

Nirogacestat (OGSIVEO)

Criteria for Use

February 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive nirogacestat.

- Severe renal impairment (e.g. eGFR \leq 40 ml/min/1.73m²)
- Severe hepatic impairment (e.g. Child-Pugh Class C)
- Unmanageable drug-drug interactions (e.g. concomitant CYP3A inhibitors/inducers, proton pump inhibitors, etc.)
- Active or uncontrolled infection
- Known pregnancy
- Lactation

Inclusion Criteria

All of the following criteria must be met.

- Diagnosis of progressive desmoid tumor.
- Progressive disease or unmanageable toxicity from prior treatment with a tyrosine kinase inhibitor (e.g. sorafenib or pazopanib), unless contraindicated.
- Care is provided by a VA/VA Community Care hematology/oncology provider.
- Goals of care and role of Palliative Care consult have been discussed and documented.
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2.

Additional Inclusion Criteria *if applicable*

- For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits, the use of effective contraception and avoid breastfeeding during therapy and for 1 week after stopping treatment.

Other Justification

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