

<b>POLICY NAME</b>	Sohonos (palovarotene)	<b>POLICY #</b>	
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## Criteria

### 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

### 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