

Clinical Policy: Apalutamide (Erleada)

Reference Number: CP.PHAR.376

Effective Date: 03.13.18

Last Review Date: 05.18

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).

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 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 or urologist;
3. Age \geq 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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 non-metastatic CRPC and has received this medication for at least 30 days;
2. Member is responding positively to therapy with no evidence of metastases;

- 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):

- Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
- Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

GnRH: gonadotropin-releasing hormone

CRPC: castration-resistant prostate cancer

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)

V. Dosage and Administration

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

VI. Product Availability

Tablets: 60 mg

VII. 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	05.18
Added urologist as prescriber specialty option.	05.16.18	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.