Commercial/Healthcare Exchange PA Criteria

Effective: September 2016

Prior Authorization: Nilutamide

Products Affected: Nilutamide oral tablets

Medication Description:
Nilandron tablets are indicated for use in combination with surgical castration for the treatment of metastatic prostate cancer (Stage D_2). For maximum benefit, Nilandron treatment must begin on the same day as or on the day after surgical castration.

Prostate cancer is known to be androgen sensitive and responds to androgen ablation. In animal studies, nilutamide has demonstrated antiandrogenic activity without other hormonal (estrogen, progesterone, mineralocorticoid, and glucocorticoid) effects. In vitro, nilutamide blocks the effects of testosterone at the androgen receptor level. In vivo, nilutamide interacts with the androgen receptor and prevents the normal androgenic response.

Nilandron has a Boxed Warning for interstitial pneumonitis**.** Interstitial pneumonitis has been reported in 2% of patients in controlled clinical trials in patients exposed to nilutamide. A small study in Japanese subjects showed that 8 of 47 patients (17%) developed interstitial pneumonitis. Reports of interstitial changes including pulmonary fibrosis that led to hospitalization and death have been reported rarely post-marketing. Symptoms included exertional dyspnea, cough, chest pain, and fever. X-rays showed interstitial or alveolo-interstitial changes, and pulmonary function tests revealed a restrictive pattern with decreased DLco. Most cases occurred within the first 3 months of treatment with Niladron, and most reversed with discontinuation of therapy. A routine chest X-ray should be performed prior to initiating treatment with Nilandron. Baseline pulmonary function tests may be considered. Patients should be instructed to report any new or worsening shortness of breath that they experience while on Nilandron. If symptoms occur, Nilandron should be immediately discontinued until it can be determined if the symptoms are drug related.

Covered Uses: Metastatic prostate cancer (Stage D2) in combination with surgical castration.

Exclusion Criteria:
1. Patients with severe hepatic impairment (baseline hepatic enzymes should be evaluated prior to treatment)
2. Patients with severe respiratory insufficiency
3. Avoid use in women

Required Medical Information:
1. Diagnosis
2. Confirmation of treatment in combination with surgical castration
3. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 12 months

Other Criteria:

Metastatic Prostate Cancer

A. Patient has a diagnosis of metastatic prostate cancer (Stage D2); AND
B. Patient is undergoing surgical castration; AND
C. Patient will begin Nilandron on the same day as or on the day after surgical castration.

References:

1. Nilandron [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2016.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 3.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 20, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	09/13/2016
2	Update	Update policy to FDA label	Exclusion Criteria	12/11/2019
3	CCI to adopt EH policy	Alignment with enterprise, remove from CCI Oncology Policy	ALL	12/12/2019