

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Fungal Infections	P&T DATE	9/12/2023
THERAPEUTIC CLASS	Infectious Diseases	REVIEW HISTORY (MONTH/YEAR)	12/22, 12/21, 12/20, 12/19, 12/18, 12/16, 11/15, 5/15, 9/13, 6/08
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Prescription and OTC antifungal medications are used to treat a wide range of fungal infections in an outpatient setting. Generally, mild, localized infections may be treated with prescription or OTC topical antifungal products. Prescription oral and/or IV antifungal agents are required for more severe, disseminated infections. Relative to the growing public health concern of antibiotic-resistant bacterial infections, less is known about antifungal-resistant fungal infections. Nevertheless, the CDC recommends appropriate use of antifungal agents to reduce drug resistance.¹ The purpose of this Fungal Infections Coverage Policy is to review the coverage criteria of HPSJ's formulary antifungal agents (*Table 1*).

The purpose of this coverage policy is to review the available agents (*Table 1*) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Antifungal Medications

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Azoles				
--	FLUCONAZOLE (DIFLUCAN)	50 mg tablet 100 mg tablet 200 mg tablet 150 mg tablet 40 mg/ml oral suspension 10 mg/ml oral suspension	Yes	No
J1450 INJECTION, FLUCONAZOLE, 200 MG		200 mg/100 mL, 400 mg/200 mL, 100mg/50mL vial	Yes	Yes (PA)
J1833 INJECTION, ISAVUCONAZONIUM, 1 MG	ISAVUCONAZONIUM SULFATE (CRESEMBA)	186 mg capsule 372 mg vial	Yes Yes	No Yes (PA)
J1835 INJECTION, ITRACONAZOLE, 50 MG	ITRACONAZOLE (SPORANOX)	100 mg capsule 10 mg/ml oral solution 65 mg capsule 200 mg tablet	Yes	No
		Vials	Discontinued	Discontinued

--	POSACONAZOLE (NOXAFIL)	200 mg/5 ml (40 mg/ml) oral suspension	Yes	No
		100 mg DR tablet		
J3465 INJECTION, VORICONAZOLE, 10 MG	VORICONAZOLE (VFEND)	50 mg tablet	Yes	No
		200 mg tablet		
		200 mg vial	Yes	Yes (PA)
--	OTESECONAZOLE (VIVJOA)	150 mg tablet	Yes	No
Imidazoles				
--	CLOTRIMAZOLE	10 mg troche	Yes	No
--	KETOCONAZOLE (NIZORAL)	200 mg tablet	Yes	No
--	MICONAZOLE (ORAVIG)	50 mg Buccal tablets	Yes	No
Echinocandins				
J0348 INJECTION, ANIDULAFUNGIN, 1 MG	ANIDULAFUNGIN (ERAXIS)	50 mg vial, 100 mg vial	Yes	Yes (auth not required)
J0637 INJECTION, CASPOFUNGIN ACETATE, 5 MG	CASPOFUNGIN (CANCIDAS)	50 mg vial, 70 mg vial	Yes	Yes (PA)
J2248 INJECTION, MICA FUNGIN SODIUM, 1 MG	MICA FUNGIN (MYCAMINE)	50 mg vial, 100 mg vial	Yes	Yes (auth note required)
--	REZAFUNGIN (REZZAYO)	200 mg vial	Yes	Yes (PA)
Miscellaneous				
J0289 INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG	AMPHOTERICIN B LIPOSOMAL (AMBISOME)	50 mg IV Suspension	Yes	Yes (auth not required)
J0288 INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG	AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX (AMPHOTEC)	50 mg vial, 100 mg vial	Discontinued	Discontinued
J0285 INJECTION, AMPHOTERICIN B, 50 MG	AMPHOTERICIN B (FUNGIZONE)	50 mg IV Solution	Yes	Yes (auth not required)
J0287 INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG	AMPHOTERICIN B LIPID COMPLEX (ABELCET)	5 mg IV Suspension	Yes	Yes (auth not required)
--	FLUCYTOSINE (ANCOBON)	250 mg capsule	Yes	No
		500 mg capsule	Yes	No
--	GRISEOFULVIN (GRIFULVIN V, GRIS-PEG)	125 mg/5 ml microsize oral suspension	Yes	No
		500 mg microsize tablet		
		125 mg ultramicrosize tablet		
		250 mg ultramicrosize tablet		
--	NYSTATIN (MYCOSTATIN)	500,000 unit tablet	Yes	No
		50 million unit oral powder		

