BlueCross BlueShield Federal Employee Program

XTANDI (enzalutamide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xtandi (enzalutamide) is an androgen receptor inhibitor used for the treatment of prostate cancer. Xtandi inhibits androgen binding to androgen receptors; and consequently, inhibits nuclear translocation of androgen receptors and their interaction with DNA. Xtandi decreases proliferation and induces cell death of prostate cancer cells (1).

Regulatory Status

FDA-approved indications: Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with: (1)

- castration-resistant prostate cancer (CRPC).
- metastatic castration-sensitive prostate cancer (mCSPC).
- non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).

Xtandi label includes warnings for seizures, posterior reversible encephalopathy syndrome (PRES), hypersensitivity, ischemic heart disease, falls and fractures, and embryo-fetal toxicity (1).

Discontinue Xtandi in patients who develop PRES or a seizure during treatment. Monitor patients for signs and symptoms of ischemic heart disease. Discontinue Xtandi for Grade 3-4 ischemic heart disease events. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures and consider use of bone-targeted agents (1).

Xtandi can cause fetal harm and loss of pregnancy. Advise male patients 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 in pediatric and female patients have not been established (1).

Summary

Xtandi (enzalutamide) is indicated for the treatment of patients with castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive

prostate cancer with high-risk BCR. Xtandi label includes warnings for seizures, posterior reversible encephalopathy syndrome (PRES), hypersensitivity, ischemic heart disease, falls and fractures, and embryo-fetal toxicity. The safety and effectiveness of Xtandi in pediatric and female patients have not been established (1).

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

References

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US; November 2023.
2. NCCN Drugs & Biologics Compendium® Enzalutamide 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.