

Clinical Policy Title:	relugolix
Policy Number:	RxA.675
Drug(s) Applied:	Orgovyx®
Original Policy Date:	03/09/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Advanced Prostate Cancer (must meet all):

1. Diagnosis of advanced prostate cancer defined as one of the following (a, b, or c):
 - a. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent;
 - b. Newly diagnosed castration-sensitive metastatic disease;
 - c. Advanced localized disease unlikely to be cured by local primary intervention with curative intent.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Advanced Prostate Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 28, 2024.
2. Myovant Sciences GmbH. HERO: A Multinational Phase 3 Randomized, Open-label, Parallel Group Study to Evaluate the Safety and Efficacy of relugolix in Men with Advanced Prostate Cancer. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT03085095>. NLM identifier: NCT03085095. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated. 	12/13/2021	01/17/2022

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: Updated to remove diagnostic criteria “Diagnosis of castration-sensitive prostate cancer with documentation of (meets a and b): <ol style="list-style-type: none"> a. Serum testosterone levels; b. Serum PSA levels; 2. Initial Approval Criteria, I.A.1: Updated to diagnostic criteria Diagnosis of advanced prostate cancer defined as one of the following (a, b, or c): <ol style="list-style-type: none"> a. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent; b. Newly diagnosed castration-sensitive metastatic disease; c. Advanced localized disease unlikely to be cured by local primary intervention with curative intent 3. References were reviewed and updated. 	10/26/2022	01/17/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated. 	08/28/2024	9/13/2024
<p>Policy was reviewed.</p>	12/05/2024	N/A
<p>Policy reviewed.</p>	12/11/2025	12/11/2025