Clinical Policy: Apalutamide (Erleada)

Reference Number: ERX.SPA.234
Effective Date: 06.01.18
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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)
- Metastatic castration-sensitive prostate cancer (CSPC)

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Erleada is **medically necessary** when the following criteria are met:

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 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;
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:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Erleada for a covered indication 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:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

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:
  - Bilateral 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®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
  - LHRH antagonist: Firmagon® (degarelix)
  - In patients with metastatic CSPC, Erleada has a category 1 NCCN recommendation.

V. Dosage and Administration

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

VI. Product Availability
Tablets: 60 mg

VII. References
1. Erleada Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; September 2019. Available at: www.erleada.com. Accessed February 3, 2020.
2. National Comprehensive Cancer Network. Prostate Cancer Version 4.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 3, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 3, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.13.18	05.18
Added urologist as prescriber specialty option.	05.16.18	
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
Criteria updated for new FDA indication: metastatic CSPC; added length of benefit approval durations for Commercial line of business; references reviewed and updated.	10.15.19	11.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.03.20	05.20

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.`

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.