

Initial Prior Authorization

Terbinafine Tablets

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
terbinafine (brand unavailable)	terbinafine	tablets

Indications

FDA-approved Indications

Terbinafine tablets are indicated for the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium).

Prior to initiating treatment, appropriate nail specimens for laboratory testing [potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy] should be obtained to confirm the diagnosis of onychomycosis.

Compendial Uses

- Tinea Capitis²⁻⁴
- Tinea Corporis^{2,4}, Tinea Cruris^{2,4} –extensive disease, dermatophyte folliculitis is present, did not respond to topical therapy, is immunocompromised

Coverage Criteria

Onychomycosis

Authorization may be granted when the requested drug is being prescribed for the treatment of onychomycosis due to dermatophytes (tinea unguium) when ALL of the following criteria are met:

- The patient's diagnosis has been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
- The requested drug is NOT being used in a footbath.

Tinea Capitis

Authorization may be granted when the requested drug is being prescribed for the treatment of tinea capitis when the following criteria is met:

- The requested drug is NOT being used in a footbath.

Tinea Corporis, Tinea Cruris

Authorization may be granted when the requested drug is being prescribed for the treatment of tinea corporis or tinea cruris when ALL of the following criteria are met:

- The patient meets ANY of the following: has extensive disease, dermatophyte folliculitis is present, did NOT respond to topical therapy, is immunocompromised.
- The requested drug is NOT being used in a footbath.

Duration of Approval (DOA)

- 364-A: DOA: 3 months

References

1. Terbinafine tablets [package insert]. Berkeley Heights, NJ: Breckenridge Pharmaceutical, Inc.; December 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. Frazier WF, Santiago-Delgado ZM, Stupka KC. Onychomycosis: Rapid Evidence Review. Am Fam Physician. 2021;104(4):359-367.
5. Centers for Disease Control (CDC) and Prevention. Treatment of Ringworm and Fungal Nail infections. Available at: <https://www.cdc.gov/ringworm/treatment/index>. Accessed September 10, 2024.

6. Ely JW, Rosenfeld S, Stone MS. Diagnosis and Management of Tinea Infections. Am Fam Physician. 2014;90(10):702-710.

Document History

Written by: UM Development (NB)

Date Written: 12/2008

Revised: (SE) 07/2009, (TM) 07/2010, 10/2010; (SE) 12/2010 (removed requirement for no use previous 12 mo per CMS file submission), (TM) 08/2011; (RP) 08/2012, (TM) 08/2013, 08/2014; (MS) 05/2015, 05/2016 (removed Terbinex kit). (SF) 05/2017 (combined questions); (KC) 04/2018, (ME) 02/2019 (no clinical changes), (DFW) 02/2020 (removed MDC designation from title/document), 08/2020 (updated denial reasons); (PM) 12/2020 (added footbath 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: CDPR/Medical Affairs (WF) 12/2008, 07/2009, (KP) 07/2010, 10/2010, (KP) 08/2011; (DC) 08/2012, (DC) 09/2013, (LMS) 08/2014; (KC) 05/2015; (JG) 05/2017; (DC) 04/2018, (CHART) 02/27/2020, 12/31/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 12/2008, 10/2009, 12/2010, 12/2011, 12/2012, 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

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| 1 | Is the requested drug being prescribed for the treatment of onychomycosis due to dermatophytes (tinea unguium)?
[If Yes, then go to 2. If No, then go to 3.] | Yes | No |
| 2 | Has the patient's diagnosis been confirmed with a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)?
[If Yes, then go to 6. If No, then no further questions.] | Yes | No |
| 3 | Is the requested drug being prescribed for the treatment of tinea capitis?
[If Yes, then go to 6. If No, then go to 4.] | Yes | No |
| 4 | Is the requested drug being prescribed for the treatment of tinea corporis or tinea cruris?
[If Yes, then go to 5. If No, then no further questions.] | Yes | No |
| 5 | Does the patient meet any of the following: A) has extensive disease, B) dermatophyte folliculitis is present, C) did not respond to topical therapy, D) is immunocompromised? | Yes | No |

[If Yes, then go to 6. If No, then no further questions.]

6	Is the requested drug being used in a footbath? [No further questions]	Yes	No
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Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Go to 3	
2.	Go to 6	Deny	<p>Your plan only covers this drug when you have a fungal diagnostic test. We denied your request because we did not receive your results, or your test result did not show a positive test result. 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: Lab/test]</p>
3.	Go to 6	Go to 4	
4.	Go to 5	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) a fungal infection of your nail(s), B) a fungal infection of the scalp, and C) a fungal infection of the body or groin. 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>
5.	Go to 6	Deny	<p>Your plan only covers this drug if you have extensive disease, the hair follicle is inflamed, you did not respond to topical treatment, or</p>

			<p>you have a weak immune system. 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: Disease severity]</p>
6.	Deny	Approve, 3 Months	<p>Your plan only covers this drug if it is not being used in a footbath. 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: Footbath Use]</p>