

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Orgovyx Drug Quantity Management Policy – Per Rx

- Orgovyx™ (relugolix tablets – Myovant)

REVIEW DATE: 03/10/2022

OVERVIEW

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

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.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse use 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.

Automation: None.

Drug Quantity Limits

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

CRITERIA

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.
2. 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.
3. No other exceptions are recommended.

REFERENCES

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

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