

# Orgovyx (relugolix)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 6 months
Quantity Limit	Continuation requests: 6 months

Medications	Quantity Limit
Orgovyx (relugolix) tablets 120mg	1 tablet per day*

\*Initiation of therapy: May approve 3 additional tablets in the first month (28 days) of treatment for loading dose.

## **APPROVAL CRITERIA**

Initial requests for Orgovyx (relugolix) may be approved if the following criteria are met (Label, NCCN 1, 2A):

- I. Individual has a diagnosis of androgen-sensitive metastatic or advanced localized prostate cancer; **AND**
- II. One of the following clinical disease state presentations:
  - A. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent, such as surgery, radiation therapy, cryotherapy, or high-frequency ultrasound and not a candidate for salvage treatment by surgery; **OR**
  - B. Newly diagnosed androgen-sensitive metastatic disease; **OR**
  - C. Advanced localized disease unlikely to be cured by local primary intervention with either surgery or radiation with curative intent;

## **AND**

- III. Individual is using as androgen deprivation therapy; **AND**
- IV. Individual is using as a single agent; **AND**
- V. Individual has an ECOG status of 0 or 1.

Continuation requests for Orgovyx may be approved if the following criteria are met:

- I. Individual does not show evidence of progressive disease while on therapy; **AND**
- II. Individual has serum testosterone level less than 50 ng/dL.

## **Key References:**

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 14, 2023

6. Prostate Cancer. V1.2023. Revised September 16, 2022.
7. Orgovyx (relugolix) [prescribing information]. Brisbane, CA: Myovant Sciences Inc; December 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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