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

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.

For informational use only.

[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, describe circumstances why step edit is not clinically warranted]
* [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 radiographic imaging (eg, MRI or CT), worsening of symptoms, impaired functioning in daily life, or other evidence, based on your clinical discretion.]

**Treatment information**

OGSIVEOis an oral gamma secretase inhibitor that was approved by the US Food and Drug Administration (FDA) for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.1 OGSIVEO is currently the only FDA-approved therapy for the treatment of adults with progressing desmoid tumors. The efficacy and safety of OGSIVEOinforming FDA approval was demonstrated in DeFi, a randomized, double-blind, placebo-controlled, Phase 3 trial in adult patients with desmoid tumors.2 In DeFi, OGSIVEO demonstrated a manageable safety profile. Most (95%) adverse events were grade 1 or 2.2 The most frequent adverse reactions reported with OGSIVEO (>50%) were diarrhea, ovarian toxicity, rash, nausea, and fatigue. OGSIVEO has no boxed warning or contraindications.1,2

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).3

[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).3 In addition, the FDA-approved indication for OGSIVEO does not include a requirement of a prior systemic treatment.1]

As you consider this request for coverage, please also review the information below that further supports the use of OGSIVEO for [insert patient name]:

[Insert relevant treatment goals for your patient and include information that shows how OGSIVEO may help your patient achieve their particular treatment goals (ex, PFS, ORR, Pain, overall quality of life, etc).]

OGSIVEO provides the only FDA-approved treatment for adult patients with progressing desmoid tumors who require systemic treatment.

Please also refer to the enclosed materials for additional information. Feel free to contact me, [insert physician name], at [insert office phone number], for any additional information you may require. I look forward to receiving your timely response and coverage determination.

Sincerely,

[Insert physician’s name]

* Enclosures: [List enclosures such as: OGSIVEO Prescribing Information, published data (eg, the pivotal phase 3 trial, Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-Secretase Inhibitor for Desmoid Tumors. *N Engl J Med*. 2023;388(10):898-912.), clinical notes/medical records, test results, clinical practice guidelines, scans showing disease activity and progression, patient authorization and notice of release information, copy of the patient’s health plan or prescription card (front and back)].

NCCN=National Comprehensive Cancer Network® (NCCN®)

**References: 1.** OGSIVEO. Prescribing Information. SpringWorks Therapeutics, Inc. **2.** Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388(10):898-912. doi:10.1056/NEJMoa2210140 **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed October 9, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

**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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