



SpringWorks  
**CareConnections**<sup>®</sup>

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**OGSIVEO<sup>®</sup> (nirogacestat)  
Coverage Toolkit**

This coverage toolkit can help you and your team navigate through prior authorization and appeals processes to help your patient access OGSIVEO.



**Ogsiveo**<sup>®</sup>  
(nirogacestat)  
150 mg & 100 mg tablets

# How to use this guide

After you prescribe OGSIVEO® (nirogacestat) to your patients, each health insurance plan will have its own criteria for coverage. SpringWorks CareConnections® Field Access Managers (FAMs) can provide in-person or virtual support to help facilitate access to OGSIVEO by providing you and your office staff with regional payor education and timely responses to questions.

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# General Insurance Coverage Process Overview

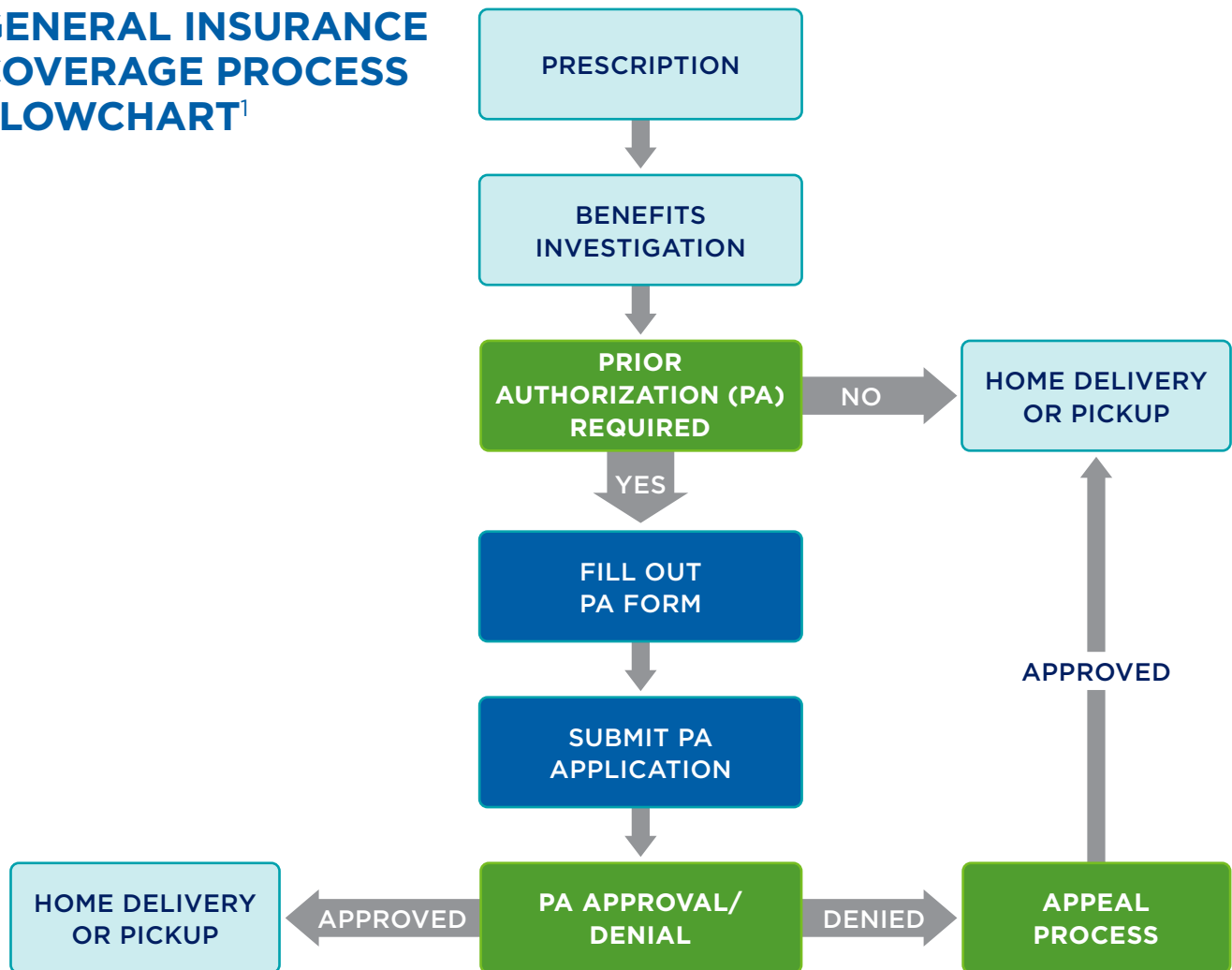
After you prescribe OGSIVEO® (nirogacestat), the insurance coverage process begins. The insurance process can sometimes be complex, but as you and your team navigate the process, SpringWorks CareConnections® Field Access Managers (FAMs) are available to answer questions to help facilitate your patients’ access to OGSIVEO.

## QUICK START

**SpringWorks CareConnections can help eligible commercially insured patients who experience a qualified delay in their insurance coverage get started on OGSIVEO at no cost for a limited period of time\***

\*Terms and conditions apply. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

## GENERAL INSURANCE COVERAGE PROCESS FLOWCHART<sup>1</sup>



This flowchart provides an example of an insurance coverage process but actual steps may vary across plans.

Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.

# Potential Drug Coverage Policies

Each health insurance plan will have specific processes and supporting documentation requirements to secure coverage for OGSIVEO® (nirogacestat). Below are potential coverage policies that you and your team may encounter.

## **COVERED** | Prior authorization may or may not be required

OGSIVEO is covered and included in the health insurance plan's formulary

- Prior authorization may or may not be required to secure coverage

## **NOT COVERED** | Prior authorization required<sup>2</sup>

Patients must meet certain insurance policy requirements to have OGSIVEO covered

- A prior authorization is required to show the patient's health insurance plan that the medication is medically necessary, and your patient meets the plan's requirements for coverage

## **NOT COVERED** | Non-formulary<sup>3</sup>

OGSIVEO is not covered, but may still be accessible through a medical exception process or additional requirements

- This may be the period before the Pharmacy and Therapeutics (P&T) Committee has added a medication to a health insurance plan's formulary
- A medical exception can be submitted to show that the medication is medically necessary for the patient

**Insurance Navigators** are additional members of the SpringWorks CareConnections® team who can help you and your team navigate the insurance process and provide additional resources as needed

The above list is not exhaustive, and you may encounter situations not described in this list.

**Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.**

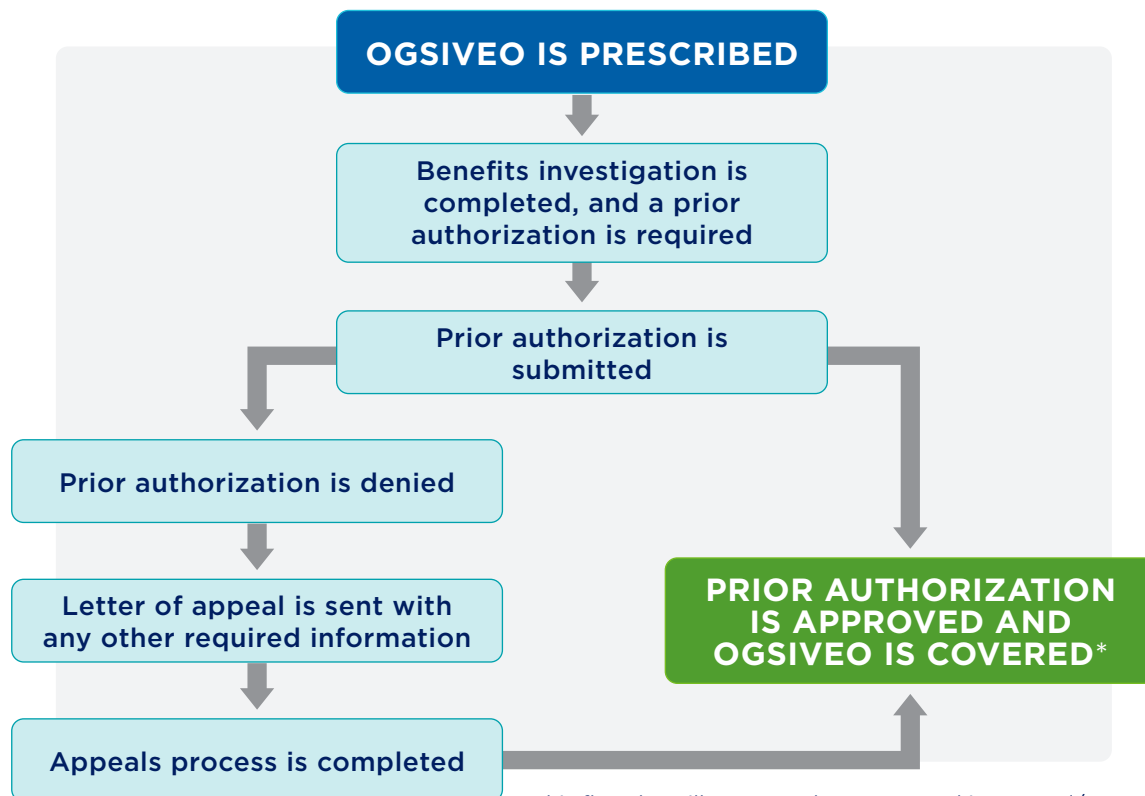
# The Prior Authorization Process

Health plans will likely require a prior authorization to be submitted for OGSIVEO® (nirogacestat).

The prior authorization process is used by health insurance companies to confirm that certain drugs or services are medically necessary and otherwise covered.<sup>2</sup> The flowchart below illustrates some potential scenarios you may encounter.

Please see the SpringWorks CareConnections® prior authorization tips and checklist (page 10) for more information.

## THE PRIOR AUTHORIZATION PROCESS



\*This flowchart illustrates when an appeal is granted/approved. See pages 7 and 8 for subsequent appeals or options if appeal is denied.



## THE QUICK START PROGRAM

SpringWorks CareConnections can help eligible commercially insured patients who experience a qualified delay in their insurance coverage get started on OGSIVEO at no cost for a limited period of time<sup>†</sup>

<sup>†</sup>Terms and conditions apply. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

5 Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.



# The Medical Necessity/Exception Process

## MEDICAL NECESSITY/EXCEPTION

A medication is deemed **medically necessary** when a physician using their professional judgment determines that the medication is the **best option for a given patient and meets the accepted standards of medicine.**<sup>4,5</sup>

A **medical exception** is needed when a medication prescribed for your patient is not **covered in their health insurance plan's formulary.**<sup>3</sup>

When submitting a letter of medical necessity/exception, consider explaining the importance of the medication prescribed, the reasons for prescribing the medication, and if applicable, why a policy-required edit through systemic therapy is not clinically warranted.<sup>3,6</sup>

**See the sample letter of medical necessity/exception (page 11) for more information.**

Coverage may be possible for patients with evidence

# Insurance Denial Types



There is a potential for the payor to initially respond that they are not approving the medication. These responses can be classified as either **administrative or clinical denials**.<sup>7</sup>

## ADMINISTRATIVE

**Administrative denials typically occur when there is an issue processing an insurance claim** and may not have to do with the necessity of the medication for your patient. When there is an administrative denial, the appeals process will not rectify the issue. Instead, correct any errors and resubmit the claim in a timely manner.<sup>7</sup>

### Examples:

- Incorrect insurance information provided for patient
- Missing signature
- Incomplete information/sections left blank

## CLINICAL

**A clinical denial means that the health insurance plan does not deem the medication necessary for the patient.** Reasons for clinical denials vary greatly, and can be complex.<sup>7,8</sup> To get the medication covered, further information is usually required to show medical necessity.

### Examples:

- Incorrect *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis codes (eg, not an approved OGSIVEO® [nirogacestat] indication)
- Lack of documentation supporting diagnosis (eg, lab values, incorrect dosage, proof of progressing desmoid tumors)<sup>9</sup>
- Additional clinical documentation needed to prove medical necessity

**Ensuring that any paperwork submitted to a health insurance plan is complete and accurate may help avoid potential delays in access to treatment. Please contact your Field Access Manager or Insurance Navigator for questions on the appeals process**

Your patient may need to appeal a plan exclusion denial if an Alternative Funding Program (AFP) is involved. Please see the sample AFP letter of appeal on page 13 for more information.

**Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.**

# Potential Levels of Appeal

**Every appeals process is different.** Here we've illustrated procedural steps that you may encounter when beginning a patient's appeal process. Keep in mind that SpringWorks CareConnections® can provide information on the appeals process if coverage, a prior authorization, or medical exception is denied.

## 1st Level

### LETTER OF APPEAL OR PEER TO PEER<sup>6</sup>

- A formal letter of appeal can be submitted to the health plan to overturn a denial
- Refer to the **Appeal Checklist on page 14** of this access toolkit
- A peer-to-peer conversation can also be pursued between the patient's healthcare provider and the medical director of the health insurance plan to explain why OGSIVEO® (nirogacestat) is the appropriate treatment option for their patient
- Refer to the **Peer-to-Peer Checklist on page 15** of this access toolkit

## 2nd Level

### INTERNAL MEDICAL DIRECTOR AT THE HEALTH PLAN REVIEW<sup>6,10</sup>

- If the first appeal is denied, another appeal letter and additional information can be sent directly to the patient's health insurance plan
- Each health insurance plan will have its own requirements for this process
- Refer to the **Appeal Checklist on page 14** of this access toolkit

## 3rd Level

### EXTERNAL INDEPENDENT REVIEW<sup>6,10,11</sup>

- When an internal appeal is denied, the formal denial letter will include information on how to begin the external review
- Information is sent to a third-party (or an Independent Review Organization) and they either approve or deny coverage for the prescribed care
- The health insurance plan may be required to accept the results of the external review

**Patients who are uninsured, underinsured, or lack coverage for OGSIVEO may be eligible to receive medication at no cost through the SpringWorks CareConnections Patient Assistance Program\***

\*Terms and conditions apply. Patient Assistance Program (PAP) eligibility criteria and annual household income limits apply. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

8 **Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.**

# Plan Exclusion, Alternative Funding Programs, and Patient Impact

## **Employers with self-funded plans may contract with AFPs to lower their costs for health insurance offered to employees.**

- They do this by excluding coverage for high-cost specialty medications and classifying them as “non-essential health benefits” simply to save money<sup>12,13</sup>
- Patients pay premiums for health insurance and think they have “good insurance” that will take care of their healthcare needs if they ever get sick but end up being denied coverage for specialty medications that they need
- When patients are denied coverage, they are then told to work with the AFP to try to get the medication through a manufacturer’s patient assistance program or other form of charitable assistance<sup>13</sup>
- These programs, however, are designed for patients who have a financial need and are truly uninsured, and have eligibility requirements that insured patients may not meet. While the intent is to provide these patients with a way to access their medication, many are not eligible to participate in assistance programs due to income or other requirements

**For patients who are impacted by AFPs,** they have the option of sending a letter to their company’s Human Resources (HR) contact and/or to their health insurance company asking for their support in appealing the decision to deny coverage.

- SpringWorks CareConnections® has sample letters with information patients can consider including in appeal letters to their employer and insurance company
- **Note:** the employer or insurance company may have specific requirements for documentation that should be included in an appeal

**See AFP sample letter of appeal on page 13.**

**If your patient receives a coverage denial for OGSIVEO and is directed to work with an AFP, contact SpringWorks CareConnections for available options and resources**

# Prior Authorization Tips and Checklist



## Prior Authorization Tips and Checklist

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are medically necessary and otherwise covered. This resource provides a checklist and relevant tips that may be useful when creating a letter of medical necessity or medical exception to support a prior authorization request. Use of the information in this checklist does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

