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(palovarotene) capsules
1 mg | 1.5 mg | 2.5 mg | 5 mg | 10 mg

Guide to Writing a Supporting Statement for a Medicare Part D Exception Request

A supporting statement for a Medicare Part D exception request explains the prescriber's rationale and clinical decision-making for choosing a specific treatment option.

There are 2 types of exception requests[1]:

Tier exception

A request to obtain a non-preferred drug at a lower cost-sharing level

Formulary exception

A request to obtain a non-formulary drug or to have a utilization management requirement waived (eg, step therapy, prior authorization)

Use of this information **does not** guarantee that a health plan will provide coverage for Sohonos and is not intended to be a substitute for, or or to influence, your independent medical judgment.

The following pages share tips for writing an effective supporting statement and a template you can use to write your statement for individual patients.

Call 1-866-435-5677 Monday – Friday, 8:00 AM – 8:00 PM ET, for additional information, or visit us online at IPSENCARES.com

Reference: 1. Exceptions. Centers for Medicare & Medicaid Services. September 10, 2024. Accessed June 18, 2025. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions

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Tips for Writing an Effective Supporting Statement for Medicare Part D Patients

Before you begin a supporting statement, have the following information ready:

- Patient's full name and date of birth
- Patient's insurance policy/ID number
- Case ID number
- Brief medical history, including diagnosis, ICD-10 code, comorbidities, and allergies
- Patient's current and prior therapeutic regimens (include start/stop dates and the reason[s] for discontinuation)
- Background on the patient's current condition and symptoms
- Clinical support for your recommendation

Consider these additional points when writing your statement for Sohonos® (palovarotene) capsules:

- **Review the health plan's coverage criteria** for Sohonos and provide details for the criteria that your patient meets. If applicable, provide your rationale for excluding your patient from criteria they do not meet
- **Clearly state** why Sohonos is medically necessary for the patient and that the preferred drug(s) (for tier exceptions) or covered option(s) (for **formulary exceptions**) would not be as effective and/or would have adverse effects[1]
- **Provide clinical justification** to support your decision to prescribe Sohonos and attach relevant clinical data, such as chart notes, laboratory test results, and pregnancy status, if applicable[2]
- **Describe** any other patient characteristics and/or clinical considerations relevant to Sohonos therapy
  - Attach clinical documentation that supports your recommendation[2]

Be mindful of following preferred health plan processes.

- Read the process for submitting the statement to ensure that you are meeting the requirements of the health plan and state guidelines, including how to submit the request (eg, fax, phone, email, health plan website)
- Track the status of your request and follow up with the health plan if needed

IPSEN CARES® can help provide logistical information about submitting statements

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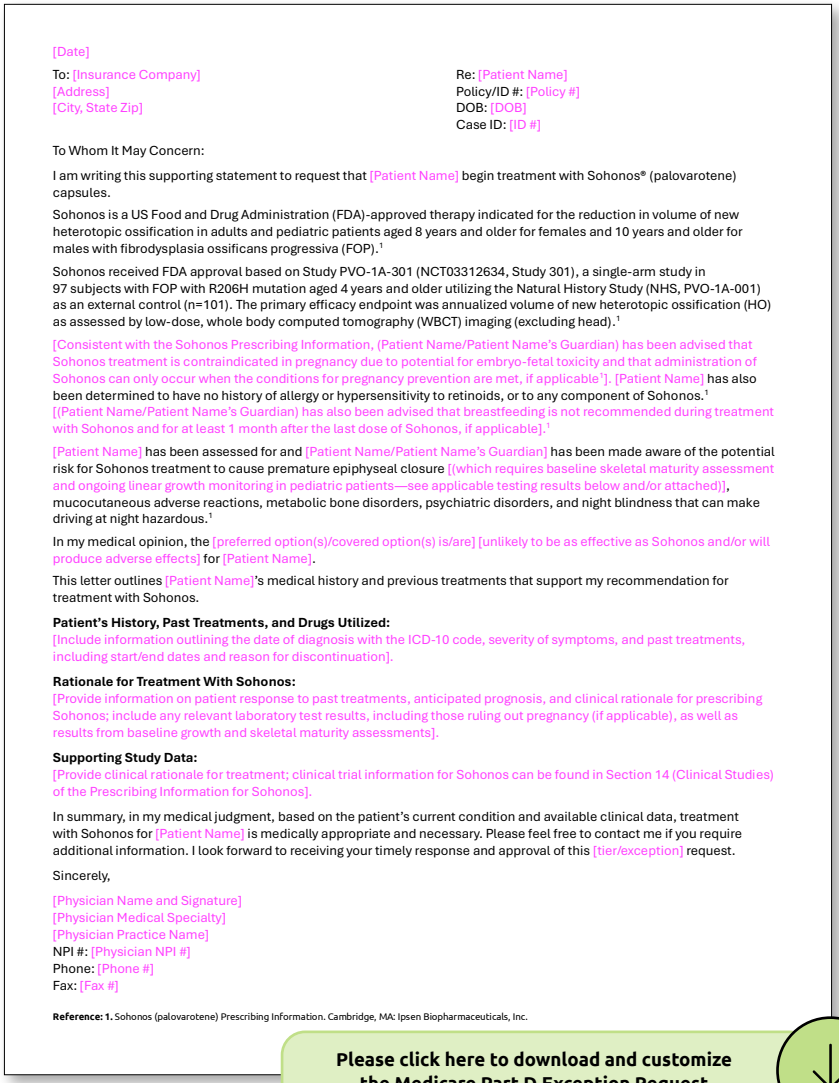
ICD-10, International Classification of Diseases, 10th Revision.

