

Applicable Drugs: Ogsiveo (nirogacestat)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/14/2024

Date Last Reviewed / Revised: 11/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:
FDA-approved indication
 - A. Desmoid tumor
 - i. Histologically-confirmed diagnosis of progressing desmoid tumors, defined as a $\geq$ 20% progression according to the Response Evaluation Criteria in Solid Tumors (RECIST) criteria in the past 12 months.
 - ii. Baseline liver function and comprehensive metabolic panel results (from within the last 12 months).
 - iii. Clinical documentation from physician that systemic treatment is required.
 - iv. For females of childbearing age, a recent negative pregnancy test and a documented contraceptive plan must be provided.
 - v. Age $\geq$ 18 years old
- II. Treatment must be prescribed by or in consultation with an oncologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- History of ALT or AST increase $>$ 5x ULN (Grades 3 or 4) while treated with nirogacestat.
- Pregnancy or breastfeeding.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Sixty (60) 150 mg tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 1 year, an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Ogsiveo. Prescribing Information. SpringWorks Therapeutics, Inc.; 2024. Accessed August 21, 2025. <https://springworkstx.com/wp-content/uploads/2024/04/OGSIVEO-US-Prescribing-Information-04.04.24.pdf>
2. Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer*. 2009;45(2):228-247. doi: 10.1016/j.ejca.2008.10.026
3. 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
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 1.2025. Updated May 2, 2025. Accessed September 22, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.