BlueCross BlueShield
Federal Employee Program

OGSIVEO
(nirogacestat)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.; April 2024.
2. NCCN Drugs & Biologics Compendium® Ogsiveo 2024. National Comprehensive Cancer Network, Inc. Accessed on October 7, 2024.