JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS078
		Effective Date	07/17/2013
		Review Date	09/12/2023
	Subject **Zytiga and Xtandi**	*Revision Date*	07/15/2020
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: xtandi, zytiga

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I. POLICY

A. Zytiga (abiraterone acetate) and Xtandi (enzalutamide) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Abiraterone (generic Zytiga) may be approved for ALL the following:
   1. Patient is male and 18 years of age or older
   2. Documentation has been submitted showing:
      a. One of the following diagnoses:
         I. Metastatic castration-resistant prostate cancer
         II. Metastatic high-risk castration-sensitive prostate cancer
      b. Intent to use abiraterone in combination with prednisone
      c. One of the following:
         I. Patient will be on concurrent therapy with a gonadotropin-releasing hormone analog
         II. Patient has had bilateral orchiectomy
   3. *Brand name Zytiga request will have an additional requirement of previous trial and inadequate response, or intolerance with generic abiraterone

B. Xtandi may be approved for ALL the following:
   1. Patient is male and 18 years of age or older
   2. Documentation has been submitted showing:
      a. One of the following diagnoses:
         I. Metastatic castration-resistant prostate cancer and prior treatment with docetaxel
         II. Metastatic high-risk castration-sensitive prostate cancer
      b. One of the following:
         I. Patient will be on concurrent therapy with a gonadotropin-releasing hormone analog
         II. Patient has had bilateral orchiectomy

c. Patient has had prior trial and inadequate response or intolerance with abiraterone or Zytiga

*For requests based on NCCN compendium listings that do not fall specifically under the policy criteria noted above, consideration for approval will be based on clinical data showing efficacy and safety.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be provided for up to 12 months of therapy.
B. Continuation of therapy may be extended in 12-month intervals with clinical documentation showing the patient has had a beneficial response to treatment.
C. Limitations:
   1. Generic abiraterone, Zytiga, and Xtandi may be approved for a maximum supply of 120 tablets per 30 days

IV. EXCLUSIONS

A. Abiraterone, Zytiga, and Xtandi will not be approved for the following:
   1. Women who are pregnant, or may become pregnant
   2. Pediatric patients, as the safety and effectiveness has not been established in this population
   3. Any indication or usage that is not FDA-approved, or guideline-support
B. Additionally, Abiraterone and Zytiga will not be approved for the following:
   1. Doses greater than the FDA-approved dose of 1000mg daily.
   2. AST>5xULN
   3. Total Bilirubin >3x ULN
   4. Patients with left ventricular ejection fraction < 50%
   5. Patients with a Class II to IV of New York Heart Association (NYHA) classification
C. Additionally, Xtandi will not be approved for the following:
   1. Individuals who have seizures/ a low seizure threshold
   2. Dose greater than the FDA-approved dose of 160 mg daily.
D. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Xtandi [Prescribin Information]. Horsham, PA: Janssen Biotech Inc.; September 2022.
2. Zytiga [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; August 2021.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information
07/27/2017	Updated Exclusions Section regarding physician samples
07/01/2018	Removed EHP Line of Business

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07/15/2020	Clarified and updated the coverage criteria for Zytiga and Xtandi based FDA-approved prescribing information

Review/Revision Dates: 07/17/2013, 04/20/2016, 07/27/2017, 07/01/2018, 06/08/2020, 07/15/2020, 09/12/2023