# **QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA**

BRAND NAME (generic)

(clotrimazole troches/lozenges)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

# **POLICY**

#### FDA-APPROVED INDICATIONS

Clotrimazole lozenges are indicated for the local treatment of oropharyngeal candidiasis. The diagnosis should be confirmed by a KOH smear and/or culture prior to treatment.

Clotrimazole lozenges are also indicated prophylactically to reduce the incidence of oropharyngeal candidiasis in patients immunocompromised by conditions that include chemotherapy, radiotherapy, or steroid therapy utilized in the treatment of leukemia, solid tumors, or renal transplantation. There are no data from adequate and well-controlled trials to establish the safety and efficacy of this product for prophylactic use in patients immunocompromised by etiologies other than those listed in the previous sentence.

#### **INITIAL QUANTITY LIMIT\*\***

# **INITIAL LIMIT QUANTITY**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug 1 Month Limit\* 3 Month Limit\*

Clotrimazole Lozenges (Troches) 90 lozenges / 25 days 270 lozenges / 75 days

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

\*\*If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

#### **COVERAGE CRITERIA**

#### **Oropharyngeal Candidiasis**

Authorization may be granted when the requested drug is being used for the treatment of oropharyngeal candidiasis when the following criteria is met:

The requested drug is NOT being used in a footbath

# **QUANTITY LIMITS APPLY**

140 lozenges per 21 days.\* The 12 week limit does not apply.\*\*

- \* The duration of 21 days is used for a 28-day fill period to allow time for refill processing.
- \*\* These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3-month supplies filled.

# **DURATION OF APPROVAL (DOA)**

4328-HJ: DOA: 3 months

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# **REFERENCES**

- 1. Clotrimazole Lozenges (clotrimazole troche) [package insert]. Minneapolis, MN: Padagis; May 2022.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2024; Accessed February 1, 2024.
- 3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed February 1, 2024.

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