Ogsiveo (nirogacestat)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ogsiveo (nirogacestat) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Adult patients with progressing desmoid tumors who require systemic treatment

Compendial Use
Desmoid tumors without progression – concerns for morbidity or significant symptoms

POLICY

Criteria for Initial Approval
Desmoid tumor
Authorization of 12 months may be granted for treatment of progressive morbid, or symptomatic desmoid tumors as a single agent.

Continuation of Therapy
Desmoid tumor

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for the treatment of desmoid tumors when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Ogsiveo is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits
Ogsiveo 50 mg – 180 tablets per 30 days
Ogsiveo 100 mg – 60 tablets per 30 days
Ogsiveo 150 mg – 60 tablets per 30 days

CLINICAL RATIONALE

Ogsiveo is the first treatment approved for adult patients with progressing desmoid tumors (DTs) who require systemic treatment. Approximately 900 to 1500 new cases of DT are diagnosed in the United States per year. DTs are related to cancers of connective tissues but are not considered metastatic because they do not spread throughout the body. However, DTs can be locally aggressive and invasive and have a high rate of recurrence. The resulting tumor growth can cause chronic pain, disfigurement, internal bleeding, and impaired range of motion.

Surgery has traditionally been the standard of care, but there has been a paradigm shift toward more conservative management in recent years. According to The Desmoid Tumor Working Group's 2020 consensus guideline, surgery is the accepted second-line treatment only for sporadic DTs located in the abdominal wall failing observation. Medical therapies are the second-line treatments for sporadic DTs located at all other sites and for all familial DTs failing observation, and local ablative treatments (e.g., cryotherapy, radiotherapy) can be considered as an alternative to medical therapies on an individual basis. Until recently, no medical therapies were FDA-approved for DT. Targeted therapies (sorafenib, pazopanib, imatinib), chemotherapy (doxorubicin, dacarbazine, methotrexate, vinorelbine, and vinblastine), and hormonal therapies have been the only available therapies with recommendations for off-label use in treating DTs.

Approval was based on results of the Phase 3 DeFi study (NCT03785964), in which Ogsiveo met the primary endpoint of improving progression-free survival (PFS), demonstrating a statistically significant 71% reduction in the risk of disease progression or death compared to placebo. The confirmed objective response rate (ORR) was 41% with Ogsiveo versus 8% with placebo; the complete response rate was 7% in the Ogsiveo arm and 0% in the placebo arm. Frequent adverse events included diarrhea (84% of patients) nausea (54%), and hypophosphatemia (42%); 95% of AEs were grade 1 or 2.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- n/a

REFERENCES

- Ogsiveo [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; November 2023.
- 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.
- Kasper B, et al. An update on the management of sporadic desmoid-type fibromatosis: a European Consensus Initiative between Sarcoma PAtients EuroNet (SPAEN) and European Organization for Research and Treatment of Cancer (EORTC)/Soft Tissue and Bone Sarcoma Group (STBSG). Ann Oncol. 2017;28(10):2399–2408.
- IPD Analytics: New Drug Review - Ogsiveo (nirogacestat). December 2023.

POLICY HISTORY

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