**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] RE: [Insert Patient name]

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

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

[Insert city, state, ZIP] 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 OGSEVEO 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]

**Indication**

OGSIVEO 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 × 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 (≥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 ≥2% of patients were ovarian toxicity (4%).
* The most common laboratory abnormalities (≥15%) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

**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 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.

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

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