Pharmacy Medical Necessity Guidelines: Sohonos™ (palovarotene)

Effective: January 13, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Sohonos (palovarotene) is a retinoid indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressive (FOP).

COVERAGE GUIDELINES

The plan may authorize coverage of Sohonos for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of fibrodysplasia ossificans progressive

AND

2. Documentation of genetic testing confirming the presence of the ACVR1 R206H mutation

AND

3. Documentation of **ONE** (1) of the following:
    a. If female, patient is at least 8 years of age
    b. If male, patient is at least 10 years of age

AND

4. Prescribed by or in consultation with a physician who specializes in rare connective tissue diseases

Reauthorization Criteria

1. Documented diagnosis of fibrodysplasia ossificans progressive

AND

2. Documentation of genetic testing confirming the presence of the ACVR1 R206H mutation

AND

3. Documentation of **ONE** (1) of the following:
    a. If female, patient is at least 8 years of age
    b. If male, patient is at least 10 years of age

AND

4. Prescribed by or in consultation with a physician who specializes in rare connective tissue diseases

AND

5. Documentation the patient has experienced a therapeutic response based on provider attestation (e.g., decrease in flares, decrease in HO volume, improved function and/or quality of life

LIMITATIONS

- Initial approval of Sohonos will be authorized for six (6) months. Reauthorization of Sohonos will be provided in six (6)-month intervals.
- Patients new to the plan stable on Sohonos should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Sohonos (palovarotene) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.;March 2025.

2. Kaplan FS, et al. The medical management of fibrodysplasia ossificans progressive: current treatment considerations. Proc Intl Clin Council FOP 2: 1-127, 2022.

APPROVAL HISTORY

February 13, 2024: Reviewed by the Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

1. January 14, 2025: No changes (eff 1/14/25).
2. January 13, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services