PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

NOXAFIL (all dosage forms) (posaconazole)

Status: CVS Caremark Criteria Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Treatment of Invasive Aspergillosis

Noxafil injection and **Noxafil delayed-release tablets** are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

Prophylaxis of Invasive Aspergillus and Candida Infections

Noxafil is indicated for the prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- Noxafil Injection: adults and pediatric patients 2 years of age and older
- Noxafil delayed-release tablets: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
- Noxafil oral suspension: adults and pediatric patients 13 years of age and older
- Noxafil PowderMix for delayed-release oral suspension: pediatric patients 2 years of age and older who
 weigh 40 kg or less

<u>Treatment of Oropharyngeal Candidiasis Including Oropharyngeal Candidiasis Refractory to Itraconazole and/or Fluconazole</u>

Noxafil oral suspension is indicated for the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

The requested drug is being prescribed for the prevention of invasive Aspergillus and Candida infections in a
patient who is at a high risk of developing these infections due to being severely immunocompromised

OR

- Noxafil injection or Noxafil delayed-release tablets are being prescribed for the treatment of invasive aspergillosis
 OR
- Noxafil oral suspension (immediate-release) is being prescribed for the treatment of moderate to severe oropharyngeal candidiasis

REFERENCES

- Noxafil [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2021.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed January 12, 2021.
- 3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 12, 2021.

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4.	Pappas P, Kauffman C, Andes D, et al. Clinical Practice Guidelines for the Management of Candidiasis: 2016 Upda by the Infectious Diseases Society of America. <i>Clinical Infectious Diseases</i> . 2016;62:1-50.	
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