

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Nilutamide Prior Authorization Policy

- Nilandron<sup>®</sup> (nilutamide tablets – Concordia, generic)

**REVIEW DATE:** 01/17/2024

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### OVERVIEW

Nilutamide, in combination with surgical castration, is indicated for the treatment of **metastatic prostate cancer (Stage D<sub>2</sub>)**.<sup>1</sup> 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 4.2023 – September 7, 2023) recommend nilutamide in combination with luteinizing hormone-releasing hormone agonists [Lupron<sup>®</sup> (leuprolide subcutaneous injection), Lupron Depot<sup>®</sup> (leuprolide acetate intramuscular injection), Trelstar<sup>®</sup> (triptorelin pamoate intramuscular injection), Zoladex<sup>®</sup> (goserelin acetate subcutaneous implant), Vantas<sup>®</sup> (histrelin acetate subcutaneous implant)] with or without external beam radiation therapy for androgen deprivation therapy.<sup>2,3</sup>

### 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.

01/17/2024

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## REFERENCES

1. Nilandron® [prescribing information]. St. Michael, Barbados: Concordia; May 2017.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – September 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 10, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 10, 2024. Search term: nilutamide.