



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Orgovyx Prior Authorization Policy
- Orgovyx™ (relugolix tablets – Myovant Sciences)

REVIEW DATE: 12/29/2020; 01/20/2021 selected revision

OVERVIEW

Orgovyx, a gonadotropin-releasing hormone (GnRH) receptor antagonist, is indicated for the treatment of adult patients with **advanced prostate cancer**.¹

Guidelines

Orgovyx is not addressed in the guidelines. The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 3.2020 – November 17, 2020) recommend the use of leutinizing hormone-releasing hormone (LHRH) agonist or antagonist in various stages of the disease. These agents are used for androgen deprivation therapy, to lower and maintain castration levels of testosterone (< 50 ng/dL) in men with prostate cancer.

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 Indications

1. **Prostate Cancer.** Approve for 3 years if the patient meets the following criteria (A and B):

A) Patient is ≥ 18 years of age; AND

B) Patient has advanced disease.

Note: Advanced disease is defined as disease that has spread to other parts of the body, beyond the prostate. It can also include patients with persistent prostate specific antigen (PSA) levels or rising PSA levels after radiotherapy or surgery. Metastatic disease is also considered as advanced disease.

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 tablets [prescribing information]. Brisbane, CA: Myovant Sciences, Inc.; December, 2020.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2020 – November 17, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed December 18, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/29/2020
Selected Revision	Prostate Cancer: Added the following to the existing Note to further define advanced disease: “It can also include patients with persistent prostate specific antigen (PSA) levels or rising PSA levels after radiotherapy or surgery”.	01/20/2021