PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ogsiveo Prior Authorization Policy
- Ogsiveo™ (nirogacestat tablets – SpringWorks Therapeutics)

REVIEW DATE: 11/29/2023; selected revision 01/03/2024

OVERVIEW

Ogsiveo, a gamma secretase inhibitor, is indicated for **progressing desmoid tumors** that require systemic treatment in adults.[1]

Disease Overview

Desmoid tumors, or aggressive fibromatosis, are rare soft-tissue tumors.[2] These types of tumors are locally aggressive and invasive, leading to morbidity, but rarely mortality. Desmoid tumors are not metastatic tumors. The enlarged size of some of the tumors can lead to compression of vital structures, resulting in severe pain, functional impairment, nerve damage, and bowel obstruction or perforation. Pain is associated with disease progression and can lead to opioid dependence or suboptimal pain management due to the concern for opioid dependence. Surgery used to be the mainstay of treatment; however, due to high morbidity and postsurgical recurrence rates of up to 50% to 88%, it is used less frequently. Other treatments include cytotoxic chemotherapy, tyrosine kinase inhibitors, local ablation, or radiation therapy.

Clinical Efficacy

The efficacy of Ogsiveo was assessed in a Phase III, double-blind, randomized, placebo-controlled trial in adults with progressing desmoid tumors not amenable to surgery.[1,3] Eligible patients (n = 142) were ≥ 18 years of age with a histologically confirmed diagnosis of progressing desmoid tumors, defined as ≥ 20% progression (according to Response Evaluation Criteria in Solid Tumors [RECIST], version 1.1) within 12 months before screening. Patients were randomized to receive Ogsiveo 150 mg or placebo orally twice daily until disease progression or unacceptable toxicity. Patients treated with Ogsiveo had a significant progression-free survival benefit over placebo. In the Ogsiveo group, 17% of patients had a progression event compared with 51% of patients in the placebo group (hazard ratio 0.29; 95% confidence interval: 0.15, 0.55; $P < 0.001$). The objective response rate was also significantly better in the Ogsiveo group compared with placebo: 41% vs. 8%, respectively ($P < 0.001$).

Guidelines

The National Comprehensive Cancer Network (NCCN) soft tissue sarcoma guidelines (version 3.2023 – December 12, 2023) recommend the following therapies as "preferred" regimens for desmoid tumors (aggressive fibromatosis):[4] Ogsiveo (category 1), sorafenib (category 1), methotrexate and vinorelbine, methotrexate and vinblastine, imatinib, pazopanib, doxorubicin ± dacarbazine, and Doxil® (liposomal doxorubicin for intravenous injection) [except for Ogsiveo and sorafenib, all other agents listed are category 2A recommendations]. Sulindac or other nonsteroidal anti-inflammatory drugs, including celecoxib are recommended for pain under "useful in certain circumstances" (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ogsiveo. All approvals are provided for the duration noted below.

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ogsiveo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Desmoid Tumors (Aggressive Fibromatosis).** Approve for 1 year if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** According to the prescriber, the patient has progressing desmoid tumors; AND
     Note: Progressing desmoid tumors are defined as ≥ 20% progression within 12 months.
   - **C)** The desmoid tumors are not amenable to surgery or radiotherapy; AND
   - **D)** According to the prescriber, the patient requires systemic treatment.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ogsiveo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ogsiveo™ tablets [prescribing information]. Stamford, CT: SpringWorks Therapeutics; November 2023.
2. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388:898-912.
3. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388:898-912.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2023 – December 12, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 16, 2023.

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