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

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
relugolix (Orgovyx™)	Advanced prostate cancer	Loading dose of 360 mg PO on the day 1, followed by 120 mg taken once daily, at approximately the same time each day	Refer to dosing regimen

Dosage Forms

- Tablets: 120 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Advanced Prostate Cancer (must meet all):

1. Diagnosis of castration-sensitive prostate cancer with documentation of (meets both of below):
   a. Serum testosterone levels;
   b. Serum PSA levels;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Member is age 18 or older;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 360 mg on day 1, then 120 mg per day thereafter; or
   b. 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. 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 or b):
   a. New dose does not exceed 360 mg on day 1, then 120 mg per day thereafter; or
   b. 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

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

GnRH: gonadotropin-releasing hormone
PO: by mouth
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Androgen Deprivation Therapy Agents:

Drug Name	Dosing Regimen	Maximum Dose
Lupron™, Eligard™ (leuprolide)	IM: • *Lupron™ Depot 7.5 mg (monthly):* 7.5 mg every month **or** • *Lupron™ Depot 22.5 mg (3 month):* 22.5 mg every 12 weeks **or** • *Lupron™ Depot 30 mg (4 month):* 30 mg every 16 weeks **or** • *Lupron™ Depot 45 mg (6 month):* 45 mg every 24 weeks SubQ: • *Eligard™:* 7.5 mg monthly **or** 22.5 mg every 3 months **or** 30 mg every 4 months **or** 45 mg every 6 months • *Leuprolide acetate 5 mg/mL solution:* 1 mg daily	Refer to dosing regimen

Drug Name	Dosing Regimen	Maximum Dose
Firmagon™ (degarelix)	SubQ: • Loading dose: 240 mg administered as two 120 mg (3 mL) injections • Maintenance dose: 80 mg administered as one 4 mL injection every 28 days (beginning 28 days after initial loading dose)	Refer to dosing regimen

Therapeutic alternatives are listed as Brand name™ (generic) when the drug is available by brand name only and generic (Brand name™) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

None.

References

1. Orgovyx Prescribing Information. Myovant Sciences, Inc. Available at: https://www.myovant.com/wp-content/uploads/2020/12/NDA-214621-Final-USPIandPI.pdf Accessed February 18, 2021.
2. National Comprehensive Cancer Network. Prostate Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 18, 2021.
3. American Urological Association. Advanced Prostate Cancer: AUA/ASTRO/SUO Guideline. Available at: https://www.auanet.org/guidelines/advanced-prostate-cancer. Accessed February 18, 2021.
4. 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 February 18, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021