References: 1. Exceptions. Centers for Medicare & Medicaid Services. September 10, 2024. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/exceptions **2.** Sohonos (palovarotene) Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information, including BOXED WARNING, and Medication Guide.

Sample Medicare Part D Supporting Statement for Sohonos® (palovarotene) Capsules

The image below shows the format for a sample supporting statement for Sohonos that uses a downloadable template. Take a look to get a sense of what a statement format may look like, and then you may download the template to customize it based on your medical opinion and your individual patient's needs.



[Date]

To: [Insurance Company]
[Address]
[City, State Zip]

Re: [Patient Name]
Policy/ID #: [Policy #]
DOB: [DOB]
Case ID: [ID #]

To Whom It May Concern:

I am writing this supporting statement to request that [Patient Name] begin treatment with Sohonos® (palovarotene) capsules.

Sohonos is a US Food and Drug Administration (FDA)-approved therapy 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).[1]

Sohonos received FDA approval based on Study PVO-1A-301 (NCT03312634, Study 301), a single-arm study in 97 subjects with FOP with R206H mutation aged 4 years and older utilizing the Natural History Study (NHS, PVO-1A-001) as an external control (n=101). The primary efficacy endpoint was annualized volume of new heterotopic ossification (HO) as assessed by low-dose, whole body computed tomography (WBCT) imaging (excluding head).[1]

[Consistent with the Sohonos Prescribing Information, (Patient Name/Patient Name's Guardian) has been advised that Sohonos treatment is contraindicated in pregnancy due to potential for embryo-fetal toxicity and that administration of Sohonos can only occur when the conditions for pregnancy prevention are met, if applicable[1]]. [Patient Name] has also been determined to have no history of allergy or hypersensitivity to retinoids, or to any component of Sohonos.[1] [(Patient Name/Patient Name's Guardian) has also been advised that breastfeeding is not recommended during treatment with Sohonos and for at least 1 month after the last dose of Sohonos, if applicable].[1]

[Patient Name] has been assessed for and [Patient Name/Patient Name's Guardian] has been made aware of the potential risk for Sohonos treatment to cause premature epiphyseal closure [(which requires baseline skeletal maturity assessment and ongoing linear growth monitoring in pediatric patients—see applicable testing results below and/or attached)], mucocutaneous adverse reactions, metabolic bone disorders, psychiatric disorders, and night blindness that can make driving at night hazardous.[1]

In my medical opinion, the [preferred option(s)/covered option(s) is/are] [unlikely to be as effective as Sohonos and/or will produce adverse effects] for [Patient Name].

This letter outlines [Patient Name]'s medical history and previous treatments that support my recommendation for treatment with Sohonos.

Patient's History, Past Treatments, and Drugs Utilized:
[Include information outlining the date of diagnosis with the ICD-10 code, severity of symptoms, and past treatments, including start/end dates and reason for discontinuation].

