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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Antineoplastic Drugs	**Original Policy Date:**	January 29, 2021
Subject:	Orgovyx	**Page:**	1 of 4

Last Review Date: September 6, 2024

Orgovyx

Description

Orgovyx (relugolix)

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).

Related policies
Erleada, Nilandron, Nubeqa, Yonsa, Xtandi, Zytiga

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age

Gender Male

Diagnosis

Patient must have the following:

Advanced prostate cancer

AND ALL of the following:

1. Prescriber agrees to monitor for QTc prolongation periodically
2. Patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Orgovyx and for 2 weeks after the final dose

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity Loading dose + 90 tablets per 90 days

Duration 12 months

Prior–Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 12 months

Rationale

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.

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.

Policy History

Date	Action
January 2021	Addition to PA
March 2021	Annual editorial review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.