XTANDI (entalutamide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Xtandi is indicated for men with castration-resistant prostate cancer (CRPC, prostate cancer that is resistant to medical or surgical treatments that lower testosterone). Prostate cancer is an androgen-dependent disease. Xtandi (entalutamide) targets multiple steps in the androgen receptor-signaling pathway, the major driver of prostate cancer growth. It works by competitively inhibiting androgen binding to androgen receptors and inhibits androgen receptor nuclear translocation and interaction with DNA (1).

Regulatory Status
FDA-approved indication: Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer (1).

Xtandi is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. Xtandi is not indicated for use in females. Advise males with female partners of reproductive potential to use effective contraception during treatment with Xtandi and for 3 months after the last dose of Xtandi. Xtandi should not be handled by females who are or may become pregnant (1).

The safety and effectiveness of Xtandi have not been established in pediatric patients (1).

Summary
Xtandi is FDA-approved for treatment of patients with castration-resistant prostate cancer (CRPC). The safety and effectiveness of Xtandi have not been established in the pediatric population (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Xtandi while maintaining optimal therapeutic outcomes.

References