UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2322-2
Program	Prior Authorization/Medical Necessity
Medication	Sohonos™ (palovarotene)
P&T Approval Date	1/2024, 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 **all** of the following criteria:

   a. Diagnosis of fibrodysplasia ossificans progressiva (FOP)

   -AND-

   b. Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene

   -AND-

   c. **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-

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

   -AND-

e. Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Sohonos** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response (e.g., reduction in new HO volume, improved CAJIS and FOP-PFQ scores, improved quality of life)

   -AND-

   b. Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

   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 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

4. References:

1. Sohonos [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; August 2023.
2. The International Clinical Council (ICC) on Fibrodysplasia Ossificans Progressiva (FOP). The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. July 2024. Available at: Guidelines | International Clinical Council (ICC) on Fibrodysplasia Ossificans Progressiva (FOP) (iccfop.org). Accessed on August 29, 2024.

Program	Prior Authorization/Medical Necessity - Sohonos (palovarotene)
Change Control	
1/2024	New program.
10/2024	Annual review with no changes to coverage criteria. Updated references.