Clinical Policy Title:	apalutamide
Policy Number:	RxA.376
Drug(s) Applied:	Erleada®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Apalutamide (Erleada®) is an androgen receptor inhibitor.

It is indicated for the treatment of patients with:

- Non-metastatic castration-resistant prostate cancer (nMCRPC)
- Metastatic castration-sensitive prostate cancer (mCSPC)

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
apalutamide (Erleada®)	Non-metastatic CRPC, metastatic CSPC	240 mg orallyonce daily	240 mg/day

Dosage Forms

- Tablets: 60 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer that is characterized as one of the following (a or b):
   a. Non-metastatic and castration-resistant, as evidenced by disease progression (PSADT ≤ 10 months) despite bilateral orchiectomy or other androgen deprivation therapy (see Appendix D);
   b. Metastatic and castration-sensitive;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age 18 years of age or older;
4. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
5. Request meets one of the following (a or b):*

a. Dose does not exceed 240 mg (four 60 mg tablets) per day;
b. Dose is supported by practice guideline 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

II. Continued Therapy Approval

A. Prostate Cancer (must meet all)**:**

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If CRPC, there is no evidence of metastases;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 240 mg (four 60 mg tablets) per day;
   b. New dose is supported by practice guideline 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
FDA: Food and Drug Administration
CRPC: Castration-resistant prostate cancer
CSPC: Castration-sensitive prostate cancer
GnRH: Gonadotropin-releasing hormone
LHRH: Luteinizing-hormone releasing hormone
PSADT: PSA doubling time

APPENDIX B: Therapeutic Alternatives

- Enzalutamide (Xtandi), Nubeqa (Darolutamide), arbiraterone (Yonsa, Zytiga)

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information

- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL). Per the NCCN, androgen deprivation therapy should be continued in the setting of CRPC while additional therapies are applied.
- Examples of androgen deprivation therapy include:
  - Orchiectomy (surgical castration)

- Luteinizing-hormone releasing-hormone (LHRH) agonist given with or without an anti-androgen:
- LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot® or Eligard®), Trelstar® (triptorelin)
- Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi®(enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
- LHRH antagonist: Firmagon® (degarelix)

References

1. Erleada® Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; November 2020. Available at: www.erleada.com. Accessed May 31, 2021.
2. National Comprehensive Cancer Network. Prostate Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 31, 2021.National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 31, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Background updated. 2) Appendices updated 3) References were updated.	06/2020	09/14/2020
Policy was reviewed: 1) Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy.. 2) Initial Approval Criteria I.A.1.a was updated to include “progression (PSADT ≤ 10 months).” 3) Appendix A was updated to include abbreviation PSADT. 4) Appendix B: Therapeutic Alternatives was updated to include “Enzalutamide (Xtandi), Nubeqa (Darolutamide), arbiraterone (Yonsa, Zytiga)…” 5) References were reviewed and updated.	05/31/2021	09/14/2021