

Erleada® (apalutamide) (Oral)

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I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

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

- Erleada 60 mg tablets: 4 tablets per day

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

- 240 mg daily

III. Initial Approval Criteria^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Universal Criteria

- Patient will receive concurrent treatment with a GnRH-analog 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 †

- Patient has NON-metastatic castration-resistant prostate cancer (NM-CRPC)
- Patient has metastatic castration-sensitive prostate cancer (M-CSPC)

† FDA Approved Indication(s)

IV. Renewal Criteria^{1,2}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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, any other Grade 3 or above side effects that are intolerable to patient, etc.

V. Dosage/Administration¹

Indication	Dose
Prostate Cancer	Administer 240 mg (four 60 mg tablets) orally once daily

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

- Erleada 60 mg tablet: 59676-0600-xx

VII. References

1. Erleada [package insert]. Horsham, PA; Janssen Pharmaceuticals; September 2019. Accessed April 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for apalutamide. National Comprehensive Cancer Network, 2020. 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 2020.
3. Agarwal N, McQuarrie K, Bjartell A, Chowdhury S, Pereira de Santana Gomes AJ, Chung BH, Özgüroğlu M, Juárez Soto Á, Merseburger AS, Uemura H, Ye D, Given R, Cella D, Basch E, Miladinovic B, Dearden L, Deprince K, Naini V, Lopez-Gitlitz A, Chi KN; TITAN investigators. 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, Chung BH, Pereira de Santana Gomes AJ, Given R, Juárez Soto Á, Merseburger AS, Özgüroğlu M, Uemura H, Ye D, Deprince K, Naini V, Li J, Cheng S, Yu MK, Zhang K, Larsen JS, McCarthy S, Chowdhury S; TITAN Investigators. 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, Hadaschik BA, Mainwaring PN, Oudard S, Graff JN, McQuarrie K, Li S, Hudgens S, Lawson J, Lopez-Gitlitz A, Yu MK, Smith MR, Small EJ. 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, Oudard S, Hadaschik BA, Graff JN, Olmos D, Mainwaring PN, Lee JY, Uemura H, Lopez-Gitlitz A, Trudel GC, Espina BM, Shu Y, Park YC, Rackoff WR, Yu MK, Small EJ; SPARTAN Investigators. 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)

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 Determination (NCD), Local Coverage Articles (LCA) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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