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

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.

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]

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). 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

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 progressing desmoid tumors.2 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).3

[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 radiographic imaging (eg, MRI or CT), 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. Please 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 (such as the pivotal phase 3 trial), clinical notes/medical records, test results, clinical practice guidelines, scans showing disease activity and progression, patient authorization and notice of release of 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.1.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 2, 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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