Rationale for Treatment With Sohonos:
[Provide information on patient response to past treatments, anticipated prognosis, and clinical rationale for prescribing Sohonos; include any relevant laboratory test results, including those ruling out pregnancy (if applicable), as well as results from baseline growth and skeletal maturity assessments].

Supporting Study Data:
[Provide clinical rationale for treatment; clinical trial information for Sohonos can be found in Section 14 (Clinical Studies) of the Prescribing Information for Sohonos].

In summary, in my medical judgment, based on the patient's current condition and available clinical data, treatment with Sohonos for [Patient Name] is medically appropriate and necessary. Please feel free to contact me if you require additional information. I look forward to receiving your timely response and approval of this [tier/exception] request.

Sincerely,

[Physician Name and Signature]
[Physician Medical Specialty]
[Physician Practice Name]
NPI #: [Physician NPI #]
Phone: [Phone #]
Fax: [Fax #]

Reference: 1. Sohonos (palovarotene) Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.

Please click here to download and customize the Medicare Part D Exception Request

This template is for informational purposes only, providing an outline of the types of information that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional. IPSEN makes no representations or warranties about the template or its fitness for any specific use. IPSEN is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information, including BOXED WARNING, and Medication Guide.

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INDICATION

SOHONOS® is 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).

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY and PREMATURE EPIPHYSEAL CLOSURE IN GROWING PEDIATRIC PATIENTS

- **SOHONOS is contraindicated in pregnancy. SOHONOS may cause fetal harm. Because of the risk of teratogenicity and to minimize fetal exposure, SOHONOS is to be administered only if conditions for pregnancy prevention are met.**
- **Premature epiphyseal closure occurs in growing pediatric patients treated with SOHONOS, close monitoring is recommended.**

Contraindications

SOHONOS is contraindicated in patients during pregnancy, or with a history of allergy or hypersensitivity to retinoids, or to any component of SOHONOS. Anaphylaxis and other allergic reactions have occurred with other retinoids.

Warnings and Precautions

- **Embryo-Fetal Toxicity:** SOHONOS can cause fetal harm and is contraindicated during pregnancy. SOHONOS is a retinoid which is associated with birth defects in humans. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment, periodically during therapy and one month after treatment discontinuation. Advise females of reproductive potential to use an effective method of contraception at least 1 month prior to treatment, during SOHONOS treatment and for 1 month after the last dose. If a pregnancy occurs during treatment, discontinue treatment immediately and refer the patient to an obstetrician/gynecologist experienced in reproductive toxicity. Inform patients not to donate blood during SOHONOS treatment and for 1 week following discontinuation.
- **Premature Epiphyseal Closure in Growing Pediatric Patients:** SOHONOS can cause irreversible premature epiphyseal closure and potential adverse effects on growth. In clinical studies, premature epiphyseal closure occurred with SOHONOS treatment in growing pediatric patients with FOP. Monitor linear growth in growing pediatric patients. Prior to starting treatment with SOHONOS, all growing pediatric patients should undergo baseline assessment of skeletal maturity. Continued monitoring is recommended every 6-12 months until patients reach skeletal maturity or final adult height. If a patient exhibits signs of premature epiphyseal closure or adverse effects on growth based on clinical or radiologic evaluations, further evaluation may be required, including an assessment of the benefits and risks of continued treatment, or temporary or permanent discontinuation of SOHONOS until the patient achieves epiphyseal closure and skeletal maturity.
- **Mucocutaneous Adverse Reactions:** Dry skin, lip dry, pruritus, rash, alopecia, erythema, skin exfoliation (skin peeling), and dry eye occurred in 98% of patients treated with SOHONOS. SOHONOS may contribute to an increased risk of skin and soft tissue infections, particularly paronychia and decubitus ulcer, due to a decreased skin barrier from adverse reactions such as dry and peeling skin. Some of these adverse reactions led to dose reductions which occurred more frequently during flare-up dosing suggesting a dose response relationship. Prophylactic measures to minimize risk and/or treat the mucocutaneous adverse reactions are recommended (e.g., skin emollients, sunscreen, lip moisturizers, or artificial tears). Some may require dose reduction or discontinuation. Photosensitivity reactions (e.g., burning, erythema, blistering) involving areas exposed to the sun have been associated with the use of retinoids and may occur with SOHONOS. Precautionary measures for phototoxicity are recommended (use of sunscreens, protective clothing, and use of sunglasses).
- **Metabolic Bone Disorders:** Retinoids are associated with bone toxicity, including reductions in bone mass and spontaneous reports of osteoporosis and fracture. In FOP clinical studies, SOHONOS resulted in decreased vertebral bone mineral content and bone density, and an increased risk of radiologically observed vertebral fractures in treated patients compared to untreated patients. Periodic radiological assessment of the spine is recommended. Retinoids have been associated with hyperostotic changes (bone spurs) and calcification of tendons or ligaments may occur with SOHONOS.
- **Psychiatric Disorders:** New or worsening psychiatric events were reported with SOHONOS including depression, anxiety, mood alterations, and suicidal thoughts and behaviors. There is a relatively high background prevalence of psychiatric disorders in untreated patients with FOP. Monitor for development of new or worsening psychiatric symptoms during treatment with SOHONOS. Individuals with a history of psychiatric illness may be more susceptible to these adverse effects. Patients and/or caregivers should contact their healthcare provider if new or worsening psychiatric symptoms develop during treatment with SOHONOS.

