Pharmacy Drug Policy & Procedure

Policy Name:	Sohonos (palovarotene)	Policy#:	3247P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Sohonos (palovarotene).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Sohonos (palovarotene) under the pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP) confirmed by genetic testing
- Genetic testing documentation must confirm pathogenic variant of ACVR1^{R206H} mutation
- Chart note documentation supporting signs and symptoms of FOP (must include big toe malformation present at birth)

1.2 Age 8 years or older (females) or 10 years or older (males)

1.3 Prescribed by or in consultation with an endocrinologist (hormone condition doctor), geneticist (gene doctor) or physician who specializes in rare connective tissue diseases

1.4 Documentation of baseline skeletal (bone) maturity and historical linear growth (height) in growing pediatric patients
- Prescriber attestation that benefits outweigh the risks of use in growing pediatric patients due to the boxed warning of premature epiphyseal growth closure

1.5 Documentation of radiologic testing (such as x-ray, CT scan, MRI, or PET scan) to confirm heterotopic ossification (HO, bone growth outside the skeletal area) and support Sohonos is being used to reduce volume of new HO

1.6 Patients of reproductive potential must submit attestation that appropriate contraception methods will be used throughout treatment duration and at least one month after

1.7 Request for coverage is reviewed by both a pharmacist and a medical director

2. Exclusion Criteria

2.1 Pregnancy

2.2 Any other pathogenic variant of the ACVR1 gene

2.3 Severe kidney impairment

2.4 Moderate-severe liver impairment

3. Managed Dose Limit

3.1 #30 capsules per 30 days
- Requests for treatment of an active flare with require a temporary quantity limit exception to allow for 10mg #56 capsules/28 days for first 4 weeks if one of the following criteria is met:
  - Patient is currently experiencing symptoms of an acute flare such as increased localized pain, soft tissue swelling/inflammation, redness, warmth, decreased range of motion, or stiffness
  - Patient is undergoing a substantial high-risk traumatic event likely to lead to a flare such

as surgery, intramuscular injection, mandibular block for dental procedure, muscle fatigue, blunt trauma from bumps/bruises/falls or an influenza-like viral illness

- If patient is undergoing treatment of an acute flare and symptoms markedly worsen or flare in a new location, restarting 12 week treatment may be necessary

4. Approval Period

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with documentation supporting clinically significant improvement of condition stabilization (such as decreased volume of abnormal bone growth or improvement in functional outcomes or quality of life)

CPT Codes	
HCPCS Codes	
References	

1. Sohonos (palovarotene) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.
2. Pignolo RJ, Hsiao EC, Al Mukaddam M, et al. Reduction of New Heterotopic Ossification (HO) in the Open-Label, Phase 3 MOVE Trial of Palovarotene for Fibrodysplasia Ossificans Progressiva (FOP). J Bone Miner Res. 2023 Mar;38(3):381-394.
3. Pignolo RJ, Baujat G, Brown MA, et al. Natural history of fibrodysplasia ossificans progressiva: cross-sectional analysis of annotated baseline phenotypes. Orphanet J Rare Dis. 2019;14:98.
4. Shaikh U, Khan A, Kumari P, et al. Novel Therapeutic Targets for Fibrodysplasia Ossificans Progressiva: Emerging Strategies and Future Directions. Cureus. 2023 Jul 28;15(7):e42614.
5. Kaplan FS, Al Mukaddam M, Baujat G, et al, for the Internation council on FOP (ICC) & Consultants. The medical management of fibrodysplasia ossificans progressive: current treatment considerations. Updated May 2022. https://www.iccfop.org/dvlp/wp-content/uploads/2022/05/guidelines-updated-May-2022.pdf

Created Date: 06/05/24
Effective Date: 06/05/24
Posted to Website: 06/05/24
Revision Date: