**The sample letter provided on the next page can be used to communicate to your health insurance company that:**

1. You have been prescribed OGSIVEO® (nirogacestat) by your healthcare provider
2. Your health insurance plan through the employer has denied coverage of OGSIVEO
3. Your health insurance plan directed you to an Alternative Funding Program (AFP) to obtain OGSIVEO, and
4. The AFP instructed you to enroll in the manufacturer's patient assistant program (PAP)
5. You were notified that you are not eligible to participate in the manufacturer's PAP because you do not meet the requirements
6. You have no way of accessing the medication that has been prescribed to you
7. You are requesting that they override the denial and approve coverage for OGSIVEO

**We encourage you to follow the steps above so that you can access your medication.**

**Here Are Some Tips for Submitting a Letter to Your Health Insurance Company:**

* You may consider first contacting your human resources (HR) department to request that they override the
plan’s decision to deny coverage of OGSIVEO. You can download a “**Sample Letter to Employer Regarding
OGSIVEO® (nirogacestat) Coverage Denial**” at springworkstxcares.com/patient/resources to help you write this communication
* Please make sure to always contact your health insurance company to understand the appeal process and any requirements for appealing a denial
* You can use the letter on the next page to start a patient-led appeal to your health insurance plan
* For your letter to the health insurance plan, be sure to obtain and include the name(s) of the intended recipient(s), if possible, do not include a generic salutation, such as “To Whom It May Concern”
* If you prefer to send the letter electronically, remember to copy your employer’s HR contact on the email, or request to be copied on the communication if they are submitting a letter on your behalf
* Provide supporting documents with the letter that describe your diagnosis and treatment plan
* Once you have sent the letter to the health insurance plan, consider following up with a phone call to confirm receipt and document who you spoke to
* Contact your healthcare provider to inform them that you have submitted an appeal to your health insurance plan and request that they provide the health insurance plan with any additional information in support of the appeal

**Sample Letter of Reconsideration for OGSIVEO® (nirogacestat) Coverage Denial**

For informational use only.

**Please note:** The information in this letter provides suggestions for the type of information to consider including when a patient-led appeal of a coverage denial may be warranted. Use of this letter does not guarantee that your health insurance company will approve your request for coverage for OGSIVEO. However, it may present an opportunity to provide additional context and rationale to the plan for further consideration. You should always defer to any requirementsfor submittingappeals that are established by your health plan. Nothing in this letter is intended to substitute your prescriber's independent clinical decision making. This letter is intended to be used by adult patients with progressing desmoid tumors who require systemic therapy and have been prescribed OGSIVEO.

[Date]

Attn: [Insert health insurance plan contact name] RE: [Insert your name]

[Insert name of insurance company] DOB: [Insert your date of birth]

[Insert street address] Policy number: [Insert subscriber policy number]

[Insert city, state, ZIP] Group number: [Insert subscriber group number] Prescriber name: [Insert prescriber name]

 Prescriber address: [Insert prescriber address]

 Prescriber phone: [Insert prescriber phone #]

Dear [Health insurance plan contact name],

My name is [insert full name] and I am currently under the care of [Healthcare provider name] for desmoid tumor[s]. I was diagnosed with [a] desmoid tumor[s][on/in my (location of tumor)] [length of time since diagnosis] ago, and my doctor prescribed OGSIVEO® (nirogacestat), which is currently the only treatment approved by the US Food and Drug Administration for my condition.

On [insert date] I was notified that [Health insurance plan name] has denied coverage of my prescription for OGSIVEO and they have directed me to an Alternative Funding Program (AFP) to try to obtain the medication. Per the mandated process, I applied to the manufacturer patient assistance program (PAP) to try and access OGSIVEO.

However, on [insert date], I was notified that I was not eligible for the manufacturer PAP and my application for the PAP was denied. Additionally, [insert health insurance plan name] is still refusing to cover my medication. Per my physician, OGSIVEO has been prescribed to treat my desmoid tumor. Since I am not eligible for the PAP and [insert health insurance plan name] has denied coverage, I have no way of accessing the 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 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 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.

[OPTIONAL: To the extent you are comfortable sharing this information with your health insurance plan, insert a sentence about why taking OGSIVEO is important to you]. As you consider this request for coverage, please also refer to the enclosed materials for additional information. My healthcare provider may also reach out to share additional information.

