PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**XTANDI**
(generic)	**(enzalutamide)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 816-A***

FDA-APPROVED INDICATIONS[1]

Xtandi is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.

COMPENDIAL USES[2]

- Prostate cancer:
  - Used as a single agent as secondary hormone therapy for progression or metastases following medical or surgical androgen deprivation therapy (ADT)
  - In combination with ADT
    - As part of neoadjuvant/concomitant/adjuvant ADT to enhance effectiveness of radiation therapy
    - In ADT-naïve patients for a minimum of 7 days in patients with overt metastases who are at risk of developing symptoms associated with androgen flare
    - Following inadequate testosterone suppression with ADT alone

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of prostate cancer? [If no, no further questions.]	Yes	No
2	Does the patient have a metastatic castration-resistant prostate cancer? [If yes, no further questions.]	Yes	No
3	Will Xtandi be used in combination with androgen deprivation therapy? [If no, no further questions.]	Yes	No
4	Will Xtandi be used to enhance the effectiveness of radiation therapy? [If yes, no further questions.]	Yes	No
5	Will Xtandi be used to supplement androgen deprivation therapy if the patient experienced inadequate testosterone suppression? [If yes, no further questions.]	Yes	No
6	Will Xtandi be used to prevent androgen flare in androgen deprivation therapy naive patients who are at risk of developing symptoms?	Yes	No

Guidelines for Approval							
Duration of Approval				**12 months**			
Set 1: Castration-resistant, metastatic		**Set 2: ADT, enhance effectiveness of radiation**		**Set 3: ADT, inadequate suppression**		**Set 4: ADT, flare**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	1	2	1	2	1	2
2		3		3	4	3	4
		4		5		6	5

Internal Use Only – Mapping Instructions		
	Yes	**No**
1.	Go to 2	Deny
2.	Approve, 12 months	Go to 3
3.	Go to 4	Deny
4.	Approve, 12 months	Go to 5
5.	Approve, 12 months	Go to 6
6.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc., October 2015.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 29, 2016.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (KR) 09/2012
Revised:	KW 09/2013 (CMS); AS 10/2013, TS 08/2014 (CMS), TS 09/2014, 02/2015 (added Zytiga step), 08/2015 (CMS); ST 07/2015, 06/2016 (CMS); JP 07/2016, 02/2017 ((removed Zytiga step therapy req per Trade), 07/2017 (CMS)
Reviewed:	CDPR/LMS 09/2012; DNC 07/2013, MCM 08/2014, SES 02/2015, DNC 08/2015, 08/2016; AN 02/2017
External Review:	09/2012, 09/2013, 09/2014, 03/2015, 09/2015, 09/2016