

Clinical Policy Title:	apalutamide
Policy Number:	RxA.376
Drug(s) Applied:	Erleada®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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;
 - b. Metastatic and castration-sensitive;
2. Patient meets ONE of the following (i or ii):
 - i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
 - ii. Patient has had a bilateral orchiectomy.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 24, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) References were updated.	06/2020	09/14/2020
Policy was reviewed: 1) Initial Approval Criteria I.A.1.a was updated to include “progression (PSADT ≤ 10 months).” 2) References were reviewed and updated.	05/31/2021	09/14/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Updated approval duration. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated. 	12/18/2023	01/01/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Updated continuation of therapy language. 2. Removed prescriber criteria. 3. References were reviewed and updated. 	03/24/2025	04/10/2025
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Updated continuation of therapy language. 	7/1/2025	N/A
<p>Policy reviewed.</p>	12/11/2025	12/11/2025