Reference number(s)
4411-A

SPECIALTY GUIDELINE MANAGEMENT

ORGOVYX (relugolix)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Orgovyx is indicated for the treatment of adult patients with advanced prostate cancer.

B. Compendial Uses
Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer when used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., maintaining serum testosterone to less than 50ng/dL) and who have not experienced an unacceptable toxicity.

IV. REFERENCES

1. Orgovyx [package insert]. Brisbane, CA: Myovant Sciences, Inc; December 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 6, 2021.