

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

|                   |                                  |
|-------------------|----------------------------------|
| Program Number    | 2025 P 1418-3                    |
| Program           | Prior Authorization/Notification |
| Medication        | Sohonos™ (palovarotene)          |
| P&T Approval Date | 10/2023, 10/2024, 10/2025        |
| Effective Date    | 12/1/2025                        |

**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<sup>a</sup>:****A. Initial Authorization**

1. **Sohonos** will be approved based on **all** 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.**

<sup>a</sup> 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 re-authorization 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.; March 2025.

| Program        | Prior Authorization/Notification - Sohonos (palovarotene)     |
|----------------|---|
| Change Control |   |
| 10/2023        | New program.  |
| 10/2024        | Annual review with no changes.                                |
| 10/2025        | Annual review with no changes to criteria. Updated reference. |