DRUG QUANTITY MANAGEMENT POLICY - PER RX

POLICY: Orgovyx™ (relugolix tablets – Myovant Sciences, Inc.) Dispensing Limit

DATE REVIEWED: 01/06/2021, selected revision 06/16/2021

OVERVIEW

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

Initiate treatment of Orgovyx with a loading dose of 360 mg on the first day and continue treatment with a 120 mg dose taken orally once daily at approximately the same time each day. Orgovyx can be taken with or without food and tablets should be swallowed whole. Tablets should not be crushed or chewed. Missed doses should be taken as soon as they remember. If the dose is missed by more than 12 hours, patients should not take the missed dose and resume with the next scheduled dose. If treatment is interrupted for greater than 7 days, restart with a loading dose of 360 mg on the first day, and continue with a dose of 120 mg once daily. Avoid co-administration with P-glycoprotein (P-gp) inhibitors. If unavoidable, take Orgovyx first, separate dosing by at least 6 hours. Co-administration of Orgovyx with combined P-gp AND strong CYP3A inducers should be avoided. If co-administration is unavoidable, increase the dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended dose of 120 mg once daily.

This Drug Quantity Management Policy has been developed to complement the coverage provided by *Oncology - Orgovyx Prior Authorization Policy*. Consult the *Oncology - Orgovyx Prior Authorization Policy* for detailed information about evidence-supported approved treatment regimens and durations.[2]

Orgovyx 120 mg tablets Maximum quantity per Rx = 30 tablets

A quantity of 30 of the 120 mg tablets per Rx will be covered without prior authorization. This is enough drug for a 30-day supply. For coverage of additional quantities for patients taking Orgovyx with a P-gp and strong CYP3A inducers, a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for indications covered by the *Oncology - Orgovyx Prior Authorization Policy*.[2]

CRITERIA

Orgovyx 120 mg tablets

1. For patients taking a combined P-gp inducer **AND** a strong CYP3A inducer (i.e., apalutamide, carbamazepine, fosphenytoin, phenobarbital, phenytoin, rifampin), approve 60 tablets/Rx for 12 months.
2. For patients initiating therapy and require a dose of 360 mg on the first day of therapy, a one-time override of 32 tablets per dispensing may be approved.

REFERENCES

1. Orgovyx™ [prescribing information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.
2. Oncology - Orgovyx prior authorization policy. Updated 04/07/2021.