

Applicable Drugs: Sohonos (palovarotene)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/22/2024

Date Last Reviewed / Revised: 12/12/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VIII are met)

- I. Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) with activin A type 1 receptor (*ACVR1^{R206H}*) pathogenic variant confirmed by genetic testing.
- II. Minimum age requirement must meet either criteria A or B:
 - A. For males:
 - i. Age 10 years or older.
 - B. For females:
 - i. Age 8 years or older.
 - ii. For females of reproductive age, must have documented negative pregnancy test within 1 week prior to treatment initiation, and at least monthly thereafter.
- III. For patients who have not reached skeletal maturity or final adult height, chart notes must meet BOTH criteria A and B:
 - A. Baseline assessment of growth and skeletal maturity (e.g., bone-age X-rays, growth-plate status, or height and growth-curve measurements).
 - B. Clinical and radiographic monitoring every 6 to 12 months until patients reach skeletal maturity or final adult height.
- IV. Baseline documentation of heterotopic ossification volume as assessed by low-dose whole-body computed tomography (WBCT; excluding the head)
- V. Baseline documentation of score on Cumulative Analogue Joint Involvement Scale (CAJIS) and FOP Physical Function Questionnaire (FOP-PFQ).
- VI. Drug is prescribed by or in consultation with a FOP specialist (e.g., orthopedic, orthopedic surgeon, genetic specialist, pediatric endocrinologist or rheumatologist)
- VII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VIII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy
- Hypersensitivity to retinoids
- Concomitant use with CYP3A4 inducers or inhibitors
- Concomitant use with tetracyclines
- Concomitant use with vitamin A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Maintenance dosing quantity limit: 30 capsules per 30 days
- Dosing is in at or below the recommended dose based on patient weight.
- For flare-up dosing, quantity limit may be increased to 60 capsules per 30 days for 4 weeks in accordance with Table 1.
- Palovarotene is available in 1 mg, 1.5 mg, 2.5 mg, 5 mg, and 10 mg capsules.

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

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing that patient continues to meet initial criteria and has experienced improvement or maintenance in heterotopic ossification volume assessed by WBCT with the medication. Additionally, there must be documentation that medication is tolerated without incident of any serious treatment emergent adverse event(s), such as premature fusion of epiphyses, bone fractures, or severe mucocutaneous events.

APPENDIX

N/A

REFERENCES

1. Sohonos™. Prescribing Information. Ipsen Pharmaceuticals; March 2025.. Accessed December 12, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215559s002lbl.pdf
2. Ipsen Pharmaceuticals. US FDA approves Ipsen's Sohonos™ (palovarotene) capsules, the first and only treatment for people with fibrodysplasia ossificans progressiva. Ipsen.com. Accessed July 21, 2024. <https://www.ipsen.com/us/press-releases/us-fda-approves-ipsens-sohonostm-palovarotene-capsules-the-first-and-only-treatment-for-people-with-fibrodysplasia-ossificans-progressiva/>.
3. National Organization for Rare Diseases. Fibrodysplasia Ossificans Progressiva. Rarediseases.org. Accessed December 12, 2025. <https://rarediseases.org/rare-diseases/fibrodysplasia-ossificans-progressiva/>.
4. Pignolo, RJ, 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: <https://doi.org/10.1002/jbmr.4762>.
5. Mukaddam MA, Pignolo RJ, Baujat G, et al. OR29-05 A Natural History Study of Fibrodysplasia Ossificans Progressiva (FOP): 12-Month Outcomes. J Endocr Soc. 2020;4(Suppl 1):OR29-05. doi: <https://doi.org/10.1210%2Fjendso%2Fbvaa046.254>.
6. Kaplan, FS, Pignolo, RJ, et. al. The Medical Management of Fibrodysplasia Ossificans Progressiva: Current Treatment Considerations. International Fibrodysplasia Ossificans Progressiva Association. Accessed December 12, 2025. <https://assets.nationbuilder.com/ifopa/pages/1042/attachments/original/1721244354/FOP-GUIDELINES-FINAL-2024.pdf?1721244354>.
7. Canadian Agency for Drugs and Technologies in Health. Palovarotene (Sohonos): CADTH Reimbursement Recommendation. Canadian J of Health Tech. 2023;3(8). Available from: https://www.cadth.ca/sites/default/files/DRR/2023/SR0761-Sohonos_combined.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.