- Complete a PA request form**
  - Complete and submit the PA request form to the insurer. Some plans accept a standardized PA form, while others require you to complete a form they provide. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.
- Compose a written letter demonstrating the medical necessity of the prescribed therapy** (ie, letter of medical necessity or medical exception)
  - Insurers may require a letter of medical necessity or medical exception. Even if it is not required, it can be helpful to describe the importance of the prescribed treatment. A sample letter of medical necessity or medical exception is available at [www.springworkstxcares.com/hcp/resources-forms](http://www.springworkstxcares.com/hcp/resources-forms). As a reminder, the sample letter only serves as a guide. As the patient's healthcare provider, you can modify the content based on your medical judgment or you can write your own letter if the insurer does not require a specific form.
- Provide a copy of the patient's records and ensure there is a valid OGSIVEO® (nirogacestat) prescription**
  - Remember to provide copies of relevant patient records (eg, charts, test results), including a valid prescription for OGSIVEO. OGSIVEO is indicated for adult patients with progressing desmoid tumors who require systemic treatment.<sup>1</sup>
- Provide identification number(s) and *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code(s)***
  - Indicate the individual provider ID number versus the group practice/facility provider ID number on the prescription form.
  - As of October 1, 2023, location-specific ICD-10-CM diagnosis codes for desmoid tumors are available.<sup>2,3</sup>
- Provide additional supporting documentation**
  - All supporting documents required by the specific insurer should be submitted with the PA request. Commonly required documents include:
    - Patient authorization and notice of release of information
    - Copy of the patient's health plan or prescription card (front and back)
    - Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
    - Additional test results related to patient's desmoid tumor diagnosis
    - OGSIVEO supporting documentation (eg, Prescribing Information, published clinical studies)
    - Clinical practice guidelines
- Follow up as needed**
  - Follow up with your patient's health plan if you have not received a decision in 5-7 days.
- Reauthorization requirements**
  - Remember to confirm reauthorization requirements specific to your patients' health plans. Certain plans may require reauthorization after 3, 6, or 12 months of use.

**Please see Indication and Important Safety Information for OGSIVEO on page 2, or [click here](#) for full Prescribing Information.**



Make sure to double check that the prior authorization request form is complete before submitting. Incomplete requests can lead to delayed coverage determination and postpone your patient's treatment initiation

Include the specific ICD-10-CM diagnosis code that notes the location of the patient's desmoid tumor

To access the OGSIVEO® (nirogacestat) Prior Authorization Tips and Checklist, please visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources).

# Sample Letter of Medical Necessity/Exception

## Sample Letter of Medical Necessity or Medical Exception for OGSIVEO® (nirogacestat)

For informational use only.

This is an example of a letter to a patient's insurance company supporting the medical necessity or medical exception for OGSIVEO. The information in this letter provides suggestions for the type of information to consider when a letter of medical necessity or medical exception is requested. Use of the information in this letter does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

[Date]

Attn: [Insert medical director's name]  
[Insert name of insurance company]  
[Insert street address]  
[Insert city, state, ZIP]

[Physician letterhead]

RE: [Insert patient name]  
DOB: [Insert patient's date of birth]  
Policy number: [Insert subscriber policy number]  
Group number: [Insert subscriber group number]

To whom it may concern:

I am writing on behalf of the above-mentioned patient, [insert patient name], to [document the medical necessity and support coverage for] [request a medical exception to cover] OGSIVEO® (nirogacestat). OGSIVEO is an oral gamma secretase inhibitor that is approved by the US Food and Drug Administration (FDA) for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.<sup>1</sup>

The efficacy and safety of OGSIVEO informing FDA approval was demonstrated in DeFi, a randomized, double-blind, placebo-controlled, Phase 3 trial in adult patients with progressing desmoid tumors.<sup>2</sup> OGSIVEO is currently the only FDA-approved therapy for the treatment of adults with progressing desmoid tumors who require systemic treatment. I have enclosed a copy of the OGSIVEO Prescribing Information for your reference.

In addition, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma recommend nirogacestat (OGSIVEO) as a NCCN Category 1 Preferred systemic therapy option for patients with desmoid tumors (aggressive fibromatosis).<sup>3</sup>

[Patient name] has been under my care since [date]. Treatment of [insert patient name] with OGSIVEO is medically appropriate and necessary and should be covered and reimbursed based on [insert patient name]'s medical history, diagnosis, and rationale for treatment, as detailed below.

- [Patient's diagnosis, date of diagnosis, ICD-10-CM diagnosis code(s), condition, and history]
- [Management/previous therapies used for treating the symptoms associated with the desmoid tumors]
- [Patient's response to these therapies, including reasons for discontinuation]
- [Brief description of the patient's recent symptoms and conditions]
- [Summary of your professional opinion of the patient's need for treatment]
- [Additional relevant, medically necessary clinical determinations]

[Consider using this paragraph to include additional clinical information that demonstrates progression of your patient's desmoid tumor(s), such as documented tumor growth on imaging, worsening of symptoms, impaired functioning in daily life.]

As you consider this request for coverage, please also refer to the enclosed materials for additional information.

[For ease of review, please see below for the location of each enclosure within the submission.]

[History of Desmoid Tumor Diagnosis]

- [Document name]
- [Document name]

[Document Page Number]

- [X]
- [X]

[Symptom Management/Previous Therapies Used]

- [Document name]
- [Document name]

[Document Page Number]

- [X]
- [X]

[Response to Previous Therapies Used]

- [Document name]
- [Document name]

[Document Page Number]

- [X]
- [X]

Include complete and accurate patient information including DOB, policy number, and group number

Include any prior treatments the patient has tried and failed

ICD-10-CM codes, description of current symptoms, and medical history should be included when possible

It can be useful to include evidence of desmoid tumor progression to support that OGSIVEO is medically appropriate and necessary for your patient

Supporting documentation like the OGSIVEO Prescribing Information and data from the DeFi clinical trial can provide additional support for coverage

To access the OGSIVEO® (nirogacestat) **Sample Letter of Medical Necessity**, please visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources).

