



Commercial/Healthcare Exchange Prior Authorization Criteria Effective: October 3, 2023

Prior Authorization: Sohonos (palovarotene)

Products Affected: Sohonos (palovarotene) oral capsules

Medication Description: 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). Palovarotene is an orally bioavailable retinoid that acts as a retinoic acid receptor (RAR) agonist with particular selectivity at the gamma subtype of RAR. In patients with fibrodysplasia ossificans progressiva (FOP), abnormal bone formation, including heterotrophic ossification (HO), is driven by a gain-of-function mutation in the bone morphogenetic protein (BMP) type I receptor ALK2 (ACVR1). Through binding to RAR-gamma, palovarotene 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.

Covered Uses:

1. Fibrodysplasia ossificans progressiva (FOP)

Exclusion Criteria:

1. Pregnancy

Required Medical Information:

1. Diagnosis

Prescriber Restriction: The medication is prescribed by or in consultation with an endocrinologist or physician who specializes in bone disease.

Age Restriction: Females 8 years of age and older and males 10 years of age and older

Coverage Duration: 6 months

Other Criteria:

Initial Approval Criteria

1. Fibrodysplasia ossificans progressiva.

- A. Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)^{R206H} consistent with a diagnosis of fibrodysplasia ossificans progressiva; **AND**
- B. Patient has heterotopic ossification as confirmed by radiologic testing; **AND**
Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan.

September 2023



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.



References:

1. Product Information: SOHONOS™capsules, palovarotene oral capsules. Ipsen Biopharmaceuticals Inc (per FDA), Cambridge, MA, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/3/2023

