DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Orgovyx Drug Quantity Management Policy – Per Rx
- Orgovyx® (relugolix tablets – Sumitomo)

REVIEW DATE: 03/03/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

Dosing

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 QD thereafter. It is recommended to avoid coadministration of Orgovyx with P-glycoprotein (P-gp) inhibitors. If coadministration is unavoidable, Orgovyx should be taken first with the dose separated 6 hours from the P-gp inhibitor. Coadministration of Orgovyx with combined P-gp AND strong cytochrome P450 (CYP)3A inducers should be avoided. If coadministration 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.

Availability

Orgovyx is supplied as a 120 mg tablet in bottles of 30 tablets.[1]

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, unless otherwise noted below. "One-time" overrides are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Orgovyx® (relugolix tablets)	120 mg tablets (30 tablets/bottle)	30 tablets	90 tablets

***Oncology – Orgovyx Drug Quantity Management Policy – Per Rx* product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

1. If the patient is taking a combined P-gp inducer AND a strong CYP3A inducer, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
Note: Examples of strong CYP3A inducers include, but are not limited to, apalutamide, carbamazepine, fosphenytoin, phenobarbital, phenytoin, and rifampin.

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 for 32 tablets at retail or home delivery.

REFERENCES

1. Orgovyx® [prescribing information]. Brisbane, CA: Myovant; October 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	03/13/2023

Annual Revision	No criteria changes.	03/27/2024
Annual Revision	Policy statement was updated to clarify that “One-time” overrides are provided for 30 days.	03/03/2025