MEDICAL MUTUAL®

Drug Policy

Policy:	Sohonos (palovarotene)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023

OVERVIEW

Sohonos 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 progressive (FOP).

POLICY STATEMENT

This policy involves the use of Sohonos. Sohonos. Prior authorization is recommended for pharmacy benefit coverage of Sohonos. Sohonos approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sohonos as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sohonos be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sohonos is recommended in those who meet the following criteria:

1. **Fibrodysplasia ossificans progressive (FOP)**
   Criteria. *Patient must meet the following criteria*
   - **A. Patient meets ONE of the following**
     - **a. Patient is female and ≥ 8 years of age; OR**
     - **b. Patient is male and ≥ 10 years of age; AND**
   - **B. Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1) consistent with a diagnosis of fibrodysplasia ossificans progressive [documentation required]; AND**
   - **C. Patient has heterotopic ossification as confirmed by radiologic testing; AND**
     Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging, or positron emission tomography (PET) scan [documentation required].

D. **The medication is prescribed by or in consultation with an endocrinologist or physician who specializes in bone disease; AND**
E. **If the patient is a female of childbearing potential, there must be documentation of a negative serum pregnancy test 1 week prior to therapy initiation due to embryo-fetal toxicity risks. The patient should also be counseled to use at least 1 highly effective method of contraception or 2 effective methods at least 1 month prior to treatment, during treatment, and 1 month after the last dose.**

Initial Approval/ Extended Approval.
A) *Initial Approval: 6 months*
B) *Extended Approval:6 months*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sohonos has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Chronic Obstructive Pulmonary Disease (COPD).** Sohonos is not indicated for the management of COPD. Palovarotene was previously studied for the treatment of COPD, but was found to be ineffective for this condition.

2. **Osteochondroma(s).** Sohonos is not indicated for the treatment and/or prevention of osteochondroma. One Phase II study was initiated to evaluate Sohonos for the prevention of disease progression in pediatric patients with multiple osteochondromas. However, this study was terminated early in order to analyze accumulated date and evaluate the future of Sohonos for this use. Results are not available. More data are needed.

3. **Allergy or hypersensitivity to retinoids**. Sohonos is contraindicated in this patient group.

4. **Severe renal impairment (CrCl 15-29 mL/min)**. Sohonos is not recommended for use in patients with severe renal impairment.

5. **Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.** Sohonos undergoes extensive hepatic metabolism. Use of Sohonos in moderate or severe hepatic impairment is not recommended.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sohonos™ capsules [prescribing information]. Cambridge, MA: Ipsen; August 2023.
2. Kaplan FS, Al Mukaddam M, Baujat G, et al, for the Internation council on FOP (ICC) & Consultants. The medical management of fibrodysplasia ossificans progressive: current treatment considerations. Updated May 2022. Available at: https://www.iccfop.org/dvlp/wp-content/uploads/2022/05/guidelines-updated-May-2022.pdf. Accessed on August 4, 2023.
3. Akesson LS, Svarirayan R, Adam MP, et al., editors. Fibrodysplasia ossificans progressiva. Gene Reviews® [Internet]. Seattle, WA: Univeristy of Washington, Seattle. Last revised May 11, 2023. Available at: https://www.ncbi.nlm.nih.gov/books/NBK558090/?report=printable. Accessed on August 4, 2023.
4. Pignolo RJ, Baujat G, Brown MA, et al. The natural history of fibrodysplasia ossificans progressive: a prospective, global 36-month study. *Genet Med*. 2022;24(12):2422-2433.
5. Pignolo RJ, Hsiao EC, Mukaddam MA, et al. Reduction of new heterotopic ossification (HO) in the open-label, phase 3, MOVE trial of palovarotene for fibrodysplasia ossificans progressive (FOP). *J Bone Miner Res*. 2023;38(3):381-394.
6. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 Aug 4]. Available from: https://clinicaltrials.gov/. Search term: palovarotene.