

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Ogsiveo (nirogacestat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ogsiveo, approved by the FDA in 2023, is a gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors (DT) who require systemic treatment. It is the first treatment approved for this indication. Ogsiveo acts by blocking activation of the Notch receptor.

Desmoid tumors, also referred to as aggressive fibromatosis, are rare, locally invasive, slow growing soft tissue tumors. Although considered benign because of their inability to metastasize, desmoid tumors can cause significant morbidity. In the Phase 3 DeFi trial, Ogsiveo showed a 71% decrease in the risk of disease progression or mortality compared to a placebo.

Ogsiveo (nirogacestat) will be considered for coverage when the following criteria are met:

Desmoid Tumors

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist/oncologist; AND
3. Member has a confirmed diagnosis of progressing desmoid tumor requiring systemic therapy; AND
4. Tumor has progressed by 20% or more over the last 12 months.
5. **Dosage allowed/Quantity limit:** 150 mg (3 tablets) orally twice daily until disease progression or unacceptable toxicity. QL: 180 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as radiographic stabilization or reduction in tumor volume, decreased pain, or improved physical functioning.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ogsiveo (nirogacestat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/18/2023	New policy for Ogsiveo created.

References:

1. Ogsiveo [prescribing information]. SpringWorks Therapeutics, Inc.; 2023.
2. 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
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed December 21, 2023.
4. Desmoid Tumor Working Group. The management of desmoid tumours: A joint global consensus-based guideline approach for adult and paediatric patients. *Eur J Cancer*. 2020;127:96-107. doi:10.1016/j.ejca.2019.11.013
5. Zhou MY, Bui NQ, Charville GW, Ghanouni P, Ganjoo KN. Current management and recent progress in desmoid tumors. *Cancer Treat Res Commun*. 2022;31:100562. doi:10.1016/j.ctarc.2022.100562
6. Loong HH, Gupta A, Gronchi A. NIRO or No-go? Positioning a Novel Systemic Treatment Option for Desmoid Tumours. *Ann Surg Oncol*. 2023;30(5):2570-2573. doi:10.1245/s10434-022-12924-z

Effective date: 07/01/2024

Revised date: 12/18/2023