BlueCross BlueShield Federal Employee Program

YONSA
(abiraterone acetate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Yonsa (abiraterone acetate) is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC). Yonsa is converted in vivo to abiraterone, an androgen biosynthesis inhibitor, which inhibits the enzyme 17 α-hydroxylase/C17,20-lyase (CYP17). The CYP17 enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. By inhibiting this enzyme, androgen biosynthesis is diminished, thereby decreasing the androgen production by the adrenals and in the tumor. Androgen deprivation therapies such as GnRH agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor (1).

Regulatory Status

FDA-approved indication: Yonsa is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC) (1).

Based on animal reproductive studies and mechanism of action, Yonsa can cause fetal harm and potential loss of pregnancy. Prescribers should advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the last dose (1).

Yonsa may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Yonsa should be used with caution in patients with a history of cardiovascular disease. Blood pressure, serum potassium, and symptoms of fluid retention should be monitored at least monthly. Adrenal cortical insufficiency may occur with the use of Yonsa. Caution should be used and monitor for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from methylprednisolone, have methylprednisolone dose reductions, or experience unusual stress (1).

Yonsa may cause hepatotoxicity. Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. Serum transaminases (ALT and AST) and bilirubin levels should be measured prior to initiation of therapy, every two weeks for the first three months of treatment, and monthly thereafter (1).

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

Summary

Yonsa (abiratone acetate) is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC). Yonsa may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Yonsa may cause hepatotoxicity. Increases in liver enzymes have led to drug interruption, dose modification and/or discontinuation. The safety and effectiveness of Yonsa 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 Yonsa while maintaining optimal therapeutic outcomes.

References

1. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
2. NCCN Drugs & Biologics Compendium® Abiraterone 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.