Nilandron

Description

Nilandron (nilutamide)

Background
Nilandron is used as a combination agent with surgical castration for the treatment of metastatic prostate cancer. Nilandron is an orally active antiandrogen drug that works by blocking the effects of testosterone at the androgen receptor level thereby preventing an androgenic response. Nilandron interrupts the effect that testosterone has on the prostate and deprives it of signals typically responsible for growth and cell differentiation in the prostate (1).

Regulatory Status
FDA-approved indication: Nilandron is for use in combination with surgical castration for the treatment of metastatic prostate cancer. For maximum benefit, Nilandron treatment must begin on the same day as or on the day after surgical castration (1).

Nilandron is contraindicated in patients with severe hepatic impairment and patients should have a baseline liver enzymes test prior to initiation of therapy. Nilandron has a black box warning for patients who have severe respiratory insufficiency due to potentially fatal interstitial pneumonitis developing in patients resulting in pulmonary fibrosis that can lead to hospitalization and death (1).

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

Related policies
Erleada, Nubeqa, Xtandi, 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.

Nilandron may be considered **medically necessary** in patients that are 18 years of age and older with metastatic prostate cancer and if the conditions indicated below are met.

Nilandron is considered **investigational** in patients that are less than 18 years of age and for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age or older  
**Gender** Male  
**Diagnoses**  
Patient must have the following:

1. Metastatic prostate cancer  

   **AND** all of the following:

   a. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
      i. Generic nilutamide  
      ii. Bicalutamide  
      iii. Flutamide  

   b. Baseline liver enzymes test with **NO** severe hepatic impairment  

   c. Chest x-ray with **NO** severe respiratory insufficiency findings  

   d. Used in combination with surgical castration  

   e. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)

### Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older
Gender  Male

Diagnosis

Patient must have the following:

1. Metastatic prostate cancer

   AND ALL of the following:
   
   a. NO severe respiratory insufficiency
   b. Prescriber agrees to monitor ALT and AST levels at regular intervals
   c. NO dual therapy with another androgen receptor inhibitor (see Appendix 1)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration  12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Nilandron is an orally active antiandrogen indicated for the treatment of metastatic prostate cancer with surgical castration. Nilandron is only indicated for use in men and should not be used in patients with severe respiratory insufficiency or in patients with a history of liver dysfunction or elevated liver enzymes. This drug can cause fetal harm and men with women partners of reproductive age should use contraception. The safety and efficacy of Nilandron in pediatric patients have not been studied (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Nilandron while maintaining optimal therapeutic outcomes.
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Antineoplastic Agents  Original Policy Date: November 21, 2016
Subject: Nilandron  Page: 4 of 5

References

Policy History
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<tr>
<td>November 2016</td>
<td>Addition to PA</td>
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<tr>
<td>March 2017</td>
<td>Annual review</td>
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<tr>
<td>June 2017</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>September 2018</td>
<td>Annual editorial review</td>
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<tr>
<td>June 2019</td>
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<tr>
<td>August 2019</td>
<td>Addition of no dual therapy requirement and addition of Appendix 1</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review and reference update</td>
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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

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