Reference number(s)
6138-A

Specialty Guideline Management
Sohonos

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sohonos	palovarotene

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

Sohonos is indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:

- Genetic testing results confirming diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented activin receptor type 1 (ACVR1) mutation (e.g., R206H).

- Chart notes or medical record documentation supporting signs and symptoms of FOP.

Continuation requests:

- Chart notes or medical record documentation supporting benefit from therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who is experienced in the treatment of fibrodysplasia ossificans progressiva (FOP) (e.g., orthopedist, rheumatologist).

Coverage Criteria

Fibrodysplasia ossificans progressiva (FOP)[1-4]

Authorization of 12 months may be granted for reduction in the volume of new heterotopic ossification in fibrodysplasia ossificans progressiva (FOP) when all of the following criteria are met:

- Member has a genetically confirmed diagnosis of FOP with genetic testing indicating the patient has an activin receptor type 1 (ACVR1) mutation (e.g., R206H).
- Member has signs and symptoms of FOP (e.g., malformation of the great toe, abnormal vertebral morphology, ectopic ossification in ligament or muscle tissue).
- Member meets either of the following age criteria:
  - Member is a male 10 years of age or older.
  - Member is a female 8 years of age or older.

Continuation of Therapy[1-4]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when both of the following criteria are met:

- Member meets either of the following age criteria:
  - Member is a male 10 years of age or older.
  - Member is a female 8 years of age or older.
- Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the volume of new heterotopic ossification).

References

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.
2. ClinicalTrials.gov. National Library of Medicine (US). Identifier NcT03312634. An Efficacy and Safety Study of Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva (MOVE). Last updated November 29, 2023. Accessed August 8, 2024. Available from: http://classic.clinicaltrials.gov/ct2/show/NCT03312634.
3. Kaplan FS, Mukaddam MA, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2024;3:1-159.
4. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated July 2024. Accessed August 12, 2024. https://rarediseases.info.nih.gov.