

## Xtandi® (enzalutamide) (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]:

- Xtandi 40 mg capsules: 4 capsules per day

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

- 160 mg per day

### III. Initial Approval Criteria<sup>1-7</sup>

Coverage is provided in the following conditions:

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

#### Universal Criteria

- Will not be used in combination with other androgen receptor inhibitors (e.g., darolutamide, apalutamide, etc.); **AND**

#### Prostate Cancer) †<sup>1-7</sup>

- Patient is receiving gonadotropin-releasing hormone (GnRH) therapy or has had prior bilateral orchiectomy; **AND**
  - Patient has castration-resistant prostate cancer (CRPC); **OR**
  - Patient has metastatic castration-sensitive prostate cancer (mCSPC)

† FDA Approved Indication(s)

#### IV. Renewal Criteria<sup>1-7</sup>

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, posterior reversible encephalopathy syndrome (PRES), hypersensitivity reactions, ischemic heart disease, falls/fractures, etc.

#### V. Dosage/Administration<sup>1,2,3,4,5,6,7</sup>

Indication	Dose
Prostate Cancer	160 mg (four 40mg capsules) orally once daily

#### VI. Billing Code/Availability Information

HCPCS:

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

NDC:

- Xtandi 40 mg capsule: 00469-0125-xx

#### VII. References

1. Xtandi [package insert]. Northbrook, IL; Astellas Pharma US, Inc; December 2019. Accessed April 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>®</sup>) for enzalutamide. National Comprehensive Cancer Network, 2020. The NCCN Compendium<sup>®</sup> is a derivative work of the NCCN Guidelines<sup>®</sup>. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> 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. Scher HI, Fizazi K, Saad F, et al. Increased survival with enzalutamide in prostate cancer after chemotherapy. N Engl J Med. 2012 Sep 27;367(13):1187-97. Epub 2012 Aug 15.
4. Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in Metastatic Prostate Cancer before Chemotherapy. N Engl J Med. 2014 Jul 31; 371(5): 424–433.

5. Shore ND, Chowdhury S, Villers A, et al. Efficacy and safety of enzalutamide versus bicalutamide for patients with metastatic prostate cancer (TERRAIN): a randomised, double-blind, phase 2 study. *Lancet Oncol.* 2016 Feb;17(2):153-163. doi: 10.1016/S1470-2045(15)00518-5. Epub 2016 Jan 14.
6. Hussain M, Fizazi K, Saad F, et al. Enzalutamide in Men with Nonmetastatic, Castration-Resistant Prostate Cancer. *N Engl J Med.* 2018 Jun 28;378(26):2465-2474. doi: 10.1056/NEJMoa1800536.
7. Armstrong AJ, Szmulewitz RZ, Petrylak DP, et al. ARCHES: A Randomized, Phase III Study of Androgen Deprivation Therapy With Enzalutamide or Placebo in Men With Metastatic Hormone-Sensitive Prostate Cancer. *J Clin Oncol.* 2019 Nov 10;37(32):2974-2986. doi: 10.1200/JCO.19.00799. Epub 2019 Jul 22.

## 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 Determinations (LCDs), and Local Coverage Articles (LCAs) 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/Articles): 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.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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