BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.30.088

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	September 8, 2023
Subject:	Sohonos	**Page:**	1 of 4

Last Review Date: September 6, 2024

Sohonos

Description

Sohonos (palovarotene)

Background
In patients with fibrodysplasia ossificans progressiva (FOP), abnormal bone formation, including heterotopic ossification (HO), is driven by a gain-of-function mutation in the bone morphogenetic protein (BMP) type I receptor ALK2 (ACVR1). Sohonos (palovarotene) is an orally bioavailable retinoic acid receptor agonist, with particular selectivity at the gamma subtype of RAR. Through binding to RARγ, Sohonos decreases the BMP/ALK2 downstream signaling pathway by inhibiting the phosphorylation of SMAD1/5/8, which reduces ALK2/SMAD-dependent chondrogenesis and osteocyte differentiation resulting in reduced endochondral bone formation (1).

Regulatory Status
FDA-approved indications: 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 progressiva (FOP) (1).

Sohonos includes a boxed warning citing embryo-fetal toxicity and premature epiphyseal closure in growing pediatric patients. Sohonos is contraindicated in pregnancy due to the risk of teratogenicity. To minimize fetal exposure, Sohonos should be administered only if conditions for pregnancy prevention are met. Sohonos also causes premature epiphyseal closures in growing pediatric patients with FOP, close monitoring is recommended. Assess baseline skeletal maturity prior to therapy and monitor linear growth in growing pediatric patients (1).

Sohonos can cause mucocutaneous adverse reactions, metabolic bone disorders, psychiatric disorders, and night blindness. Skin emollients, sunscreen, and artificial tears should be used to prevent or treat dermatologic adverse effects and dry eyes. Decreased vertebral bone mineral content and bone density may occur. Assess for spinal fracture periodically using radiologic method. Depression, anxiety, mood alterations, and suicidal thoughts and behaviors occurred with Sohonos use. Monitor for development of new or worsening psychiatric symptoms during treatment. Driving a vehicle at night may potentially be hazardous during treatment. Advise patients to be cautious when driving at night and to seek medical attention in the event of vision impairment (1).

The safety and effectiveness of Sohonos have not been established in pediatric patients less than 8 years of age for females and less than 10 years of age for males (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sohonos may be considered **medically necessary** if the conditions indicated below are met.

Sohonos may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 8 years of age or older in females
10 years of age or older in males

Diagnosis

Patient must have the following:

Fibrodysplasia ossificans progressiva (FOP)

AND ALL of the following:

1. Female patients of reproductive potential **only:** patient has had a negative pregnancy test

2. Female patients of reproductive potential **only**: patient will be advised to use effective contraception 1 month prior to treatment with Sohonos, during treatment, and for 1 month after the last dose
3. Pediatric patients **only**: prescriber agrees to monitor for premature epiphyseal closure or adverse effects on growth

Prior – Approval *Renewal* Requirements

Age 8 years of age or older in females
10 years of age or older in males

Diagnosis

Patient must have the following:

Fibrodysplasia ossificans progressiva (FOP)

AND ALL of the following:

1. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Sohonos and for 1 month after the last dose
2. Pediatric patients **only**: prescriber agrees to monitor for premature epiphyseal closure or adverse effects on growth

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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 progressiva (FOP). A negative pregnancy test should be obtained in females of reproductive potential. Due to premature epiphyseal closure in growing pediatric patients, close monitoring is recommended. Sohonos can cause mucocutaneous adverse reactions, metabolic bone disorders, psychiatric disorders, and night blindness (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sophonos while maintaining optimal therapeutic outcomes.

References

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.