

# PHARMACY POLICY STATEMENT

## Marketplace

<b>DRUG NAME</b>	<b>Sohonos (palovarotene)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Sohonos, initially approved by the FDA in 2023, is a retinoid indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). Through binding to RAR $\gamma$ , Sohonos decreases the BMP/ALK2 downstream signaling pathway by inhibiting the phosphorylation of SMAD1/5/8, which reduces ALK2/SMAD-dependent chondrogenesis and osteocyte differentiation resulting in reduced endochondral bone formation.

FOP is an ultra-rare condition that causes abnormal bone growth in areas outside of the skeleton such as ligaments, tendons, and muscles. The disease progresses with flare-up episodes that lead to rapid heterotopic ossification (HO), severely restricting mobility and function as well as quality of life.

Approval was based on the phase 3 MOVE trial which did not meet the primary endpoint of annualized volume of new HO measured by low-dose whole-body computed tomography (WBCT). However, a post hoc 18-month interim analysis showed that Sohonos reduced annualized HO volume by 54% compared with standard of care.

Sohonos (palovarotene) will be considered for coverage when the following criteria are met:

### Fibrodysplasia Ossificans Progressiva (FOP)

For **initial** authorization:

1. If member is female, member is at least 8 years of age; OR
2. If member is male, member is at least 10 years of age; AND
3. Medication must be prescribed by or in consultation with an orthopedic, orthopedic surgeon, genetic specialist, pediatric endocrinologist or rheumatologist; AND
4. Member has a diagnosis of FOP with the ACVR1 R206H mutation confirmed by genetic testing; AND
5. If member has not reached skeletal maturity or final adult height, chart notes must include **BOTH** of the following:
  - a) Radiological evidence of baseline bone age (x-ray results must be included);
  - b) Baseline linear growth chart; AND,
6. If member is of reproductive potential, attestation that member is **NOT** pregnant.

**7. Dosage allowed/Quantity limit:**

Adults and Pediatric Patients 14 Years and Older

- a) Daily dose: 5 mg daily
- b) Flare-up dose: 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.

Pediatric Patients Aged 8 to 13 Years for Females and Aged 10 to 13 Years for Males

- a) Daily dose: weight based (see table below).
- b) Flare-up dose: weight based (see table below). Administer the initial flare-up dosage once daily for 4 weeks, then administer the lower flare-up dosage once daily for 8 weeks (for a total of 12 weeks of flare-up treatment), even if symptoms resolve earlier, then return to daily dosing.

**Table 1. Recommended SOHONOS Weight-Based Dosage for Pediatric Patients Aged 8 to 13 Years for Females and 10 to 13 Years for Males \***

Weight	Daily Dosage	Week 1 to 4 Flare-up Dosage	Week 5 to 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

\* once daily

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (such as reduced volume of new heterotopic ossifications, decreased flare ups, decreased pain or increased mobility); AND
2. If member has not reached skeletal maturity or final adult height, chart notes must include radiological evidence of appropriate bone age (x-ray results must be included) and linear growth.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Sohonos (palovarotene) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
11/9/2023	New policy for Sohonos created.

References:

1. Sohonos [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 2023.
2. Pignolo RJ, Hsiao EC, Al Mukaddam M, et al. Reduction of New Heterotopic Ossification (HO) in the Open-Label, Phase 3 MOVE Trial of Palovarotene for Fibrodysplasia Ossificans Progressiva (FOP). *J Bone Miner Res.* 2023;38(3):381-394. doi:10.1002/jbmr.4762.
3. Kaplan FS, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. *Proc Intl Clin Council FOP 2*: 1-127, 2022.
4. Smilde BJ, Botman E, de Ruyter RD, et al. Monitoring and Management of Fibrodysplasia Ossificans Progressiva: Current Perspectives [published correction appears in *Orthop Res Rev.* 2022 May 04;14:147-148]. *Orthop Res Rev.* 2022;14:113-120. Published 2022 Apr 20. doi:10.2147/ORR.S337491

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