Clinical Policy: Palovarotene (Sohonos)

Reference Number: PA.CP.PHAR.548
Effective Date: 08/2024
Last Review Date: 07/2025

Description
Palovarotene is a retinoic acid receptor (RAR)-γ agonist.

FDA Approved Indication(s)
Palovarotene (Sohonos™) is 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).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Sohonos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Fibrodysplasia Ossificans Progressiva (must meet all)**:**

1. Diagnosis of FOP;
2. Prescribed by or in consultation with a pediatric or adult orthopedics, orthopedic surgery, rheumatology, endocrinology, or metabolic disease specialist;
3. Age meets one of the following (a or b):
   a. For females: ≥ 8 years;
   b. For males: ≥ 10 years;
4. Presence of R206H *ACVR1* mutation;
5. Request meets both of the following (a and b):
   a. Dose does not exceed either of the following (i and ii):
      i. For chronic treatment, both of the following (1 and 2):
         1. 5 mg per day;
         2. 1 capsule per day;
      ii. For flare-up treatment, both of the following (1 and 2):
         1. 20 mg per day for 4 weeks followed by 10 mg per day for 8 weeks;
         2. 2 capsules per day for 4 weeks followed by 1 capsule per day for 8 weeks;
   b. Chronic treatment and flare-up treatment are not used concurrently.

Approval duration:
Chronic treatment – 6 months
Flare-up treatment – 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Fibrodysplasia Ossificans Progressiva (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy based on the prescriber's assessment;
3. Request meets both of the following (a and b):
   a. If request is for a dose increase, new dose does not exceed either of the following (i and ii):
      i. For chronic treatment, both of the following (1 and 2):
         1. 5 mg per day;
         2. 1 capsule per day;
      ii. For flare-up treatment, both of the following (1 and 2):
         1. 20 mg per day for 4 weeks followed by 10 mg per day for 8 weeks;
         2. 2 capsules per day for 4 weeks followed by 1 capsule per day for 8 weeks;
   b. Chronic treatment and flare-up treatment are not used concurrently.

Approval duration:
Chronic treatment – 12 months
Flare-up treatment – 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
FOP: fibrodysplasia ossificans progressiva
HO: heterotopic ossification
NSAID: nonsteroidal anti-inflammatory drug
RAR: retinoic acid receptor
WBCT: whole body computed tomography

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy; hypersensitivity to retinoids or any component of Sohonos
- Boxed warning(s): embryo-fetal toxicity and premature epiphyseal closure in growing pediatric patients

Appendix D: General Information

- A flare-up is painful soft tissue swelling that may lead to extraskeletal HO
- Flare-up symptoms include, but are not limited to pain, swelling, redness, decreased range of motion, stiffness, and warmth.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
FOP	*Adults and pediatric patients ≥ 14 years*: 5 mg PO QD, with an increase in dose at the time of a flare-up to 20 mg PO QD for 4 weeks, followed by 10 mg PO QD for 8 weeks for a total of 12 weeks (20/10 mg flare-up treatment). Stop daily dosing when flare-up dosing begins. *Pediatric patients < 14 years*: Weight-adjusted for daily and flare-up dosing. Recommended dosage range from 2.5 to 5 mg PO QD. Stop daily dosing when flare-up dosing begins. Refer to table in Prescribing Information for complete pediatric dosing.	Age ≥ 14 years: 20 mg/day Age < 14 years: 10 mg/day

VI. Product Availability

Capsules: 1 mg, 1.5 mg, 2.5 mg, 5 mg, 10 mg

VII. References

1. Sohonos Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals; March 2025. Available at: https://www.sohonos.com/hcp/dosing-and-administration-r-sohonos-palovarotene-hcp. Accessed April 15, 2025.
2. ClinicalTrials.gov. An efficacy and safety study of palovarotene for the treatment of fibrodysplasia ossificans progressiva. Available at: https://clinicaltrials.gov/ct2/show/NCT03312634. Accessed May 25, 2025.
3. Fibrodysplasia ossificans progressiva. Genetic and Rare Disease (GARD) Information Center; 2021. Available at: https://rarediseases.info.nih.gov/diseases/6445/fibrodysplasia-ossificans-progressiva. Accessed May 25, 2025.
4. Pignolo RJ, Kaplan FS. Clinical staging of fibrodysplasia ossificans progressiva (FOP). Bone. 2018 Apr;109:111-114. doi: 10.1016/j.bone.2017.09.014.
5. Kaplan FS, Al Mukaddam M, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP; 2022. Available at: https://www.iccfop.org/dvlp/wp-content/uploads/2024/07/FOP-GUIDELINES-FINAL-2024.pdf. Accessed May 25, 2025.

Reviews, Revisions, and Approvals	Date
Policy created	07/2024
3Q 2025 annual review: no significant changes; references reviewed and updated.	07/2025