Clinical Policy: Apalutamide (Erleada)

Reference Number: PA.CP.PHAR.376
Effective Date: 03.13.18
Last Review Date: 04.18.18

Revision Log

Description
Apalutamide (Erleada™) is an androgen receptor inhibitor.

FDA Approved Indication(s)
Erleada is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (CRPC).

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

It is the policy of health plans affiliated with PA Health & Wellness® that Erleada is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of non-metastatic CRPC, as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy (*see Appendix C*);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
5. Dose does not exceed 240 mg (four 60 mg tablets) daily.

Approval duration: 12 months

B. Other diagnoses/indications

Refer to PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy with no evidence of metastases;
3. If request is for a dose increase, new dose does not exceed 240 mg (four 60 mg tablets) daily.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
CRPC: castration-resistant prostate cancer
GnRH: gonadotropin-releasing hormone
Luteinizing-hormone releasing-hormone

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: General Information

- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL).
- Examples of androgen deprivation therapy for non-metastatic, castration-naïve prostate cancer include:
  - Orchiectomy (surgical castration)
  - Luteinizing-hormone releasing-hormone (LHRH) agonist given with or without a first-generation anti-androgen:
    - LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot® or Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide, and nilutamide (Nilandron®)
  - LHRH antagonist: Firmagon® (degarelix)

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Non-metastatic CRPC	240 mg PO QD	240 mg/day

V. Product Availability

Tablets: 60 mg

VI. References

1. Erleada Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; February 2018. Available at: www.erleada.com. Accessed February 22, 2018.
2. National Comprehensive Cancer Network; Prostate cancer Version 1.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 22nd, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.13.18	04.18.18