

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Orgovyx Prior Authorization Policy

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

REVIEW DATE: 02/07/2024

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 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).^{2,3} 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.²

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Orgovyx is recommended in those who meet the following criteria:

FDA-Approved Indication

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Orgovyx is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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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.