Generic Name: palovarotene

Therapeutic Class or Brand Name: Sohonos™

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

VSI Excluded Drugs: Sohonos™ (palovarotene)

Date of Origin: 7/22/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) AND must meet all criteria listed:
   A. Diagnosis of FOP with *ACVR1*^{R206H} pathogenic variant confirmed by genetic testing.
   B. For males:
      i. Age 10 years or older.
   C. For females:
      i. Age 8 years or older.
      ii. For females of reproductive age, must have documented negative pregnancy test within 1 month prior to treatment initiation, and at least quarterly thereafter.

II. For patients less than 16 years old, documentation confirming closure of epiphyseal growth plates.

III. Baseline documentation of heterotopic ossification volume as assessed by low-dose whole-body computed tomography (WBCT; excluding the head)

IV. Baseline documentation of score on Cumulative Analogue Joint Involvement Scale (CAJIS) and FOP Physical Function Questionnaire (FOP-PFQ).

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Drug is prescribed by or in consultation with a FOP specialist.

VII. 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

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- 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 below dosing.
- 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 initiation 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; August 2023. Accessed July 21, 2024. https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-

d53c45ae33ff/d27518f0-6251-4d68-8df2-9dfc72320f42/d27518f0-6251-4d68-8df2-9dfc72320f42_source__v.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 July 21, 2024. 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 Progessiva: Current Treatment Considerations. International Fibrodysplasia Ossificans Progessiva Association. Accessed July 21, 2024. 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