

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Nilutamide Prior Authorization Policy

- Nilandron® (nilutamide tablets – Concordia, generic)

REVIEW DATE: 02/05/2025

OVERVIEW

Nilutamide, in combination with surgical castration, is indicated for the treatment of **metastatic prostate cancer (Stage D₂)**.¹ For maximum benefit, nilutamide treatment must begin on the same day as or on the day after surgical castration.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **prostate cancer** (version 1.2025 – December 4, 2024) recommend nilutamide in combination with luteinizing hormone-releasing hormone agonists [Lupron® (leuprolide subcutaneous injection), Lupron Depot® (leuprolide acetate intramuscular injection), Trelstar® (triptorelin pamoate intramuscular injection), Zoladex® (goserelin acetate subcutaneous implant), Vantas® (histrelin acetate subcutaneous implant)] with or without external beam radiation therapy for androgen deprivation therapy.^{2,3}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of nilutamide. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of nilutamide is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Prostate Cancer.** Approve for 1 year if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.

Note: Examples are Lupron (leuprolide subcutaneous injection), Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of nilutamide is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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1. Nilandron® tablets [prescribing information]. St. Michael, Barbados: Concordia; May 2017.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 28, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 28, 2025. Search term: nilutamide.