nilutamide (Nilandron®)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO199

Description

Nilutamide (Nilandron) is an orally active first-generation nonsteroidal antiandrogen agent, which blocks effects of testosterone at the androgen receptor level, preventing androgen response.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
Nilutamide (Nilandron)*	150 mg tablet	Metastatic prostate cancer	**Initial**: 60 tablets/ 30 days for one month **Maintenance**: 30 tablets/ 30 days

*Generic nilutamide is a formulary agent and does not require prior authorization

Initial Evaluation

I. Nilutamide (Nilandron) may be considered medically necessary when following criteria are met:

A. Member is 18 years of age or older; **AND**

B. The medication is prescribed by, or in consultation with, an oncologist or urologist; **AND**

C. A diagnosis of **metastatic prostate cancer**; **AND**

D. Treatment with generic nilutamide has been ineffective, contraindicated or not tolerated

II. Nilutamide (Nilandron) is considered investigational when used for all other conditions.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**

II. Member has absence of unacceptable toxicity from the medication; **AND**

III. Disease response to treatment defined by stabilization of disease or decrease in tumor size or tumor spread

Supporting Evidence

I. Nilutamide (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.

II. Nilutamide (Nilandron) is FDA-approved for adult members (18 years and older) as a combination agent with surgical castration for the treatment of metastatic prostate cancer (Stage D2).

III. There are multiple treatment modalities for prostate cancer, wherein the choice of therapy depends on the manifestations of the disease. The initial and continued approach should be directed by a specialist due to the nuances of treatment, monitoring of disease, treatment safety, evaluation of efficacy, and consideration for patient specific goals. Therefore, nilutamide (Nilandron) should be prescribed by, or in consultation with, and oncologist or urologist.

IV. Coverage of brand name nilutamide (Nilandron) requires failure, intolerance or contraindication to generic nilutamide. Nilutamide is the AB-rated generic to nilutamide (Nilandron), and is deemed to be bioequivalent to the brand formulation; however, is a more cost-effective option.

References

1. Nilandron (nilutamide) [prescribing information]. St. Michael, Barbados: Concordia Pharmaceuticals; received May 2017.
2. Orange Book: approved drug products with therapeutic equivalence evaluations. U.S. Food & Drug Administration. Accessed October 2020. Available at: https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	**10/2020**