Please see Important Safety Information on pages 4 and 5 and full Prescribing Information, including BOXED WARNING, and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **Night Blindness:** This may be dose-dependent, making driving a vehicle at night potentially hazardous during treatment. Advise patients to be cautious when driving or operating any vehicle at night and seek medical attention in the event of vision impairment.

Adverse Reactions

The most common adverse reactions (≥ 10%) are dry skin, lip dry, arthralgia, pruritus, pain in extremity, rash, alopecia, erythema, headache, back pain, skin exfoliation (skin peeling), nausea, musculoskeletal pain, myalgia, dry eye, hypersensitivity, peripheral edema, and fatigue.

Drug Interactions

- Co-administration with Strong or Moderate CYP3A4 inhibitors may increase SOHONOS exposure which may increase the risk of SOHONOS adverse reactions. Avoid concomitant use of strong and Moderate CYP3A4 inhibitors. If co-administration will occur with Moderate CYP3A4 inhibitors, reduce the SOHONOS dose by half.
- Co-administration with Strong or Moderate CYP3A4 inducers may decrease SOHONOS exposure which may reduce the effectiveness. Avoid concomitant use of strong or moderate CYP3A4 inducers.
- The use of both vitamin A and SOHONOS at the same time may lead to additive effects. Concomitant administration of vitamin A in doses higher than the recommended daily allowance and/or other oral retinoids must be avoided due to risk of hypervitaminosis A.
- Systemic retinoid use has been associated with cases of benign intracranial hypertension (pseudotumor cerebri), some of which involved the concomitant use of tetracyclines. Avoid coadministration of SOHONOS with tetracycline derivatives.

Use in Specific Populations

- **Pregnancy:** SOHONOS is contraindicated during pregnancy. Obtain a negative serum pregnancy test within 1 week prior to SOHONOS therapy and periodically, as needed, over the course of treatment with SOHONOS and 1 month after treatment discontinuation unless patient is not at risk of pregnancy. If pregnancy occurs during treatment with SOHONOS, stop treatment immediately and refer the patient to an obstetrician/gynecologist or other specialist experienced in reproductive toxicity for evaluation and advice.
- **Lactation:** Advise females that breastfeeding is not recommended during treatment with SOHONOS, and for at least 1 month after the last dose.
- **Females of Reproductive Potential:** Advise females of reproductive potential to use effective contraception at least 1 month prior to and during treatment, and for 1 month after the last dose unless continuous abstinence is chosen.
- **Pediatric Use:** SOHONOS is not recommended for use in patients younger than 8 years of age for females and 10 years of age for males because of the potential for premature epiphyseal closure. All growing pediatric patients should undergo baseline assessment of growth and skeletal maturity before starting treatment and continued clinical and radiographic monitoring every 6-12 months until patients reach skeletal maturity or final adult height.
- **Geriatric Use:** Clinical studies of SOHONOS did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Dose selection should be cautious starting at the low end of the dosing range, reflecting greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- **Renal or Hepatic Impairment:** Use of SOHONOS in patients with severe renal impairment, or with moderate or severe hepatic impairment is not recommended.

Please see full Prescribing Information, including BOXED WARNING, and Medication Guide.

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