Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Sohonos™ (palovarotene)

Effective: May 12, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:
Commercial Products
☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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).

Clinical Guideline Coverage Criteria

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

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. Initial approval of Sohonos will be authorized for six (6) months. Reauthorization of Sohonos will be provided in six (6)-

month intervals.

3. 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.; August 2023.
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 And Revision History

February 13, 2024: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 14, 2025: No change (eff 1/14/25).
- May 12, 2026: No changes, template updated to remove CareLink from the Medical Necessity Guideline template.

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.