Please contact me at [contact information such as phone number or email address] if you need any additional information. Thank you in advance for your help. I look forward to your timely response and coverage determination that provides me access to the medication I need.

Sincerely,

[Insert your name]

Enclosures: [If possible, include denial letter[s], proof of diagnosis from prescriber, OGSIVEO Prescribing Information, which can be found at https://springworkstx.com/wp-content/uploads/2023/11/OGSIVEO-US-Prescribing-Information-11.27.23.pdf, and any other information that supports your request, and any other information that supports your request]

**What is OGSIVEO?**

OGSIVEO is a prescription medication used to treat adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy). It is not known if OGSIVEO is safe and effective in children.

**IMPORTANT SAFETY INFORMATION**

**Before taking OGSIVEO tell your healthcare provider about all of your medical conditions, including if you:**

* Have liver problems.
* Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment.

**Females who are able to become pregnant:**

* Your healthcare provider will give you a pregnancy test before you start treatment with OGSIVEO.
* You should use effective birth control during treatment and for 1 week after the last dose. Talk to your healthcare provider about methods that may be right for you.
* Stop taking OGSIVEO and tell your healthcare provider right away if you become pregnant.

**Males** with female partners who are able to become pregnant should use effective birth control during treatment with OGSIVEO and for 1 week after the last dose.

* Are breastfeeding or plan to breastfeed. It is not known if OGSIVEO passes into your breast milk. Do not breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

You should avoid taking proton pump inhibitors (PPIs) and H2 blockers during treatment with OGSIVEO. Ask your healthcare provider if you are not sure if you take one of these medicines.

**How should I take OGSIVEO?**

* Take OGSIVEO exactly as your healthcare provider tells you to take it.
* Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO if you develop side effects.
* Take OGSIVEO 2 times a day with or without food.
* Swallow OGSIVEO tablets whole. Do not break, crush, or chew.
* If you take an antacid medicine, take OGSIVEO 2 hours before or 2 hours after the antacid.
* If you vomit after taking a dose or miss a dose of OGSIVEO, take your next dose at your regular time. Do not take 2 doses of OGSIVEO to make up the dose.

**What should I avoid while taking OGSIVEO?**

Avoid eating or drinking grapefruit products, Seville oranges, and starfruit during treatment with OGSIVEO.

**What are the possible side effects of OGSIVEO?**

OGSIVEO can cause serious side effects, including:

* **Diarrhea.** Diarrheais common with OGSIVEO and may sometimes be severe. Your healthcare provider may tell you to drink more fluids or to take antidiarrheal medicines. Tell your healthcare provider right away if you have diarrhea that lasts longer than a few days and does not get better after taking antidiarrheal medicines.
* **Ovarian problems.** Females who are able to become pregnant may have ovarian problems and changes in their menstrual cycle during treatment. OGSIVEO may affect fertility which may affect your ability to have a child. Tell your healthcare provider if you have any changes in your menstrual cycle or hot flashes, night sweats, or vaginal dryness during treatment.
* **Liver problems.** OGSIVEO can increase liver enzymes. Your healthcare provider will do blood tests to check your liver function before you start and during treatment with OGSIVEO.
* **New non-melanoma skin cancers.** Your healthcare provider will do skin exams before and during treatment with OGSIVEO if you are at risk for skin cancer. Tell your healthcare provider if you have any new or changing skin lesions.
* **Electrolyte (salt) problems.** Your healthcare provider will do blood tests to check your phosphate and potassium levels during treatment and may give you medicines to treat low phosphate or low potassium if needed. Tell your healthcare provider if you develop any muscle pain or weakness.

Tell your healthcare provider right away if you have any side effect that bothers you or that does not go away. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO.

**The most common side effects of OGSIVEO are:**

|  |  |
| --- | --- |
| * rash
* nausea
* tiredness
* mouth sores
* headache
 | * stomach (abdominal) pain
* cough
* hair loss
* upper respiratory infection
* shortness of breath
 |

OGSIVEO can affect fertility in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**Please** [**click here**](https://www.springworkstx.com/ogsiveo-prescribing-information) **for full Prescribing Information.**

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