

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

palovarotene (Sohonos)

Notes:

- Quantity Limits: No

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **palovarotene (Sohonos)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a geneticist or endocrinologist or physician who specializes in bone disease.
- Patient is female and ≥ 8 years of age; OR Patient is male* and ≥ 10 years of age.
- Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)^{R206H} consistent with a diagnosis of fibrodysplasia ossificans progressive.
- Patient has heterotopic ossification as confirmed by radiologic testing.

Continued use criteria (12 months after initiation): Non-formulary **palovarotene (Sohonos)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Continues to be prescribed by a geneticist or endocrinologist or physician who specializes in bone disease.
- Documentation of positive clinical response (e.g., reduction in new heterotopic ossification volume, improved cumulative analogue joint involvement scale (CAJIS) or Fibrodysplasia Ossificans Progressiva Physical Function Questionnaire scores, improved quality of life)