Xtandi

Description

Xtandi (enzalutamide)

Background
Xtandi is indicated for men with castration-resistant prostate cancer (CRPC, prostate cancer that is resistant to medical or surgical treatments that lower testosterone). Prostate cancer is an androgen-dependent disease. Xtandi (enzalutamide) targets multiple steps in the androgen receptor-signaling pathway, the major driver of prostate cancer growth. It works by competitively inhibiting androgen binding to androgen receptors and inhibits androgen receptor nuclear translocation and interaction with DNA (1).

Regulatory Status
FDA-approved indication: Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer (1).

Xtandi is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. Xtandi is not indicated for use in females. Advise males with female partners of reproductive potential to use effective contraception during treatment with Xtandi and for 3 months after the last dose of Xtandi. Xtandi should not be handled by females who are or may become pregnant (1).

The safety and effectiveness of Xtandi have not been established in pediatric patients (1).

Related policies
Erleada, Nilandron, Nubeqa, Yonsa, Zytiga
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xtandi may be considered medically necessary in male patients who are 18 years of age or older with a confirmed diagnosis of castration-resistant prostate cancer and if the conditions indicated below are met.

Xtandi is considered investigational in patients who are female, in patients less than 18 years of age, and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Gender
Male

Diagnosis

Patient must have the following:

Castration-Resistant Prostate Cancer (CRPC)

AND ONE of the following:
1. Patient is receiving gonadotropin-releasing hormone (GnRH) analog
2. Patient has had a bilateral orchiectomy

AND ALL of the following:
1. NO dual therapy with another androgen receptor inhibitor (see Appendix 1)
2. Prescriber agrees to advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Xtandi
Prior – Approval *Renewal* Requirements

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

*Quantity* 360 capsules per 90 days

*Duration* 12 months

**Prior – Approval *Renewal* Limits**

Same as above

**Rationale**

**Summary**

Xtandi is FDA-approved for treatment of patients with castration-resistant prostate cancer (CRPC). The safety and effectiveness of Xtandi have not been established in the pediatric population (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Xtandi while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Reason</th>
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<tbody>
<tr>
<td>October 2012</td>
<td>New addition to PA</td>
</tr>
<tr>
<td>December 2012</td>
<td>Removal of prior docetaxel use requirement (based on expert opinion).</td>
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<tr>
<td></td>
<td>Annual editorial review and update</td>
</tr>
<tr>
<td>March 2014</td>
<td>Annual review</td>
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**Section:** Prescription Drugs  
**Effective Date:** January 1, 2020  
**Subsection:** Antineoplastic Agents  
**Original Policy Date:** October 4, 2012  
**Subject:** Xtandi  
**Page:** 4 of 5

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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| June 2016 | Annual editorial review and reference update  
              Policy number change from 5.04.21 to 5.21.21                                             |
| March 2017 | Annual editorial review and reference update  
              Addition of no dual therapy with another androgen receptor inhibitor                          |
| June 2018 | Annual editorial review and reference update                                                        |
| August 2018 | Removal of metastatic prostate cancer requirement, addition of  
                     requirement of patient is receiving GnRH analog or patient has had bilateral orchiectomy,  
                     if patient or their partner are of child bearing age, the patient has been instructed  
                     to practice effective contraception during therapy and for 3 months after stopping  
                     therapy |
| September 2018 | Annual editorial review                        |
| June 2019  | Annual review                                   |
| December 2019 | Annual review                                  |

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.
Appendix 1 - List of Androgen Receptor Inhibitors

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tr>
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