

Generic Name: Enzalutamide

Therapeutic Class or Brand Name: Xtandi

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2140243000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/26/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of castration-resistant prostate cancer (CRPC).
- II. Documentation that the patient is receiving gonadotropin-releasing hormone (GnRH) analog concurrently or had bilateral orchiectomy.
- III. Prior treatment with abiraterone (Zytiga®) has been ineffective, contraindicated, or not tolerated.
- IV. Minimum age requirement: 18 years old.
- V. Prescriber is an oncologist or urologist.

EXCLUSION CRITERIA

- Female patients.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 120 capsules per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network (NCCN). Prostate Cancer Version 2.2019. Updated April 17, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
2. Medi-Span.
3. Xtandi® [Package insert] Northbrook, IL: Astellas Pharma; July 2018. Available at: <https://www.astellas.us/docs/us/12A005-ENZ-WPI.pdf>.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
7/26/2019	<ol style="list-style-type: none"> 1. Removed "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru280reg.pd." Added "https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf" under References.
11/8/2018	<ol style="list-style-type: none"> 1. Changed "I. Documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)" to "I. Documented diagnosis of castration-resistant prostate cancer (CRPC)" under Prior Authorization Criteria. 2. Added "II. Documentation that the patient is receiving gonadotropin-releasing hormone (GnRH) analog concurrently or had bilateral orchiectomy" under Prior Authorization Criteria. 3. Removed "http://blue.regence.com/trgmedpol/drugs/dru280.pdf." Added "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru280reg.pdf" under References.
12/13/2017	<ol style="list-style-type: none"> 1. Policy reviewed: no changes made.
10/6/2016	<ol style="list-style-type: none"> 1. Policy reviewed: no changes made.
4/15/2015	<ol style="list-style-type: none"> 1. Removed "Prior treatment with taxane chemotherapy (i.e. docetaxel, cabazitaxel) has been ineffective, contraindicated, or not tolerated" under Prior Authorization Criteria. 2. Changed "Prescriber is an oncologist" to "Prescriber is an oncologist or urologist" under Prior Authorization Criteria. 3. Changed "N/A" to "Female patients" under Exclusion Criteria.
12/4/2013	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Updated references to include Medi-Span.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer

to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.