SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Sohonos™ (palovarotene)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage for Members 14 years of age and older:

- Daily Dose (maintenance): 5 mg daily.
- Flare-Up Dose: 20 mg daily for 4 weeks, followed by 10 mg daily for 8 weeks (for a total of 12 weeks of flare-up treatment), even if symptoms resolve earlier, then return to daily dosing of 5 mg.

Recommended Dosage for Members aged 8 to 13 years for females and aged 10 to 13 years for males:

- Daily Dose (maintenance): Weight-based ranging from 2.5 mg to 5 mg daily. Stop daily dosing when flare-up dosing begins.
- Flare-Up Dose: Weight based. Administer the initial flare-up dosage once daily for 4 weeks, then administer the lower flare-up dosage once daily for 8 weeks (for a total of 12 weeks of flare-up treatment), even if symptoms resolve earlier, then return to daily dosing.

Quantity Limits:

- 1, 1.5 & 10 mg capsules: 2 capsules daily
- 2.5 & 5 mg capsules: 1 capsule daily

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member must meet **ONE** of the following age requirements:
  - ❑ If female: Member is at least 8 years of age or older
  - ❑ If male: Member is at least 10 years of age or older
- ❑ Prescribed by or in consultation with a specialist with expertise in treating patients with fibrodysplasia ossificans progressiva
- ❑ Member has an established diagnosis of fibrodysplasia ossificans progressiva as confirmed by **ALL** the following findings **(submit documentation)**:
  - ❑ Clinical (e.g., congenital hallux valgus deformity that is most often bilateral, progressive heterotopic ossification, limb reduction defects that may affect the fingers in atypical or nonclassical FOP)
  - ❑ Imaging (e.g., radiographs of the halluces demonstrate short, malformed first metatarsals and a single dysplastic phalanx; radiographs of affected areas demonstrate heterotopic ossification (extraosseous bone formation))
  - ❑ Identification of a heterozygous pathogenic variant in the ACVR1 gene (e.g., c.617G>A being the most common), by molecular genetic testing
- ❑ Requested medication will be used for the reduction in volume of new heterotopic ossification lesions
- ❑ Members that are females of reproductive potential must have a negative pregnancy test within one week prior to initiating treatment and periodically during therapy
- ❑ Member will avoid agents and/or circumstances that will predispose to soft-tissue injury, to the extent possible (e.g., intramuscular injections, arterial punctures, dental procedures, procedures related to anesthesia, biopsies, removal of heterotopic bone, nonemergent surgical procedures, contact sports, overstretching of soft tissues, muscle fatigue, falls)
- ❑ Member does **NOT** have a history of allergy or hypersensitivity to retinoids
- ❑ Member has had a baseline assessment of skeletal maturity via hand/wrist and knee x-rays, standard growth curves and pubertal staging and will have continued monitoring throughout therapy until the patient reaches skeletal maturity or final adult height **(submit documentation)**
- ❑ Member will avoid excessive exposure to sun or artificial ultraviolet light, and protection from sunlight will be used when exposure cannot be avoided (e.g., use of sunscreens, protective clothing, and use of sunglasses)
- ❑ Member will avoid concomitant therapy with **ALL** the following:
  - Strong CYP3A4 inhibitors (e.g., grapefruit/pomelo juice, fluconazole, itraconazole)
  - Strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort)
  - Vitamin A or tetracyclines

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., premature epiphyseal closure, severe mucocutaneous reactions, spinal fractures, severe or worsening psychiatric disorders, night blindness)
- ❑ Member's exhibiting signs of premature closure of epiphyses should be evaluated to assess benefits/risks of discontinuation until achievement of skeletal maturity
- ❑ Member has shown a beneficial response to treatment as evidenced by at least **ONE** of the following **(submit documentation)**:
  - ❑ Reduction, stabilization, or slowing of the rate of annualized volume of new heterotopic ossification (HO) as assessed by low-dose, whole body CT (WBCT) imaging (excluding head)
  - ❑ Reduction or improvement in the signs and symptoms of, or number of flare-ups as compared to baseline

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****