

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 1418-2
Program	Prior Authorization/Notification
Medication	Sohonos [™] (palovarotene)
P&T Approval Date	10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

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 progressiva (FOP).

2. Coverage Criteria^a:

A. Initial Authorization

- 1. Sohonos will be approved based on <u>all</u> of the following criteria:
 - a. Diagnosis of fibrodysplasia ossificans progressiva (FOP)

-AND-

- b. **One** of the following:
 - (1) **Both** of the following:
 - (a) Patient is female
 - (b) Patient is aged 8 years and older

-OR-

- (2) **Both** of the following:
 - (a) Patient is male
 - (b) Patient is aged 10 years and older

-AND-

c. Sohonos is being used to reduce the volume of new heterotopic ossification (HO)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Sohonos** will be approved based on the following criterion:



a. Documentation of positive clinical response to Sohonos therapy

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.

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Change Control	
10/2023	New program.
10/2024	Annual review with no changes.