

| Market Applicability | | | | | | |
|----------------------|----|----|----|----|----|----|
| Market | GA | KY | MD | NJ | NY | WA |
| Applicable | X | X | X | X | X | X |

Xtandi (enzalutamide)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|-----------------------|-----------------------------------|
| Xtandi (enzalutamide) | May be subject to quantity limits |

APPROVAL CRITERIA

Requests for Xtandi (enzalutamide) may be approved if the following is met:

- I. Individual is diagnosed with one of the following:
 - A. Individual has a diagnosis of castration-resistant* prostate cancer (CRPC) (Label, NCCN 2A); **OR**
 - B. Individual has a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC);

AND

- II. One of the following:
 - A. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron (leuprolide, Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix); **OR**
 - B. Individual has had a bilateral orchiectomy.

*Castration-resistant refers to disease progression following either surgically or medically induced methods of castration. Medically-induced methods of castration include luteinizing hormone-releasing hormone (LHRH) agonists (such as leuprolide and goserelin) or LHRH antagonists (such as degarelix).

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 19, 2020.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
- NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 19, 2020.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- a. Prostate Cancer. V1.2020. Revised March 16, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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