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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 15, 2023
Subject:	Ogsiveo	**Page:**	1 of 4

Last Review Date: March 8, 2024

Ogsiveo

Description

Ogsiveo (nirogacestat)

Background

Ogsiveo (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 (1).

Regulatory Status

FDA-approved indication: Ogsiveo is a gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors who require systemic treatment (1).

Ogsiveo contains warnings for the following: diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, and embryo-fetal toxicity. The dose should be modified based on severity of symptoms. Females and males of reproductive potential should be advised to use effective contraception during treatment and for 1 week after the last dose (1).

The safety and effectiveness of Ogsiveo in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ogsiveo may be considered **medically necessary** if the conditions indicated below are met.

Ogsiveo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Progressing desmoid tumors

AND ALL of the following:
1. Patient requires systemic treatment
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ogsiveo and for 1 week after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ogsiveo and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Desmoid tumors

AND ALL of the following:
1. **NO** disease progression or unacceptable toxicity

2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ogsiveo and for 1 week after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ogsiveo and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 300 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Ogsiveo (nirogacestat) is a gamma secretase inhibitor indicated for patients with progressing desmoid tumors who require systemic treatment. Treatment has been associated with an increased risk of diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, and embryo-fetal toxicity (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Ogsiveo while maintaining optimal therapeutic outcomes.

References

1. Ogsiveo [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; November 2023.
2. NCCN Drugs & Biologics Compendium® Ogsiveo 2024. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2024.

Policy History

Date	Action
December 2023	Addition to PA
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.