Sohonos (palovarotene)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Sohonos (palovarotene) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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).

POLICY

Required Documentation

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

A. Initial requests:
    1. Genetic testing results confirming diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented *activin receptor type 1 (ACVR1)* mutation (e.g., R206H).
    2. Chart notes or medical record documentation supporting signs and symptoms of FOP.
B. 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).

Criteria for Initial Approval

Fibrodysplasia ossificans progressiva (FOP)

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:

A. 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).
B. Member has signs and symptoms of FOP (e.g., malformation of the great toe, abnormal vertebral morphology, ectopic ossification in ligament or muscle tissue).
C. Member meets either of the following age criteria:
    1. Member is a male 10 years of age or older.
    2. Member is a female 8 years of age or older.

Continuation of Therapy

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

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

Sohonos (palovarotene) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA-recommended dosing

Sohonos (palovarotene) capsule 1 mg	28 capsules per 28 days	• Adults and pediatric patients 14 years and older: 5 mg once daily
		  • Flare-up dose: 20 mg once daily for 4 weeks, followed by 10 mg once daily for 8 weeks
		• Pediatric patients 13 years and younger: 2.5 mg to 5 mg once daily based on weight
		  • Flare-up dose: 10 mg to 20 mg once daily for 4 weeks, followed by 5 mg to 10 mg daily for 8 weeks based on weight

Sohonos (palovarotene) capsule 1.5 mg	56 capsules for 28 days	
Sohonos (palovarotene) capsule 2.5 mg	28 capsules per 28 days	
Sohonos (palovarotene) capsule 5 mg	28 capsules per 28 days	
Sohonos (palovarotene) capsule 10 mg	56 capsules per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.
- An Efficacy and Safety Study of Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva. (MOVE). ClinicalTrials.gov identifier: NCT03312634. Updated March 14, 2023. Accessed August 29, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT03312634
- Kaplan FS, Mukaddam MA, Baujat, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2022; 2:1-127. Accessed August 29, 2023. https://www.ifopa.org/for_medical_professionals
- Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated February 2023. Accessed August 29, 2023. https://rarediseases.info.nih.gov

POLICY HISTORY

Policy #: 05.05.17
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