		150 million unit oral powder		
		500 million unit oral powder		
		100,000 Unit/ml Oral Suspension		
--	TERBINAFINE HCL (LAMISIL, TERBINEX)	250 mg tablet	Yes	No
		125 mg granules packet		
--	IBREXAFUNGERP (BREXAFEMME)	150 mg tablet	Yes	No
CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Medical Benefit (Restrictions)
Topical Agents				
--	CICLOPIROX (LOPROX, CICLODAN, PENLAC)	1% shampoo	Yes	No
		0.77% cream		
		0.77% gel		
		8% solution		
Imidazoles				
--	BUTOCONAZOLE (GYNEZOL-1)	2% Vaginal cream	Yes	No
--	CLOTRIMAZOLE (GYNE-LOTRIMIN, LOTRIMIN AF, DESENEK)	1% vaginal cream (7-day)	Yes	No
		2% vaginal cream (3-day)		
		1% topical cream		
		1% topical solution		
--	CLOTRIMAZOLE/ BETAMETHASONE (LOTRISONE)	1%-0.05% topical cream	Yes	No
		Topical lotion		
--	ECONAZOLE NITRATE (ECOZA)	1% topical cream	Yes	No
--	KETOCONAZOLE (NIZORAL A-D, KETODAN, EXTINA, XOLEGEL)	1% shampoo	Yes	No
		2% shampoo		
		2% topical cream		
		KETODAN , EXTINA 2% FOAM		
		XOLEGEL 2%		
--	MICONAZOLE NITRATE (MONISTAT, MICATIN, FUNGOID TINCTURE)	2% topical ointment	Yes	No
		2% topical spray powder		
		2% topical cream		
		2% topical tincture		
		2% vaginal cream (7-day)		
		100 mg vaginal suppository		
		4% vaginal cream (200 mg/5 gram) (3-day)		
		2% vaginal kit (200 mg/9 gram suppository) (3-day)		
		2% vaginal kit (1,200 mg ovule) (1-day)		
--	OXICONAZOLE (OXISTAT)	1% topical cream	Yes	No
		1% topical lotion		
--	SERTACONAZOLE	2% topical cream	Yes	No

	(ERTACZO)			
--	SULCONAZOLE (EXELDERM)	1% topical cream	Yes	No
		1% topical solution		
--	TIOCONAZOLE (VAGISTAT-1)	6.5% vaginal ointment (1-day)	Yes	No
Miscellaneous				
--	EFINACONAZOLE (JUBLIA)	10% topical solution	Yes	No
--	NAFTIFINE (NAFTIN)	1% topical cream	Yes	No
		1% topical gel		
--	NYSTATIN (NYSTOP)	100,000 unit/gram topical cream	Yes	No
		100,000 unit/gram topical ointment		
		100,000 unit/gram topical powder		
--	NYSTATIN/ TRIAMCINOLONE (MYCOLOG-II)	100,000 unit/gram-0.1% topical cream	Yes	No
		100,000 unit/gram-0.1% topical ointment		
--	TAVABOROLE (KERYDIN)	5% topical solution	Yes	No
--	TERBINAFINE HCL (LAMISIL AT)	1% topical cream	Yes	No
--	TERCONAZOLE (TERAZOL)	80 mg vaginal suppository (3-day)	Yes	No
		0.8% vaginal cream (3-day)		
		0.4% vaginal cream (7-day)		
--	TOLNAFTATE	1% topical spray powder	Yes	No
		1% topical cream		
		1% topical powder		
		1% topical solution		

PA = Prior Authorization Required

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

CLINICAL JUSTIFICATION

HPSJ's fungal infection management policy is based on recommendations by the *Infectious Diseases Society of America (IDSA)*, *British Association of Dermatologists (BAD)*, and *American Academy of Dermatology (AAD)*. In general, mild, localized infections may be treated with topical antifungal products. Oral and/or IV antifungal agents are required for more severe, disseminated infections. One exception to this trend is for the treatment of onychomycosis—for which topical agents can be used but are often ineffective due to their poor penetration of the entire nail unit. In contrast, oral agents such as terbinafine, penetrate the nail unit rapidly and sustain therapeutic concentrations, resulting in higher efficacy and shorter treatment duration. For this reason, oral terbinafine for 6 weeks (for fingernail infection) to 12 weeks (for toenail infection) is considered first-line treatment of onychomycosis.^{2,3,4}

☒ REFERENCES

1. Fungal Diseases: Antifungal Resistance. Centers for Disease Control and Prevention Web Site. <http://www.cdc.gov/fungal/antifungal-resistance.html>. Updated October 23, 2014. Accessed November 7, 2015.
2. Del Rosso JQ. The Role of Topical Antifungal Therapy for Onychomycosis and the Emergence of Newer Agents. *J Clin Aesthet Dermatol*. 2014;7(7):10-18.
3. Elewski, BE. Onychomycosis: Pathogenesis, Diagnosis, and Management. *Clin Microbiol Rev*. 1998;11(3):415-429.
4. Fungal Diseases: Fungal Nail Infections. Centers for Disease Control and Prevention Web Site. <http://www.cdc.gov/fungal/nail-infections.html>. Updated September 30, 2014. Accessed November 7, 2015.
5. Pappas P., Kauffman C., Andes D., et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America.
6. Christenson J., Peterson G., et al. Challenges and Opportunities in the Management of Onychomycosis. *Journal of Fungi*.

☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Antifungal review 6-08.docx	6/2008	Allen Shek, PharmD
Update to Policy	Oral Ketoconazole Safety Review 2013-09-17.docx	9/2013	Jonathan Szkotak, PharmD
Update to Policy	Antifungal Class Review 5-2015.docx	5/2015	Jonathan Szkotak, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious disease – Fungal infections 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious disease – Fungal infections 2018-12.docx	12/2018	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious disease – Fungal infections 2019-12.docx	12/2019	Matthew Garrett, PharmD
Review of Policy	Fungal Infections	12/2020	Matthew Garrett, PharmD
Review of Policy	Fungal Infections	12/2021	Matthew Garrett, PharmD
Review of Policy	Fungal Infections	12/2022	Matthew Garrett, PharmD
Review of Policy	Fungal Infections	9/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy.