



## Drug Quantity Management – Per Rx Oncology – Orgovyx™ (relugolix tablets)

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### Product Identifier(s)

**Effective 1/1/23 to 3/21/23:** 108902  
**Effective 3/22/23:** 91227

#### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### National Formulary Medical Necessity

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of Orgovyx. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

#### Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Orgovyx™ (relugolix tablets)	120 mg tablets (30 tablets/bottle)	30 tablets

#### Criteria

**Cigna covers quantities as medically necessary when the following criteria are met:**

1. If the patient is taking a combined P-gp inducer **AND** a strong CYP3A inducer (i.e., apalutamide, carbamazepine, fosphenytoin, phenobarbital, phenytoin, rifampin), approve 60 tablets per dispensing.

- If the patient is initiating therapy and requires a dose of 360 mg on the first day of therapy, approve a one-time override of 32 tablets.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### Overview

Orgovyx, a gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the treatment of adults with **advanced prostate cancer**.<sup>1</sup>

### Dosing/Availability

The dose of Orgovyx is 360 mg on Day 1 of treatment, then 120 mg once daily (QD) thereafter. If treatment is interrupted for > 7 days, patients must restart with a loading dose of 360 mg on Day 1 followed by 120 mg once QD thereafter. It is recommended to avoid co-administration of Orgovyx with P-glycoprotein (P-gp) inhibitors. If co-administration is unavoidable, Orgovyx should be taken first with the dose separated 6 hours from the P-gp inhibitor. Co-administration of Orgovyx with combined P-gp AND strong cytochrome P450 (CYP)3A inducers should be avoided. If co-administration is unavoidable, the dose of Orgovyx must be increased to 240 mg QD. After discontinuation of the combined P-gp and strong CYP3A inducer, the recommended dose of 120 mg QD may be resumed.

Orgovyx is supplied as a 120 mg tablet in bottles of 30 tablets.

## References

- Orgovyx™ [prescribing information]. Brisbane, CA: Myovant; December 2020.

## Revision History

Type	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	03/10/2022

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