BlueCross BlueShield
Federal Employee Program

ORGOVYX
(relugolix)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Orgovyx (relugolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist that competitively binds to pituitary GnRH receptors, thereby, reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and consequently testosterone (1).

Regulatory Status

FDA-approved indication: Orgovyx is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer (1).

Androgen deprivation therapy, such as Orgovyx may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes (1).

Orgovyx can cause fetal harm. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment and for 2 weeks after the last dose of Orgovyx (1).

The safety and effectiveness of Orgovyx in pediatric and female patients have not been established (1).

Summary

Orgovyx (relugolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist that competitively binds to pituitary GnRH receptors, thereby, reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and consequently testosterone (1).

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

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References

1. Orgovyx [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Relugolix 2024. National Comprehensive Cancer Network, Inc. Accessed on July 24, 2024.