Mass General Brigham
Health Plan

Sohonos (palvarotene)
Effective 09/01/2025

Plan	☒ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Sohonos (palvarotene) is a retinoid indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of fibrodysplasia ossificans progressive (FOP)
2. Genetic testing results confirming FOP with documented activin receptor type 1 (ACVR1) mutation (e.g., R206H)
3. Member has signs and symptoms of FOP (e.g., malformation of the great toe, abnormal vertebral morphology, ectopic ossification in ligament or muscle tissue).
4. Member meets ONE of the following:
    a. Male member aged 10 years of age or older.
    b. Female member aged 8 years of age or older.
5. Medication is prescribed by or in consultation with a physician who is experienced in the treatment of FOP (e.g., orthopedist, rheumatologist).

Continuation of Therapy
Requests for reauthorization will be approved when all of the following criteria are met:

1. ONE of the following:
    a. Member is male 10 years of age or older
    b. Member is female 8 years of age or older

2. Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the volume of new heterotopic ossification)

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Sohonos capsule	4 capsules per day

References

1. Sohonos (palovarotene) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; March 2025.
2. An Efficacy and Safety Study of Palovarotene for the Treatment of Fibrodysplasia Ossificans Progressiva. (MOVE). ClinicalTrials.gov identifier: NCT03312634. Updated March 14, 2023. Accessed August 29, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT03312634
3. Kaplan FS, Mukaddam MA, Baujat, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2022; 2:1-127. Accessed August 29, 2023. https://www.ifopa.org/for_medical_professionals
4. Genetic and Rare Diseases Information Center (GARD). Fibrodysplasia Ossificans Progressiva. Rare Disease Database. Last updated February 2023. Accessed August 29, 2023. https://rarediseases.info.nih.gov

Review History

2/14/2024 - Created and Reviewed at Feb P&T, Effective 3/1/2024
08/13/2025 – Reviewed at August P&T. No clinical changes. Effective 09/01/2025.