SpringWorks CareConnections®
844-CARES-55 (844-227-3755)
Monday-Friday, 8 AM - 10 PM ET

Peer-to-Peer Review Checklist

You can also visit springworkstxcares.com/ogsiveo/hcp/resources

Scheduling a peer-to-peer review with the medical director at your patient's health plan may be useful when coverage for OGSIVEO® (nirogacestat) is denied under the plan's coverage policy. During the review, you will have the opportunity to explain your clinical rationale for prescribing OGSIVEO to your patient. This resource provides a checklist and relevant tips to help you prepare for and engage in a peer-to-peer discussion.

The information in this checklist does not guarantee that the health plan will accommodate a request for peer-to-peer review, or otherwise provide reimbursement, and it is not intended to be a substitute for your independent medical judgment. When completing any request, it is your responsibility as your patient's healthcare provider to adhere to the payer's specific requirements at that time.

How to Prepare for Your Peer-to-Peer Meeting

Follow the steps below to help get organized:

- ☐ **Request to speak with a peer reviewer** within the same specialty
- ☐ **Confirm the date and time** of the call
- ☐ **Review the health plan's clinical policy** to determine if all the requirements have been met
- ☐ **Gather all the documentation submitted** with the initial prior authorization (PA) to the health plan:
  - ✓ Valid prescription for OGSIVEO
  - ✓ Letter of medical necessity
  - ✓ Supporting documentation, which may include a copy of chart notes with details about the patient's diagnosis, current clinical status, laboratory values, treatment history, etc, and any literature that was provided
  - ✓ Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
- ☐ **If an appeal was pursued,** be sure to gather denial letter(s) received from the health plan as well as your letter of appeal in response

What to Expect During Your Peer-to-Peer Discussion

Be prepared to discuss the following information:

- ☐ **Applicable ICD-10-CM codes:**
  - ✓ For information on ICD-10-CM codes for desmoid tumors, visit www.ogsiveo.com/files/download/Ogsiveo_ICD-10-CM_Code_Flashcard.pdf
- ☐ **Information about OGSIVEO:**
  - ✓ **OGSIVEO indication**
  - ✓ **Recommended dosage of OGSIVEO**
  - ✓ **National Drug Code (NDC)** for dosage prescribed
  - ✓ **Why OGSIVEO is the appropriate treatment option** for your patient (eg, only FDA-approved targeted therapy for adult patients with progressing desmoid tumors who require systemic treatment, efficacy/safety profile, etc)[1]
- ☐ **Literature supporting your decision** to prescribe OGSIVEO:
  - ✓ **Clinical trial publication for OGSIVEO**
  - ✓ **Peer-reviewed journal articles** (For the OGSIVEO Evidence Compendium, visit springworkstxcares.com/ogsiveo/hcp/resources)
- ☐ **Clinical practice guidelines:**

  The National Comprehensive Cancer Network (NCCN®) Guidelines recommend nirogacestat (OGSIVEO) as a NCCN Category 1 systemic therapy option for patients with desmoid tumors[2]
- ☐ **Next steps:**
  - ✓ **Confirm timing and approval** and note any required follow-up steps

If the peer-to-peer discussion does not resolve the denial, an appeal should be pursued.
For a sample letter of appeal, appeals checklist, and other access resources, visit springworkstxcares.com/ogsiveo/hcp/resources

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification.*

Please see Important Safety Information on next page and click here for full Prescribing Information.

Ogsiveo® (nirogacestat)
150 mg & 100 mg tablets

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 for full Prescribing Information.

References: 1. OGSIVEO. Prescribing Information. SpringWorks Therapeutics, Inc. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed November 6, 2025. To view the most recent and complete version of the guideline, go online to www.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.

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