

Erleada[®] (apalutamide) (Oral)

Document Number: IC-0354

Last Review Date: 05/02/2024

Date of Origin: 03/01/2018

Dates Reviewed: 03/2018, 05/2019, 10/2019, 05/2020, 05/2021, 05/2022, 03/2023, 05/2024

I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Erleada 60 mg tablets: 4 tablets per day
- Erleada 240 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 240 mg daily

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient will receive concurrent treatment with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, triptorelin, histrelin, degarelix, etc.) or has had a bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., enzalutamide, darolutamide, etc.); **AND**

Prostate Cancer † ^{1,2}

- Patient has NON-metastatic castration-resistant prostate cancer (nmCRPC); **OR**
- Patient has metastatic castration-sensitive prostate cancer (mCSPC)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ^{1,2}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: seizures, excessive falls and/or fractures, signs and symptoms of ischemic heart disease or cerebrovascular disorders, severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), etc.

V. Dosage/Administration ¹

Indication	Dose
Prostate Cancer	Administer 240 mg orally once daily

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC(s):

- Erleada 60 mg tablet: 59676-0600-xx
- Erleada 240 mg tablet: 59676-0604-xx

VII. References

1. Erleada [package insert]. Horsham, PA; Janssen Pharmaceuticals; December 2023. Accessed April 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for apalutamide. National Comprehensive Cancer Network, 2024. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2024.
3. Agarwal N, McQuarrie K, Bjartell A, et al. Health-related quality of life after apalutamide treatment in patients with metastatic castration-sensitive prostate cancer (TITAN): a

randomised, placebo-controlled, phase 3 study. *Lancet Oncol.* 2019 Nov;20(11):1518-1530. doi: 10.1016/S1470-2045(19)30620-5. Epub 2019 Sep 29.

4. Chi KN, Agarwal N, Bjartell A, et al. Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med.* 2019 Jul 4;381(1):13-24. doi: 10.1056/NEJMoa1903307. Epub 2019 May 31.
5. Saad F, Cella D, Basch E, et al. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2018 Oct;19(10):1404-1416. doi: 10.1016/S1470-2045(18)30456-X. Epub 2018 Sep 10.
6. Smith MR, Saad F, Chowdhury S, et al. Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer. *N Engl J Med.* 2018 Apr 12;378(15):1408-1418. doi: 10.1056/NEJMoa1715546. Epub 2018 Feb 8.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC