BlueCross BlueShield
Federal Employee Program

LYSODREN
(mitotane)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lysodren (mitotane) is an adrenal cytotoxic agent with an unknown mechanism of action. Lysodren modifies the peripheral metabolism of steroids and directly suppresses the adrenal cortex. This leads to a reduction in 17-hydroxycorticosteroids in the absence of decreased corticosteroid concentrations and increased formation of 6-β-hydroxycortisol (1).

Regulatory Status

FDA-approved indication: Lysodren is an adrenal cytotoxic agent indicated for the treatment of inoperable, functional or nonfunctional, adrenocortical carcinoma (ACC) (1).

Lysodren dose should be increased incrementally to achieve a blood concentration of 14 to 20 mg/L, or as tolerated (1).

Lysodren has a boxed warning regarding adrenal crisis in the setting of shock, severe trauma, or infection. Patients taking Lysodren are at increased risk for developing adrenal crisis in the setting of shock, severe trauma, or infection that may lead to death. IF shock, severe trauma, or infection occurs or develops, temporarily discontinue Lysodren and administer exogenous steroids (1).

Lysodren also has warnings regarding CNS toxicity and adrenal insufficiency. Mitotane plasma concentrations exceeding 20 mcg/mL are associated with a greater incidence of CNS toxicity. Free cortisol and corticotropin (ACTH) levels should be measured to achieve optimal steroid replacement (1).

Lysodren can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Lysodren and after discontinuation of treatment for as long as mitotane plasma levels are detectable (1).

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

Summary

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Lysodren (mitotane) is an adrenal cytotoxic agent with an unknown mechanism of action indicated for the treatment of inoperable, functional or nonfunctional, adrenocortical carcinoma (ACC). Lysodren modifies the peripheral metabolism of steroids and directly suppresses the adrenal cortex. This leads to a reduction in 17-hydroxycorticosteroids in the absence of decreased corticosteroid concentrations and increased formation of 6-β-hydroxycortisol (1).

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

References

1. Lysodren [package insert]. Farmingdale, NJ: Direct Success Inc.; January 2024.
2. NCCN Drugs & Biologics Compendium® Mitotane 2024. National Comprehensive Cancer Network, Inc. Accessed on April 11, 2024.