# Sample Letter of Appeal

## Sample Letter of Appeal for OGSIVEO® (nirogacestat)

For informational use only.

This is an example of information that may be included in an appeal letter to a patient's insurance company. The information in this letter provides suggestions for the type of information to consider when a letter of appeal is appropriate. Use of the information in this letter does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

[Physician letterhead]

[Date]  
Attn: [Insert medical director's name]  
[Insert name of insurance company]  
[Insert street address]  
[Insert city, state, ZIP]

RE: [Insert patient name]  
DOB: [Insert patient's date of birth]  
Policy number: [Insert subscriber policy number]  
Group number: [Insert subscriber group number]  
Claim number: [Insert patient claim number]

To whom it may concern:

This letter serves as the [select one: 1st /2nd] appeal of the prior authorization denial for the treatment of my patient, [insert patient name], with OGSIVEO® (nirogacestat). I understand from your denial letter[s] dated [month, day, year] that the prior authorization for OGSIVEO has been denied because [quote denial reason as communicated in the denial letter]. After reviewing the letter[s], I maintain that OGSIVEO is the appropriate treatment for my patient for the reasons detailed below, including [insert patient's name]'s diagnosis and medical history.

- [Patient's diagnosis, date of diagnosis, ICD-10-CM diagnosis code(s), condition, and history]
- [Management/previous therapies used for treating the symptoms associated with the desmoid tumors]
- [Patient's response to these therapies, including reasons for discontinuation]
- [If plan includes language requiring a step edit prior to starting therapy with OGSIVEO, explain why step edit is not clinically warranted considering the FDA-approved indication for OGSIVEO]
- [Brief description of the patient's recent symptoms and condition]
- [Summary of your professional opinion of the patient's prognosis and need for treatment with OGSIVEO]
- [Insert any additional, relevant medically necessary clinical determinations]

[Some plans may request additional clinical information demonstrating progression of your patient's desmoid tumor[s]. Consider using this paragraph to describe your patient's tumor progression, such as documented tumor growth on imaging, worsening of symptoms, impaired functioning in daily life, or other evidence, based on your clinical discretion.]

### Treatment information

OGSIVEO is an oral gamma secretase inhibitor that is approved by the US Food and Drug Administration (FDA) for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.<sup>1</sup> OGSIVEO is currently the only FDA-approved therapy for the treatment of adults with progressing desmoid tumors who require systemic treatment.

The efficacy and safety of OGSIVEO informing FDA approval was demonstrated in DeFi, a randomized, double-blind, placebo-controlled study, and the largest completed Phase 3 trial in adult patients with desmoid tumors.<sup>2</sup>

In addition, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma recommend nirogacestat (OGSIVEO) as a NCCN Category 1 Preferred systemic therapy option for patients with desmoid tumors (aggressive fibromatosis).<sup>3</sup>

[For denials due to change in policy-required step edit through systemic therapy:]

- [I understand that the [Plan Name] Policy includes language requiring [a step edit] prior to starting therapy with OGSIVEO. [Please note, however, that the NCCN Guidelines® do not recommend prior use of sorafenib therapy before starting an adult patient with progressing desmoid tumors on nirogacestat (OGSIVEO).<sup>3</sup>] [In addition, the FDA-approved indication for OGSIVEO does not include a requirement of a prior systemic treatment.<sup>1</sup>]

[Consider inserting relevant treatment goals for your patient and including information that shows how OGSIVEO may help your patient achieve their particular treatment goals. Examples may include:]

- [The achievement of the primary (progression-free survival) and key secondary efficacy end point (objective response rate) in DeFi<sup>1,2</sup>
- Patient-reported outcome data (change in worst pain intensity) in DeFi<sup>1,2</sup>
- The availability of long-term efficacy and safety data from the post-hoc analysis data of DeFi<sup>4</sup>
- OGSIVEO has no boxed warning or contraindications<sup>1,2</sup>
- The NCCN Guidelines and Desmoid Tumor Working Group (DTWG) Guideline recommend initiating treatment for desmoid tumors in the presence of symptoms, tumor growth documented on imaging, or if the desmoid tumor is impairing or threatening in function<sup>3,5</sup>

The letter should be addressed to the contact given in the original denial, and the initial reason given for the denial

Include complete and accurate patient information

ICD-10-CM codes, description of current symptoms, and medical history should be included when possible

It can be useful to mention why step therapy, if applicable, is not appropriate for this patient given the FDA-approved indication for OGSIVEO and guideline recommendations for treatment

Include your contact information so the insurer can reach out with any questions

If your patient's coverage was denied due to an AFP, please see the AFP sample letter on page 13

To access the OGSIVEO Sample Letter of Appeal, please visit [springworkstxcare.com/ogsiveo/hcp/resources](http://springworkstxcare.com/ogsiveo/hcp/resources).

# Alternative Funding Program (AFP) Sample Letter

## Sample Letter of Appeal for OGSIVEO® (nirogacestat) to Health Plan Participating in an AFP

For informational use only.

