Medimpact

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL,	33461		GPI-10	ROUTE = ORAL
	POSACONAZOLE			(1140706000)	

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

If yes, **approve for 6 months by GPID or GPI-14.** If no, continue to #2.

- 2. Is the request for the treatment of invasive aspergillosis and the patient meets **ALL** of the following criteria?
 - The patient is 13 years of age or older
 - The request is for posaconazole (Noxafil) tablets

If yes, **approve for 12 weeks by GPID or GPI-14.** If no, continue to #3.

- 3. Is the request for prophylaxis of invasive aspergillus or candida infections **AND** the patient meets the following criterion?
 - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or has a hematologic malignancy with prolonged neutropenia from chemotherapy

If yes, continue to #4. If no, continue to #7.

- 4. Is the request for posaconazole (Noxafil) tablets and the patient meets ONE of following criteria?
 - The patient is 18 years of age or older
 - The patient is 2 years of age or older AND weighs greater than 40 kg

If yes, **approve for 6 months by GPID or GPI-14.** If no, continue to #5.

- 5. Is the request for posaconazole (Noxafil) oral suspension and the patient meets **ALL** of the following criteria?
 - The patient is 13 years of age or older
 - The patient is unable to swallow tablets

If yes, **approve for 6 months by GPID or GPI-14.** If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

- 6. Is the request for posaconazole (Noxafil) PowderMix and the patient meets **ALL** of the following criteria?
 - The patient is 2 to less than 18 years of age AND weighs less than 40 kg
 - The patient is unable to swallow tablets

If yes, **approve for 6 months by GPID or GPI-14.** If no, do not approve. **DENIAL TEXT:** See the denial text at the end of the guideline.

- 7. Does the patient have a diagnosis of oropharyngeal candidiasis (OPC) and meet **ALL** of the following criteria?
 - The patient is 13 years of age or older
 - The patient had a trial of or contraindication to fluconazole OR itraconazole
 - The request is for posaconazole (Noxafil) oral suspension

If yes, **approve for 3 months by GPID or GPI-14.** If no, continue to #8.

- 8. Does the patient have a diagnosis of esophageal candidiasis and meet **ALL** of the following criteria?
 - The patient is 13 years of age or older
 - The patient had a trial and failure of or contraindication to two of the following: fluconazole, itraconazole solution, or voriconazole

If yes, approve for 3 months by GPID or GPI-14.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:

- A. The request is for ONE of the following:
 - 1. Continuation of therapy after hospital discharge
 - 2. Treatment of invasive aspergillosis (type of fungal infection)
 - 3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
 - 4. Oropharyngeal candidiasis (fungal infection of the throat)
- 5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach) (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

- B. If the request is for treatment of invasive aspergillosis, approval also requires:
 - 1. You are 13 years of age or older
 - 2. You are requesting Noxafil (posaconazole) tablets
- C. If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:
 - You are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or you have hematologic malignancies (cancer affecting the blood) with prolonged neutropenia (low levels of a type of white blood cell) from chemotherapy (cancer treatment)
 - 2. If the request is for posaconazole (Noxafil) tablets, you meet ONE of the following:
 - a. You are 18 years of age or older
 - b. You are 2 years of age or older AND weigh greater than 40 kg
 - 3. If the request is for posaconazole (Noxafil) suspension, you meet ALL of the following:
 - a. You are 13 years of age or older
 - b. You are unable to swallow tablets
 - 4. If the request is for posaconazole (Noxafil) PowderMix, you meet the following:
 - a. You are 2 to 18 years of age AND weigh less than 40 kg
 - b. You are unable to swallow tablets
- D. If the request is for oropharyngeal candidiasis, approval also requires:
 - 1. You are 13 years of age or older
 - 2. You had a trial of or contraindication (harmful for) to fluconazole OR itraconazole
 - 3. You are requesting Noxafil (posaconazole) oral suspension
- E. If the request is for esophageal candidiasis, approval also requires:
 - 1. You are 13 years of age or older
 - 2. You had a trial and failure of or contraindication (harmful for) to TWO of the following: fluconazole, itraconazole solution, or voriconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES

• Noxafil [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Commercial Effective: 01/01/23 Created: 11/07 Client Approval: 11/22

P&T Approval: 10/22