

Generic Name: Nirogacestat

Applicable Drugs: Ogsiveo®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/14/2024

Date Last Reviewed / Revised: 10/14/2024

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of progressing desmoid tumors AND must meet criteria listed:
 - A. Age \geq 18 years old
 - B. 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.
 - C. Baseline liver function and comprehensive metabolic panel results (from within the last 12 months).
 - D. For females of childbearing age, a recent negative pregnancy test and a documented contraceptive plan must be provided.
- II. Prescriber is an oncologist.
- III. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

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

- One hundred and eighty (180) 50 mg tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months

- **Re-Authorization:** 1 year, with updated progress notes or letter of medical necessity showing improvement or maintenance with the medication with acceptable toxicity.

APPENDIX

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REFERENCES

1. Ogsiveo®. Prescribing Information. SpringWorks Therapeutics, Inc.; April 2024. Accessed August 29, 2024. <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. Soft Tissue Sarcoma (Version 2.2024). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 29, 2024.

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.