This is an example of a letter of appeal to a patient's insurance company that participates in an Alternative Funding Program (AFP) and has denied coverage of OGSIVEO. The information in this letter provides suggestions for the type of information to consider including in a letter of appeal. Use of the information in this letter does not guarantee that the health plan will cover OGSIVEO, and it is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

[Physician letterhead]

[Date]

Attn: [Insert health insurance plan contact name]  
[Insert name of insurance company]  
[Insert street address]  
[Insert city, state, ZIP]

RE: [Insert Patient name]  
DOB: [Insert Patient date of birth]  
Policy number: [Insert subscriber policy number]  
Group number: [Insert subscriber group number]

[Health plan contact name],

I am writing on behalf of the above-mentioned patient, [insert patient name], to appeal the decision to deny coverage of OGSIVEO® (nirogacestat).

[Patient name] was diagnosed with desmoid tumor on [insert date], and I have prescribed OGSIVEO, a treatment that is medically appropriate and necessary for my patient. OGSIVEO is currently the only treatment approved by the US Food and Drug Administration for the treatment of adult patients with progressing desmoid tumors who require systemic therapy. Unfortunately, [health plan name] has denied coverage for this medication.

Since denying coverage, it appears that [health plan name] has directed [patient name] to an Alternative Funding Program (AFP) to try and obtain their OGSIVEO medication.

However, after applying through the manufacturer's Patient Assistance Program (PAP), my patient was notified on [insert date] that they did not meet the program eligibility requirements, and the application for PAP was denied. Additionally, [insert health plan name] is still refusing to cover my patient's OGSIVEO medication.

Since my patient is not eligible for the PAP and [insert health plan name] has denied coverage, they have no way of accessing their medication and cannot afford to pay out of pocket. Regulations at 45 CFR § 156.122(c) mandate that:

- A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (i.e., a request for exception);
- In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135; and
- The health plan must respond within 72 hours and if the medication is deemed medically necessary, the plan is required to cover the prescription for the duration of the plan year, including refills.

In review of the above and the information enclosed, I believe [insert conclusion regarding medical necessity for patient and lack of alternative access to OGSIVEO].

Sincerely,

[Insert physician's name]

- Enclosures: [clinical documentation, medical literature, patient coverage denial letter, patient PAP denial letter]

Include accurate and complete patient information, including diagnosis

Indicate that the patient's health plan directed your patient to try gaining coverage for their medication through an AFP

Mention that your patient is not eligible for the manufacturer's patient assistance program

Regulations can support the appeal for coverage if your patient has no way of accessing their medication. Include any that are relevant to your patient's situation

If your patient was denied coverage and instructed to work with an AFP, a patient-facing **Sample Letter to Health Insurance Company** is available and may be accessed by visiting [springworkstxcares.com/ogsiveo/patient/resources/](http://springworkstxcares.com/ogsiveo/patient/resources/)

To access the OGSIVEO **Sample Letter of Appeal to Health Plan Participating in an AFP**, please visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources).

# Appeal Tips and Checklist



## Appeal Tips and Checklist

### Filing an Appeal of Prior Authorization Denial

An appeal should be pursued if a patient's prior authorization for medication is denied. This resource provides a checklist and relevant tips that may be useful when creating an appeal letter. Use of the information in this checklist does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

- Understand the reason for denial**
  - While the reason for denial may often be included in the denial letter from the patient's health plan or the Explanation of Benefits, both of which can be obtained from the insurer, the specific reason for denial may sometimes be omitted. If a denial explanation is not included in the denial letter, inquire in writing as to the reason why the prior authorization request has been denied, including whether the plan is working with an Alternative Funding Program (AFP), and who the AFP is, if relevant. It is important to identify and/or correct the reason for denial to support coverage re-determination.
- Review the plan's appeals guidelines**
  - Contact the insurer to find out if the plan has a required appeal form, the deadline to submit an appeal, the timeline for review by the plan, the number of appeals permitted, and the fax number or address where the appeal should be sent. Also, inquire whether the appeal should be submitted by the patient or the healthcare provider and proceed accordingly.
    - It is helpful to communicate this information to the patient. Even if the healthcare provider submits the letter of appeal, the patient may also have an opportunity to write a supporting letter and may want to be aware of timelines
- Compose a written letter of appeal**
  - Insurers require a written appeal from either the patient or the healthcare provider. Sample letters of appeal for healthcare providers can be found at [www.springworkstxcares.com/hcp/resources-forms](http://www.springworkstxcares.com/hcp/resources-forms). As a reminder, the sample letters only serve as a guide. As the patient's healthcare provider, you can modify the content based on your medical judgment or you can write your own letter if the insurer does not require a specific form.
- Prepare an appeal package with additional supporting documentation**
  - A patient's appeal package should include all relevant medical documentation. Note that each appeal may need different information depending on the insurer and/or patient. Be sure to follow the requirements of the patient's insurer, as insurer requirements may vary. Common supporting documents in the appeals package include:
    - Statement of medical necessity (including patient DOB, insurance information, diagnosis)
    - Laboratory values and relevant medical data
    - Patient authorization and notice of release of information
    - Copy of the patient's health plan or prescription card (front and back)
    - Documentation of location-specific *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis code(s)
    - Denial information, including the patient's denial letter and/or Explanation of Benefits
    - Letter of appeal
    - Additional test results related to patient's condition
    - OGSIVEO® (nirogacestat) supporting documentation (eg, Prescribing Information, published clinical studies)
    - Clinical practice guidelines
- Follow up as needed**
  - Follow up with your patient's health plan if you have not received a decision in 5-7 days.

