

Commercial PA Criteria Effective: December 18, 2023

Prior Authorization: Ogsiveo (nirogacestat)

Products Affected: Ogsiveo (nirogacestat) oral tablets

<u>Medication Description</u>: Nirogacestat is a gamma-secretase inhibitor that blocks proteolytic activation of the Notch receptor. When dysregulated, Notch can activate pathways that contribute to tumor growth. Gamma-secretase inhibitors, such as nirogacestat, impair Notch signaling through selective inhibition of gamma-secretase-mediated cleavage of Notch receptors and in studies have shown to prevent the release of the Notch intracellular domain

Covered Uses: adult patients with progressing desmoid tumors who require systemic treatment.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an oncologist

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

- 1. Desmoid Tumors (Aggressive Fibromatosis). Approve if the patient meets the following:
 - A. According to the prescriber, the patient has progressing desmoid tumors; AND Note: Progressing desmoid tumors are defined as ≥ 20% progression within 12 months.
 - B. The desmoid tumors are not amenable to surgery; AND
 - C. According to the prescriber, the patient requires systemic treatment.

References:

 Product Information: OGSIVEO™ oral tablets, nirogacestat oral tablets. SpringWorks Therapeutics, Inc. (per FDA), Stamford, CT, 2023.

Policy Revision history

Rev#	Type of Change	Summary of Change	Sections Affected	Date



1	New Policy	New Policy	All	12/18/2023
2	Annual Review	No criteria changes	All	5/14/2024