

Clinical Policy Title:	apalutamide
Policy Number:	RxA.376
Drug(s) Applied:	Erleada®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
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, as evidenced by disease progression (PSADT ≤ 10 months) 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. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or 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. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. If CRPC, there is no evidence of metastases;

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed December 18, 2023.

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)."	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.

2) References were reviewed and updated.		
Policy was reviewed: 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