

SOHONOS (palovarotene)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

II. CRITERIA FOR INITIAL APPROVAL

Fibrodysplasia ossificans progressiva (FOP)

Authorization of 6 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:

- A. Medication must be prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., orthopedist, rheumatologist).
- B. Documentation that the member has a documented genetically confirmed diagnosis of FOP with genetic testing indicating the patient has an *activin receptor type 1 (ACVR1)* R206H mutation.
- C. Documentation that the 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.
- E. For members of reproductive potential, documented attestation from provider that the member is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for an indication listed in Section II when both of the following criteria are met.

- A. Documentation that the 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. Documentation that the member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the volume of new heterotopic ossification).

IV. QUANTITY LIMIT

- A. Sohonos capsule 1 mg- 28 capsules per 28 days, daily dose of 1
- B. Sohonos capsule 1.5 mg- 56 capsules per 28 days, daily dose of 2
- C. Sohonos capsule 2.5 mg- 28 capsules per 28 days, daily dose of 1
- D. Sohonos capsule 5 mg- 28 capsules per 28 days, daily dose of 1
- E. Sohonos capsule 10 mg- 56 capsules per 28 days, daily dose of 2

V. DOSAGE AND ADMINISTRATION

Indication	FDA-recommended Dosing																				
FOP	<u>Adults and pediatric patients 14 years and older</u> • 5 mg daily • Flare-up Dose: ○ Stop daily dosing when flare-up dosing begins. ○ 20 mg daily for 4 weeks, followed by 10 mg daily for 8 weeks (for a total of 12 weeks of flare-up treatment), even if symptoms resolve earlier, then return to daily dosing of 5 mg. ○ If during the course of flare-up treatment, the patient experiences marked worsening of the original flare-up site or another flare-up at a new location, restart the 12-week flare-up dosing at 20 mg daily. ○ For flare-up symptoms that have not resolved at the end of the 12-week period, the 10 mg daily dosage may be extended in 4-week intervals and continued until the flare-up symptoms resolve. If new flare-up symptoms occur after the 5 mg daily dosing is resumed, flare-up dosing may be restarted.																				
	<u>Pediatric Patients Aged 8 to 13 Years for Females and Aged 10 to 13 Years for Males</u>																				
	<table><tr><th>Weight</th><th>Daily Dosage</th><th>Week 1 to 4 Flare-up Dosage</th><th>Week 5to 12 Flare-up Dosage</th></tr><tr><td>10 kg to 19.9 kg</td><td>2.5 mg</td><td>10 mg</td><td>5 mg</td></tr><tr><td>20 kg to 39.9 kg</td><td>3 mg</td><td>12.5 mg</td><td>6 mg</td></tr><tr><td>40 kg to 59.9 kg</td><td>4 mg</td><td>15 mg</td><td>7.5 mg</td></tr><tr><td>≥ 60 kg</td><td>5 mg</td><td>20 mg</td><td>10 mg</td></tr></table>	Weight	Daily Dosage	Week 1 to 4 Flare-up Dosage	Week 5to 12 Flare-up Dosage	10 kg to 19.9 kg	2.5 mg	10 mg	5 mg	20 kg to 39.9 kg	3 mg	12.5 mg	6 mg	40 kg to 59.9 kg	4 mg	15 mg	7.5 mg	≥ 60 kg	5 mg	20 mg	10 mg
	Weight	Daily Dosage	Week 1 to 4 Flare-up Dosage	Week 5to 12 Flare-up Dosage																	
	10 kg to 19.9 kg	2.5 mg	10 mg	5 mg																	
20 kg to 39.9 kg	3 mg	12.5 mg	6 mg																		
40 kg to 59.9 kg	4 mg	15 mg	7.5 mg																		
≥ 60 kg	5 mg	20 mg	10 mg																		
• If during the course of flare-up treatment, the patient experiences marked worsening of the original flare-up site or another flare-up at a new location, restart the 12-week flare-up dosing with the Week 1 to 4 dose.																					

	For flare-up symptoms that have not resolved at the end of the 12-week period, the Week 5 to 12 flare-up dose may be extended in 4-week intervals and continued until the flare-up symptoms resolve. If new flare-up symptoms occur after daily dosing is resumed, flare-up dosing may be restarted.
--	--

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; March 2025.
2. An Efficacy and Safety Study of Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva. (MOVE). ClinicalTrials.gov identifier: NCT03312634. Updated March 14, 2023. Accessed April 2, 2024. <https://classic.clinicaltrials.gov/ct2/show/NCT03312634>
3. Kaplan FS, Mukaddam MA, Baujat, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2022; 2:1-127. Accessed April 2, 2024. https://www.ifopa.org/for_medical_professionals
4. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated February 2023. Accessed April 2, 2024. <https://rarediseases.info.nih.gov>