



## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Orgovyx Prior Authorization Policy

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

**REVIEW DATE:** 02/07/2024

### **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.<sup>1</sup>

#### **Guidelines**

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 4.2023 –September 7, 2023) 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).<sup>2,3</sup> The guidelines note that Orgovyx has not been adequately studied in combination with potent androgen receptor inhibitors, such as abiraterone acetate, Xtandi® (enzalutamide capsules and tablets), Erleada® (apalutamide tablets), Nubeqa® (darolutamide tablets), nor has it be studied in combination with docetaxel or cabazitaxel chemotherapy.<sup>2</sup>

#### **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).**

**REFERENCES**

1. Orgovyx® tablets [prescribing information]. Brisbane, CA: Myovant Sciences/Pfizer; March 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – September 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed February 5, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 5, 2024. 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

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