BlueCross BlueShield Federal Employee Program

# NILANDRON (nilutamide)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### 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).

### 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 October 3, 2024.