

Initial Prior Authorization

Ketoconazole Oral

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
ketoconazole (brand unavailable)	ketoconazole	tablets

Indications

FDA-approved Indications

Ketoconazole tablets are not indicated for treatment of onychomycosis, cutaneous dermatophyte infections, or Candida infections.

Ketoconazole tablets should be used only when other effective antifungal therapy is not available or tolerated and the potential benefits are considered to outweigh the potential risks.

Ketoconazole tablets are indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis. Ketoconazole tablets should not be used for fungal meningitis because it penetrates poorly into the cerebrospinal fluid.

Compendial Uses

- Cushing's Syndrome^{2,3}

Coverage Criteria

Blastomycosis, Chromomycosis, Coccidioidomycosis, Histoplasmosis, Paracoccidioidomycosis

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient has ANY of the following diagnoses:
 - Blastomycosis.
 - Coccidioidomycosis.
 - Histoplasmosis.
 - Chromomycosis.
 - Paracoccidioidomycosis.
- Other antifungal therapies are ineffective or not tolerated.
- The patient is using the requested drug orally.

Cushing's Syndrome

Authorization may be granted when the requested drug is being prescribed for a patient with Cushing's Syndrome who cannot tolerate surgery or surgery has not been curative when the following criteria is met:

- The patient is using the requested drug orally.

Duration of Approval (DOA)

- 1024-A: DOA: 6 months

References

1. Ketoconazole Tablets [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; September 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).
4. NORD. Cushing Syndrome. Available at: <https://rarediseases.org/rare-diseases/cushing-syndrome/>. Accessed September 10, 2024.
5. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.

6. FDA Drug Safety Communication: FDA warns that prescribing of Nizoral (ketoconazole) oral tablets for unapproved uses including skin and nail infections continues; linked to patient death. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-prescribing-nizoral-ketoconazole-oral-tablets-unapproved>. Accessed September 10, 2024.

Document History

Written by: UM Development (TM)

Date Written: 08/2013

Revised: (TM) 01/2014, 08/2014; (MS) 05/2015, 05/2016, (SE) 06/2016 (created separate Med D). (SF) 05/2017, (ME) 04/2018 (no clinical changes), 02/2019 (no clinical changes); (RP) 02/2020 (no clinical changes; Removed MDC designation; Renamed criteria); (PM) 12/2020 (added oral question), 09/2021 (no clinical changes); (MRS) 09/2022 (no clinical changes); (DRS) 09/2023 (no clinical changes); (DFW) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (KP) 08/2013, (KP) 01/2014, (LMS) 08/2014; (DC) 05/2015; (LB) 05/2016; (JG) 05/2017; (CHART) 02/27/2020, 12/31/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 12/2013, 10/2014, 10/2015, 08/2016, 08/2017, 06/2018, 06/2019, 06/2020, 04/2021, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Does the patient have any of the following diagnoses: A) Blastomycosis, B) Coccidioidomycosis, C) Histoplasmosis, D) Chromomycosis, E) Paracoccidioidomycosis? [If Yes, then go to 2. If No, then go to 3.]	Yes	No
2	Are other antifungal therapies ineffective or not tolerated? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
3	Is the requested drug being prescribed for a patient with Cushing's Syndrome who cannot tolerate surgery or surgery has not been curative? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Will the patient be using the requested drug orally? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS

1.	Go to 2	Go to 3	
2.	Go to 4	Deny	<p>Your plan only covers this drug if you have tried other antifungal drugs, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy]</p>
3.	Go to 4	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) Blastomycosis, B) Coccidioidomycosis, C) Histoplasmosis, D) Chromomycosis, E) Paracoccidioidomycosis, F) Cushing's Syndrome when you cannot have surgery or surgery did not cure you. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
4.	Approve, 6 Months	Deny	<p>We have denied your request because your plan does not cover this drug if it is not taken by mouth. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Exclusion]</p>