsules per 28 days	
Sohonos 5mg	28 capsules per 28 days	
Sohonos 10mg	56 capsules per 28 days	

References:

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.
2. ClinicalTrials.gov. National Library of Medicine (US). Identifier NcT03312634. An Efficacy and Safety Study of Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva (MOVE). Last updated November 29, 2023. Accessed August 8, 2024. Available from: http://classic.clinicaltrials.gov/ct2/show/NCT03312634.
3. Kaplan FS, Mukaddam MA, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2024;3:1-159.
4. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated July 2024. Accessed August 12, 2024. https://rarediseases.info.nih.gov.