



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Orgovyx Prior Authorization Policy

- Orgovyx® (relugolix tablets – Myovant Sciences/Pfizer)

REVIEW DATE: 02/19/2025

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 **advanced prostate cancer** in adults.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 1.2025 –December 4, 2024) recommend the use of androgen deprivation therapy (ADT) for various stages of prostate cancer. Orgovyx is listed as an option for ADT for clinically localized (regional node 0 [N0], distant metastases 0 [M0]), regional (N1, M0) disease, or M0 or M1 castration-naïve disease (category 2A).^{2,3} The guidelines note that data are limited on long-term adherence to oral Orgovyx and the potential effects on optimal ADT. Ongoing monitoring for sustained suppression of testosterone (< 50 ng/dL) can be considered, and Orgovyx may not be a preferred agent if adherence to the prescribed regimen is uncertain.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Orgovyx. All approvals are provided for the duration noted below.

- **Orgovyx® (relugolix tablets (Myovant Sciences/Pfizer)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

- 1. Prostate Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

CONDITIONS NOT COVERED

Orgovyx® (relugolix tablets (Myovant Sciences/Pfizer)
is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available

REFERENCES

1. Orgovyx® tablets [prescribing information]. Brisbane, CA: Myovant Sciences/Pfizer; October 2024.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed February 14, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 14, 2025. Search term: relugolix.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/25/2023
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	No criteria changes.	02/19/2025

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