**The sample letter provided on the next page can be used to communicate to your employer's human resources (HR) department contact 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
4. The AFP instructed you to enroll in the manufacturer's patient assistance 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 Writing a Letter to Your HR Department:**

* Contact your employer or health insurance plan administrator to understand the appeal process in place and any requirements for appealing a coverage denial
* Develop an outline. Determine the requirements for appealing a coverage denial and think about how you will address each point
* Clearly explain why you are writing the letter and express the challenges you are facing because you have been denied coverage and are not eligible for patient assistance program support
* Collect supporting documentation that you are comfortable sharing with your HR department, such as a copy of your insurance card, paperwork from your doctor’s office explaining your diagnosis and your doctor’s decision to prescribe OGSIVEO, a copy of your denial letter from the health insurance plan, OGSIVEO Prescribing Information, etc., and submit it with the letter
* After explaining the reason for your appeal, request that your employer override the health insurance plan’s decision to deny coverage of your medication
* You may also consider submitting a patient-led appeal to the health insurance plan. For a sample appeal letter to
your health plan, and for tips to submit the appeal, refer to the “Sample Letter of Reconsideration for
OGSIVEO® (nirogacestat) Coverage Denial” found at springworkstxcares.com/patient/resources

**Sample Letter to Employer Regarding 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 in a communication to the HR contact at your employer regarding a coverage denial of OGSIVEO. Use of this letter does not guarantee that your insurance company will approve your request for coverage. However, it may present an opportunity to provide additional context and rationale to your employer for reconsideration of coverage. You should always defer to any requirementsfor submittingappeals that are established by your employer or 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.

To: [Insert HR contact email]

Subject line options:

* [TIME SENSITIVE: Health Insurance Coverage Policy Request]
* [IMPORTANT: Regarding Health Insurance Coverage Policy]
* [IMPORTANT: Regarding Appeal of Coverage Denial]

Dear [HR contact name]:

My name is [Insert full name] and I am writing to request reconsideration of the decision to deny coverage for OGSIVEO® (nirogacestat) for the treatment of my desmoid tumor[s]. As you may be aware, I receive my healthcare benefits through [Insert health insurance plan name]. On [insert date], I was diagnosed with a desmoid tumor and was prescribed OGSIVEO by my healthcare provider.

On [insert date] I was notified that [insert 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 obtain the medication.

However, on [insert date], I was notified that I am 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 the health plan 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 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.

OGSIVEO is currently the only FDA-approved therapy for the treatment of my condition. I am seeking your support in overriding the decision to deny coverage for OGSIVEO. [OPTIONAL: To the extent you are comfortable sharing this information with your employer, insert a sentence about why taking OGSIVEO is important to you].

In summary, I would greatly appreciate your assistance in overriding the coverage denial from [Insert health insurance plan name] and requesting that they approve coverage for this medication that my doctor has deemed medically necessary.

As you consider this request, please also refer to other enclosed materials for more context. Please feel free to contact me at [Insert phone number or email address] for any additional information. I look forward to receiving your timely response, and your support in helping me access the medication I need.

Sincerely,
[Insert your name]

Enclosures: [If possible, include denial letter[s], copy of insurance and/or Rx benefits card, 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]

**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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