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Each health insurance plan may have their own requirements for the appeals process. You can contact the insurer to ask any questions about their appeals process

Be sure that all required information included in the appeal package is correct and complete. Including supporting documentation as part of the appeal package can help justify the clinical need for OGSIVEO during the appeal process

To access the OGSIVEO Appeal Tips and Checklist, please visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources).

# Peer-to-Peer Checklist



SpringWorks  
**CareConnections**  
844-CARES-55 (844-227-3755)  
Monday-Friday, 8 AM - 10 PM ET

## Peer-to-Peer Review Checklist

You can also visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources)

Scheduling a peer-to-peer review with the medical director at your patient's health plan may be useful when coverage for OGSIVEO® (nirogacestat) is denied under the plan's coverage policy. During the review, you will have the opportunity to explain your clinical rationale for prescribing OGSIVEO to your patient. This resource provides a checklist and relevant tips to help you prepare for and engage in a peer-to-peer discussion.

The information in this checklist does not guarantee that the health plan will accommodate a request for peer-to-peer review, or otherwise provide reimbursement, and it is not intended to be a substitute for your independent medical judgment. When completing any request, it is your responsibility as your patient's healthcare provider to adhere to the payer's specific requirements at that time.

**How to Prepare for Your Peer-to-Peer Meeting**

Follow the steps below to help get organized:

- Request to speak with a peer reviewer** within the same specialty
- Confirm the date and time** of the call
- Review the health plan's clinical policy** to determine if all the requirements have been met
- Gather all the documentation submitted** with the initial prior authorization (PA) to the health plan:
  - ✓ Valid prescription for OGSIVEO
  - ✓ Letter of medical necessity
  - ✓ Supporting documentation, which may include a copy of chart notes with details about the patient's diagnosis, current clinical status, laboratory values, treatment history, etc, and any literature that was provided
  - ✓ Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
- If an appeal was pursued**, be sure to gather denial letter(s) received from the health plan as well as your letter of appeal in response

**What to Expect During Your Peer-to-Peer Discussion**

Be prepared to discuss the following information:

- Applicable ICD-10-CM codes:**
  - ✓ For information on ICD-10-CM codes for desmoid tumors, visit [www.ogsiveo.com/files/download/Ogsiveo\\_ICD-10-CM\\_Code\\_Flashcard.pdf](http://www.ogsiveo.com/files/download/Ogsiveo_ICD-10-CM_Code_Flashcard.pdf)
- Information about OGSIVEO:**
  - ✓ **OGSIVEO indication**
  - ✓ **Recommended dosage of OGSIVEO**
  - ✓ **National Drug Code (NDC)** for dosage prescribed
  - ✓ **Why OGSIVEO is the appropriate treatment option** for your patient (eg, only FDA-approved targeted therapy for adult patients with progressing desmoid tumors who require systemic treatment, efficacy/safety profile, etc)<sup>1</sup>
- Literature supporting your decision** to prescribe OGSIVEO:
  - ✓ **Clinical trial publication for OGSIVEO**
  - ✓ **Peer-reviewed journal articles** (For the OGSIVEO Evidence Compendium, visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources))
- Clinical practice guidelines:**
  - The National Comprehensive Cancer Network (NCCN®) Guidelines** recommend nirogacestat (OGSIVEO) as a NCCN Category 1 systemic therapy option for patients with desmoid tumors<sup>2</sup>
- Next steps:**
  - ✓ **Confirm timing and approval** and note any required follow-up steps

**If the peer-to-peer discussion does not resolve the denial, an appeal should be pursued.**  
For a sample letter of appeal, appeals checklist, and other access resources, visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources)

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.  
Please see Important Safety Information on next page and [click here](#) for full Prescribing Information.



Scheduling a peer-to-peer review allows you to speak directly with the medical director at your patient's health plan

Before your call, gather all information needed to verify the date and time of the call

Be prepared to discuss information about OGSIVEO® (nirogacestat) literature that supports your decision, and potential next steps

If the peer-to-peer discussion does not resolve the denial, an appeal may be pursued

To access the OGSIVEO Peer-to-Peer Checklist, please visit [springworkstxcares.com/ogsiveo/hcp/resources](http://springworkstxcares.com/ogsiveo/hcp/resources).

# The Reauthorization Process

It is important to note that **most prior authorizations expire after 12 months.** When a prior authorization expires, you may need to request a renewal of their prior authorization. This is called a **reauthorization** or an authorization renewal.<sup>14</sup> **Delayed reauthorization can interrupt a patient's medication regimen.**

If you need to submit a reauthorization, check with the patient's health insurance plan to ensure all necessary paperwork is included and confirm if there are any associated time constraints.<sup>14</sup> The documentation may include lab values, imaging, or other documentation to support that the medication is effective for your patient, but always confirm specific reauthorization requirements with the individual plan.

It's important to **promptly submit reauthorization requests** when they're required. Reauthorization can help patients continue to access treatment as you've prescribed, without potential interruptions in coverage.

**SpringWorks CareConnections® provides personalized support services and resources to help your patients get started and stay on track with OGSIVEO® (nirogacestat).**



## Connections at each point of care with OGSIVEO

- Resources, education, and assistance to support timely access to OGSIVEO
- Dedicated team of Nurse Advocates who provide treatment support as it relates to your patient's condition can provide assistance to patients and caregivers throughout their treatment journey
- Field Access Managers can provide in-person or virtual support to help facilitate access to OGSIVEO by providing you and your office staff regional payor education and timely responses to questions

**Enrolling your patient in SpringWorks CareConnections is simple and Nurse Advocates are available to help**

Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information.

