CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Sohonos (palovarotene)
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 RARγ, 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 Ruiter 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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