

# LYSODREN (mitotane)

### Pre - PA Allowance

None

## **Prior-Approval Requirements**

Age 18 years of age or older

## **Diagnosis**

Patient must have the following:

Adrenocortical carcinoma (ACC)

### AND ALL of the following:

- a. The tumor is inoperable
- b. Prescriber agrees to monitor the patient for signs and symptoms of adrenal crisis in the setting of shock, severe trauma, or infection
- c. Prescriber agrees to monitor for CNS toxicity
- d. Prescriber agrees to monitor free cortisol and corticotropin (ACTH) levels
- e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lysodren and after discontinuation of treatment for as long as mitotane plasma levels are detectable

## **Prior - Approval Limits**

**Duration** 12 months

## Prior – Approval Renewal Requirements

**Age** 18 years of age or older

### **Diagnosis**

Patient must have the following:

Adrenocortical carcinoma (ACC)

#### **AND ALL** of the following:

a. NO disease progression or unacceptable toxicity



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- b. Prescriber agrees to monitor the patient for signs and symptoms of adrenal crisis in the setting of shock, severe trauma, or infection
- c. Prescriber agrees to monitor for CNS toxicity
- d. Prescriber agrees to monitor free cortisol and corticotropin (ACTH) levels
- e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Lysodren and after discontinuation of treatment for as long as mitotane plasma levels are detectable

## Prior - Approval Renewal Limits

Same as above