

PRIOR AUTHORIZATION CRITERIA

BRAND NAME **ZYTIGA**
(generic) **(abiraterone)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

MDC
Ref # 661-A

FDA-APPROVED INDICATIONS

Zytiga is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

Zytiga is indicated in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer.

Compendial Uses

Zytiga can be used in combination with prednisone and androgen-deprivation therapy for the treatment of newly diagnosed metastatic or high-risk locally advanced hormone-sensitive/hormone-naive prostate cancer, as well as prostate cancer that was previously treated with radical surgery or radiotherapy.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of metastatic castration-resistant prostate cancer? [If no, go to question 5.]	Yes	No
2	Will Zytiga be used in combination with prednisone? [If no, no further questions.]	Yes	No
3	Has the patient been previously treated with Xtandi? [If yes, no further questions.]	Yes	No
4	Does the patient have a contraindication to treatment with Xtandi? [No further questions.]	Yes	No
5	Does the patient have metastatic castration-sensitive prostate cancer, including newly diagnosed disease? [If yes, go to question 9.]	Yes	No
6	Does the patient have newly diagnosed node-positive prostate cancer? [If yes, go to question 9.]	Yes	No
7	Does the patient have high risk locally-advanced prostate cancer? [If yes, go to question 9.]	Yes	No
8	Does the patient have prostate cancer that was previously treated with radical surgery or radiotherapy now relapsing with high-risk features? [If no, no further questions.]	Yes	No
9	Will Zytiga be used in combination with prednisone? [If no, no further questions.]	Yes	No
10	Will Zytiga be used with concurrent androgen-deprivation therapy? [If yes, no further questions.]	Yes	No

11	Has the patient had a bilateral orchiectomy?	Yes	No
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Guidelines for Approval							
Duration of Approval				12 months			
Set 1: Castration-resistant disease, prev Xtandi		Set 2: Castration-resistant, CI to Xtandi		Set 3: Metastatic castration sensitive- ADT		Set 4: Metastatic castration-sensitive-bilateral orchiectomy	
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	3	5	1	5	1
2		2		9		9	10
3		4		10		11	
Set 5: Node positive disease, with ADT		Set 6: Node positive disease, bilateral orchiectomy		Set 7: High-risk locally advanced, with ADT		Set 8: High-risk locally advanced, bilateral orchiectomy	
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)
6	1	6	1	7	1	7	1
9	5	9	5	9	5	9	5
10		11	10	10	6	11	6
							10
Set 9: Post surgery/radiotherapy, ADT		Set 10: Post surgery/radiotherapy, bilateral orchiectomy					
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)				
8	1	8	1				
9	5	9	5				
10	6	11	6				
	7		7				
			10				

Mapping Instructions		
	Yes	No
1.	Go to 2	Go to 5
2.	Go to 3	Deny
3.	Approve 12 months	Go to 4
4.	Approve 12 months	Deny
5.	Go to 9	Go to 6
6.	Go to 9	Go to 7
7.	Go to 9	Go to 8
8.	Go to 9	Deny
9.	Go to 10	Deny
10.	Approve 12 months	Go to 11
11.	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. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2018.
2. DRUGDEX ® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed January 29, 2018.
3. Fizazi K, Tran N, Fein L et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med.* 2017;377:352-60
4. James ND, de Bono JS, Spears MR, et al. Abiraterone for Prostate Cancer Not Previously Treated with Hormone Therapy. *N Engl J Med.* 2017;377:338-51.

DOCUMENT HISTORY

Written: Specialty Clinical Development (KH) 04/2011
Revised: KH 06/2011, GY 09/2011, KP 12/2012, AS 07/2013, TS 06/2014, ST 07/2015; JP 07/2016, 04/2017 (added Xtandi step therapy per Trade), LP 08/2017, LP 12/2017 (Label update and addition of STAMPEDE trial), LP 03/2018 (Removed STAMPEDE trial inclusion requirements- CMS comment)
Reviewed: CDPR/KP 05/2011, 09/2011, LMS 12/2012, DNC 07/2013, MCM 08/2014; DNC 08/2015, 08/2016; AN 04/2017, SD 07/2017, AN 08/2017, MC 02/2018
External Review: 05/2011, 10/2011, 12/2012, 09/2013, 09/2014, 09/2015, 09/2016, 09/2017