Clinical Policy Title:	relugolix
Policy Number:	RxA.675
Drug(s) Applied:	Orgovyx®
Original Policy Date:	03/09/2021
Last Review Date:	10/19/2023
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;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Member ≥ 18 years;
4. Request meets one of the following (a, b or c):*
   a. Dose does not exceed 360 mg on day 1, then 120 mg per day thereafter; or
   b. Dose does not exceed 360 mg on day 1, then 240 mg per day if combined with rifampin and combination use is unavoidable; or
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Advanced Prostate Cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Orgovyx™ for advanced prostate cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b or c):*
   a. New dose does not exceed 120 mg per day; or
   b. New dose does not exceed 240 mg per day if combined with rifampin and combination use is unavoidable; or
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 26, 2022.
2. American Urological Association. Advanced Prostate Cancer: AUA/ASTRO/SUO Guideline. Available at: https://www.auanet.org/guidelines/advanced-prostate-cancer. Accessed October 26, 2022.
3. 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 October 26, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021
Policy was reviewed: 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
Policy was reviewed: 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): 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): a. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent;	10/26/2022	01/17/2023

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.		
Policy was reviewed.	10/19/2023	10/19/2023