XTANDI
(enzalutamide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xtandi is indicated for men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body (1). Prostate cancer is an androgen-dependent disease. Xtandi (enzalutamide) 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 metastatic 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 (1).

Serious side effects related to the use of Xtandi include seizure, which occurred in 0.9% of patients receiving Xtandi 160mg once daily in a randomized controlled trial. In a dose escalation study, no seizures were reported at ≤ 240mg daily, whereas 3 seizures were reported, 1 each at 360mg, 480mg, and 600mg daily. No seizures occurred in patients treated with placebo (1).

Xtandi carries a pregnancy category X warning and is not indicated for use in women. Maternal use of an androgen receptor inhibitor could affect development of the fetus. If the patient has a partner who is pregnant or plans to become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment (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 metastatic castration-resistant prostate cancer. Xtandi has been shown to significantly prolonged the survival of men with metastatic castration-resistant prostate cancer. The safety and effectiveness has 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.

Xtandi FEP Clinical Rationale
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References