

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1350-5
Program	Prior Authorization/Notification
Medication	Orgovyx™ (relugolix)
P&T Approval Date	2/2021, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

1. Background:

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

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Orgovyx will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Prostate Cancer</u></p> <p>1. <u>Initial Authorization</u></p> <p style="padding-left: 40px;">a. Orgovyx will be approved based on the following:</p> <p style="padding-left: 80px;">(1) Diagnosis of advanced prostate cancer</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p style="padding-left: 40px;">a. Orgovyx will be approved based on the following criterion:</p> <p style="padding-left: 80px;">(1) Patient does not show evidence of progressive disease while on Orgovyx therapy</p>
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Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Please refer to plan specifics to determine exclusion status.

4. References:

1. Orgovyx [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc.; October 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed December 20, 2024.

Program	Prior Authorization/Notification – Orgovyx™ (relugolix)
Change Control	
2/2021	New program.
2/2022	Annual review with no changes to coverage criteria. Updated references.
2/2023	Annual review with no changes to coverage criteria. Added state mandate footnote and updated references.
2/2024	Annual review with no changes to coverage criteria. Updated references.
2/2025	Annual review with no changes to coverage criteria. Updated references.