

## PRIOR AUTHORIZATION POLICY

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

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

**REVIEW DATE:** 01/25/2023

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### 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 1.2023 – September 16, 2022) 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<sup>®</sup> (enzalutamide capsules and tablets), Erleada<sup>®</sup> (apalutamide tablets), Nubeqa<sup>®</sup> (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.

**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  $\geq$  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.

### REFERENCES

1. Orgovyx<sup>®</sup> tablets [prescribing information]. Brisbane, CA: Myovant Sciences/Pfizer; September 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 24, 2023.

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3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 24, 2023. Search term: relugolix.