BlueCross BlueShield Federal Employee Program

SOHONOS
(palovarotene)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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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).

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.