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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 21, 2016
Subject:	Nilandron	**Page:**	1 of 5

Last Review Date: March 8, 2024

Nilandron

Description

Nilandron (nilutamide)

Background
Nilandron (nilutamide) 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 is also contraindicated in patients with severe respiratory insufficiency (1).

Nilandron carries a boxed warning for the risk of interstitial pneumonitis, which can lead to hospitalization and death (1).

It is not known whether Nilandron can cause fetal harm when administered to a pregnant woman (1).

Patients receiving Nilandron have reported a delay in adaptation to dark when passing from a lighted area to a dark area. Patients who experience this effect should be cautioned about driving at night or through tunnels (1).

The safety and effectiveness of Nilandron in pediatric patients less than 18 years of age have not been established (1).

Related policies
Erleada, Nubeqa, Orgovyx, 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** if the conditions indicated below are met.

Nilandron may be considered **investigational** for all other indications.

Prior-Approval 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. 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 (nilutamide) 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. The safety and efficacy of Nilandron in pediatric patients less than 18 years of age 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.

References

1. Nilandron [package insert]. St. Michael, Barbados: Concordia Pharmaceuticals Inc.; July 2022.
2. NCCN Drugs & Biologics Compendium® Nilutamide 2024. National Comprehensive Cancer Network, Inc. Accessed on January 18, 2024.

Policy History

Date	Action
November 2016	Addition to PA
March 2017	Annual review
June 2017	Annual review
June 2018	Annual editorial review and reference update
September 2018	Annual editorial review
June 2019	Annual review
August 2019	Addition of no dual therapy requirement and addition of Appendix 1
September 2019	Annual review and reference update
December 2019	Annual review
June 2020	Annual review
March 2021	Annual editorial review and reference update
June 2021	Annual review and reference update
September 2022	Annual review and reference update
December 2022	Annual review and reference update. Per SME, added precaution regarding delay in dark adaptation to regulatory status
September 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of Androgen Receptor Inhibitors

Generic Name	Brand Name
abiraterone	Yonsa
abiraterone	Zytiga
abiraterone/niraparib	Akeega
apalutamide	Erleada
darolutamide	Nubeqa
enzalutamide	Xtandi
nilutamide	Nilandron