PHARMACY POLICY STATEMENT
Marketplace

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

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).