Clinical Policy:Apalutamide (Erleada)

Reference Number: CP.PCH.45
Effective Date: 03.01.22
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA

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.

It is the policy of health plans affiliated with Centene Corporation® 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, b, or c):
   a. Non-metastatic and both of the following (i and ii):
      i. Castration-resistant, as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy (*see Appendix D*);
      ii. Prostate-specific antigen doubling time (PSADT) ≤ 10 months;
   b. Non-metastatic and castration-sensitive with biochemical recurrence after radical prostatectomy and all of the following (i, ii, and iii) (off-label):
      i. PSADT ≤ 9 months;
      ii. PSA ≥ 0.5 ng/mL;
      iii. Prior adjuvant or secondary radiotherapy or not considered a candidate for radiotherapy;
   c. 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. For brand Erleada requests, member must use generic apalutamide, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg per day (1 tablet 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:
HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace/ICHRA.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, 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. Member continues to use a GnRH analog concurrently or has had a bilateral orchiectomy;
5. For brand Erleada requests, member must use generic apalutamide, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed both of the following (i and ii):
      i. 240 mg per day;
      ii. 3 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:
HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace/ICHRA; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace/ICHRA.

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 policies – CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace/ICHRA 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
PSA: prostate-specific antigen
PSADT: prostate-specific antigen doubling time

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), leuprolide (Lupron Depot® or Eligard®), Trelstar® (triptorelin)
  - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
- LHRH antagonists: Firmagon® (degarelix), Orgovyx™ (relugolix)

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, 240 mg

VII. References

1. Erleada Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; August 2024. Available at: www.erleada.com. Accessed January 12, 2026.
2. Apalutamide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 27, 2026.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 27, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2022 annual review: modified commercial approval duration from length of benefit to "12 months or duration of request, whichever is less"; references reviewed and updated.	01.25.22	05.22
Template changes applied to other diagnoses/indications.	09.29.22	
2Q 2023 annual review: no significant changes; updated *Appendix D* examples of androgen deprivation therapy per NCCN; references reviewed and updated. RT4: added new 240 mg tablet strength to Section VI.	03.15.23	05.23
2Q 2024 annual review: no significant changes; added clarification for daily quantity of 1 tablet per day; references reviewed and updated.	01.08.24	05.24
2Q 2025 annual review: per NCCN Compendium, added off-label use in non-metastatic and castration-sensitive disease; for continuation of therapy requests modified quantity limit to allow up to 3 tablets per day for dose adjustments; references reviewed and updated.	01.16.25	05.25
2Q 2026 annual review: no significant changes; references reviewed and updated.	03.25.26	05.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added ICHRA line of business.		

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.