

POLICY NAME	Sohonos (palovarotene)	POLICY #	3247P
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Criteria

Coverage Criteria

- ☐ **1.1** Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP) confirmed by genetic testing
 - Genetic testing documentation must confirm pathogenic variant of ACVR1R206H 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

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Pregnancy
- ☐ **2.2** Any other pathogenic variant of the ACVR1 gene
- ☐ **2.3** Severe kidney impairment
- ☐ **2.4** Moderate-severe liver impairment