JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS176
		Effective Date	04/17/2024
		Approval Date	04/17/2024
	Subject **Sohonos**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Sohonos

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I. POLICY

A. Sohonos (palovarotene) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Sohonos** may be approved for patients who meet the following:
   1. Patient is one of the following:
      a. 8 years of age or older and designated female at birth
      b. 10 years of age or older and designated male at birth
   2. Documentation has been submitted showing the following:
      a. Diagnosis of fibrodysplasia ossificans progressiva (FOP)
      b. Patient has an Activin A Type 1 Receptor (ACVR1) R206H variant mutation as confirmed by genetic testing
      c. Patient has radiographic evidence of heterotopic ossification (HO) (computed tomography (CT) scan, magnetic resonance imaging (MRI), x-ray, positron emission tomography (PET) scan, etc.)
      d. **Additional requirement for females of reproductive potential:
         1. Patient has had a negative pregnancy test prior to initiation of therapy, and will use an effective method of contraception during treatment
   3. Prescriber is, or has consulted with, an endocrinologist, geneticist, or a provider specializing in FOP management

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 6 months of therapy.
B. Approval for continuation of therapy can be extended in 6-month intervals with clinical documentation supporting that the patient has had a beneficial response to treatment, evidenced by a reduction in annualized HO volume.

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IV. EXCLUSIONS

A. Sohonos will not be approved for the following:
   1. Pediatric patients younger than 8 years of age for females and 10 years of age for males due to the potential for premature epiphyseal closure
   2. Patients that are pregnant or breastfeeding
   3. Patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
   4. Patients with severe renal impairment
   5. Patients with a history of allergy or hypersensitivity to retinoids, or to any component of Sohonos
   6. Concurrent use with strong cytochrome P450 3A4 (CYP3A4) inhibitors, moderate or strong CYP3A4 inducers
   7. Concurrent use with tetracyclines
   8. Any indications or uses that are not FDA-approved or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

A. Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

1. Sohonos [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.
2. Pignolo RJ, Hsiao EC, Al Mukaddam M, et al. Reduction of New Heterotopic Ossification (HO) in the Open-Label, Phase 3 MOVE Trial of Palovarotene for Fibrodysplasia Ossificans Progressiva (FOP).J Bone Miner Res. 2023 Mar;38(3):381-394.
3. Kaplan FS, Al Mukaddam M, Baujat G, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP. 2019;1: 1–111.

VII. APPROVALS

Signature on file at JHHP

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04/17/2024	Policy Creation

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