## INDICATION

OGSIVEO (nirogacestat) is indicated for adult patients with progressing desmoid tumors who require systemic treatment.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

- **Diarrhea:** Diarrhea, sometimes severe, can occur in patients treated with OGSIVEO. Diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.
- **Ovarian Toxicity:** Female reproductive function and fertility may be impaired in patients treated with OGSIVEO. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.
- **Hepatotoxicity:** ALT or AST elevations occurred in 30% and 33% of patients, respectively. Grade 3 ALT or AST elevations ( $>5 \times$  ULN) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as recommended.
- **Non-Melanoma Skin Cancers:** New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.
- **Electrolyte Abnormalities:** Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate  $<2$  mg/dL occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.
- **Embryo-Fetal Toxicity:** OGSIVEO can cause fetal harm when administered to pregnant women. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and death at maternal exposures below human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

### ADVERSE REACTIONS

- The most common ( $\geq 15\%$ ) adverse reactions were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).
- Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in  $\geq 2\%$  of patients were ovarian toxicity (4%).
- The most common laboratory abnormalities ( $\geq 15\%$ ) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

Please see additional Important Safety Information on page 18 and please [click here](#) for full Prescribing Information.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### DRUG INTERACTIONS

- **CYP3A Inhibitors and Inducers:** Avoid concomitant use with strong or moderate CYP3A inhibitors (including grapefruit products, Seville oranges, and starfruit) and strong or moderate CYP3A inducers.
- **Gastric Acid Reducing Agents:** Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO (nirogacestat) can be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).
- Consult the full Prescribing Information prior to and during treatment for important drug interactions.

### USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

**To report SUSPECTED ADVERSE REACTIONS, contact SpringWorks Therapeutics, Inc. at 1-888-400-7989 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**



**For eligible patients experiencing coverage delays or interruptions, SpringWorks CareConnections® temporary free medication programs may help.**



**Health insurance plans may have different coverage policies for OGSIVEO® (nirogacestat) and may require specific paperwork. SpringWorks CareConnections can help navigate this process.**



**Filling out all paperwork correctly and accurately can help to avoid unnecessary delays in patient access to OGSIVEO.**

**Call SpringWorks CareConnections today at 844-CARES-55 (844-227-3755), Monday-Friday, 8 AM-10 PM ET, or visit [springworkstxcares.com/ogsiveo/hcp](https://springworkstxcares.com/ogsiveo/hcp)**

**References:** **1.** Popatia S, Flood KS, Golbari NM, et al. Examining the prior authorization process, patient outcomes, and the impact of a pharmacy intervention: a single-center review. *J Am Acad Dermatol.* 2019;81(6):1308-1318. doi:10.1016/j.jaad.2019.05.024 **2.** Drug plan coverage rules. Medicare.gov. Accessed July 1, 2025. <https://www.medicare.gov/health-drug-plans/part-d/what-plans-cover/plan-rules> **3.** Filing a formulary exception. Patient Advocate Foundation. Accessed July 1, 2025. <https://www.patientadvocate.org/wp-content/uploads/Filing-a-Formulary-Exception-1.pdf> **4.** Wilkinson DJC. What is 'medical necessity'? *Clinical Ethics.* 2023;18(3):285-286. doi:10.1177/14777509231190521 **5.** Medically necessary. Healthcare.gov. Accessed July 1, 2025. <https://www.healthcare.gov/glossary/medically-necessary/> **6.** Engaging with insurers: appealing a denial. Patient Advocate foundation. Accessed July 1, 2025. <https://www.patientadvocate.org/wp-content/uploads/Navigating-the-insurance-appeals-guide-pages-1.pdf> **7.** Wilson D. Categorization of pediatric denial types. American College of Physician Advisors. Accessed July 1, 2025. <https://www.acpadvisors.org/a-primer-on-denials> **8.** Reiner G, Bird S. 4 Clinical reasons for denials. HFMA.org. Published November 2, 2018. Accessed July 1, 2025. <https://www.hfma.org/revenue-cycle/denials-management/62347/> **9.** OGSIVEO. Prescribing Information. SpringWorks Therapeutics, Inc. **10.** Appealing a health plan decision. Healthcare.gov. Accessed July 1, 2025. <https://www.healthcare.gov/appeal-insurance-company-decision/appeals/> **11.** Has your health insurer denied payment for a medical service? You have a right to appeal. Centers for Medicare & Medicaid Services. Accessed July 1, 2025. <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/appeals06152012a> **12.** Alternative funding programs. Know your rights. A resource for consumers, caregivers, and health care providers. AimeAlliance.org. Accessed July 1, 2025. <https://aimedalliance.org/wp-content/uploads/2023/12/AA-KnowYourRights-AltFunding-FINAL-2023.pdf> **13.** The high costs of alternative funding programs. Alliance for Patient Access. Accessed July 1, 2025. [https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA\\_High-Costs-of-Alternative-Funding-Programs\\_June-2023.pdf](https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA_High-Costs-of-Alternative-Funding-Programs_June-2023.pdf) **14.** Levine H. Prior authorization: what is it, when might you need it, and how do you get it? Harvard Health Publishing. Published August 5, 2024. Accessed July 1, 2025. <https://www.health.harvard.edu/staying-healthy/prior-authorization-what-is-it-when-might-you-need-it-and-how-do-you-get-it#>

**Please see Important Safety Information on pages 17 and 18 and [click here](#) for full Prescribing Information including Patient Information and Instructions for Use.**