SpringWorks CareConnections™

Prior Authorization Tips and Checklist

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are medically necessary and otherwise covered. This resource provides a checklist and relevant tips that may be useful when creating a letter of medical necessity or medical exception to support a prior authorization request. Use of the information in this checklist does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for 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.

☐ Complete a PA request form

- Complete and submit the PA request form to the insurer. Some plans accept a standardized PA form, while others require you to complete a form they provide. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.

☐ Compose a written letter demonstrating the medical necessity of the prescribed therapy (ie, letter of medical necessity or medical exception)

- Insurers may require a letter of medical necessity or medical exception. Even if it is not required, it can be helpful to describe the importance of the prescribed treatment. A sample letter of medical necessity or medical exception is available at **www.springworkstxcares.com/hcp/resources-forms**. As a reminder, the sample letter only serves as a guide. As the patient's healthcare provider, you can modify the content based on your medical judgment or you can write your own letter if the insurer does not require a specific form.

☐ Provide a copy of the patient's records and ensure there is a valid OGSIVEO® (nirogacestat) prescription

- Remember to provide copies of relevant patient records (eg, charts, test results), including a valid prescription for OGSIVEO. OGSIVEO is indicated for adult patients with progressing desmoid tumors who require systemic treatment.[1]

☐ Provide identification number(s) and *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis code(s)

- Indicate the individual provider ID number versus the group practice/facility provider ID number on the prescription form.
- As of October 1, 2023, location-specific ICD-10-CM diagnosis codes for desmoid tumors are available.[2,3]

☐ Provide additional supporting documentation

- All supporting documents required by the specific insurer should be submitted with the PA request. Commonly required documents include:
  - Patient authorization and notice of release of information
  - Copy of the patient's health plan or prescription card (front and back)
  - Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
  - Additional test results related to patient's desmoid tumor diagnosis
  - OGSIVEO supporting documentation (eg, Prescribing Information, published clinical studies)
  - Clinical practice guidelines

☐ Follow up as needed

- Follow up with your patient's health plan if you have not received a decision in 5-7 days.

☐ Reauthorization requirements

- Remember to confirm reauthorization requirements specific to your patients' health plans. Certain plans may require reauthorization after 3, 6, or 12 months of use.

Please see Indication and Important Safety Information for OGSIVEO on page 2, or 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.** Centers for Medicare & Medicaid Services 2024 ICD-10-CM codes. Centers for Medicare & Medicaid Services website. Accessed March 26, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **3.** Desmoid Tumor Research Foundation. New ICD-10-CM diagnosis codes for desmoid tumors. Accessed March 26, 2024. https://dtrf.org/icd-codes-and-desmoid-tumors/

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