

Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2020

Prior Authorization: Posaconazole

Products Affected: posaconazole oral suspension, posaconazole tablets

<u>Medication Description</u>: Posaconazole blocks the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of cytochrome P-450 dependent enzyme lanosterol 14α -demethylase responsible for the conversion of lanosterol to ergosterol in the fungal cell membrane. This results in an accumulation of methylated sterol precursors and a depletion of ergosterol within the cell membrane thus weakening the structure and function of the fungal cell membrane. This may be responsible for the antifungal activity of posaconazole.

Covered Uses:

- 1. Prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised [suspension and tablets]
- 2. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory to itraconazole and/or fluconazole [suspension only]

Exclusion Criteria:

- 1. Concomitant use with ergot alkaloids (including ergotamine and dihydroergotamine), HMG-CoA reductase inhibitors primarily metabolized by CYP3A4 (eg, atorvastatin, lovastatin, and simvastatin), sirolimus, or CYP3A4 substrates that prolong the QT interval (eg, pimozide and quinidine)
- 2. Hypersensitivity to posaconazole or other azole antifungals

Required Medical Information:

- 1. Diagnosis
- 2. Previous therapies tried/failed

Age Restrictions: Patient is 13 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

Prophylaxis of invasive Aspergillus or Candida infections [suspension and tablets]

A. Patient will be using the medication for prophylaxis of invasive Aspergillus and Candida infections and patient is at high risk of developing these infections due to being severely immunocompromised (e.g. HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy).

Oropharyngeal candidiasis [suspension only]

- A. Patient has a diagnosis of oropharyngeal candidiasis (OPC); AND
- B. Patient has a documented intolerance, contraindication, or treatment failure with, an adequate trial of fluconazole and/or itraconazole for at least 2 weeks.

Last Rev. 10/24/2019





References:

1. Noxafil(R) oral delayed-release tablets, oral suspension, posaconazole oral delayed-release tablets, oral suspension. Merck Sharp & Dohme Corp. (per FDA), Whitehouse Station, NJ, 2013.

Policy Revision history

| Rev# | Type of Change | Summary of Change | Sections Affected | Date |
|------|----------------|-------------------|-------------------|------------|
| 1 | New Policy | New Policy | All | 10/24/2019 |