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INFECTIOUS DISEASE: DERMATOLOGIC LAB TESTING

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

OVERVIEW

Fungal infection of the nails (onychomycosis) is common. Toenails are more likely than fingernails to be affected. Onychomycosis is characterized by discoloration, splitting, deformation, and brittleness of the nails and can also affect the surrounding skin. Non-fungal infections and non-infectious nail conditions, such as nail dystrophy, can mimic onychomycosis. Confirmatory testing should be performed to confirm fungal infection before initiating treatment to prevent inappropriate use of antifungal medications. Available testing methods include microscopy, culture, and molecular (PCR-based) techniques.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Criteria Sections	Example Tests (Labs)	References
Microscopy/Peroxidase Tests for Onychomycosis	Fungus Stain (LabCorp)	1, 2
	KOH Prep (Pacific Medical)	

Fungal Culture for Onychomycosis	Culture, Fungus, Miscellaneous (Quest Diagnostics)	
	Fungus (Mycology) Culture/Dermatophyte Culture (LabCorp)	
	Fungal Isolate Identification (Quest Diagnostics)	
Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis	Nail-ID (Vikor Scientific)	

CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific tests noted below are **medically necessary** when meeting the related criteria:

Onychomycosis (Nail Fungus) Testing

Microscopy/Peroxidase Tests for Onychomycosis

- I. Microscopy/oxidase tests for onychomycosis may be considered **medically necessary** when:
 - A. The member/enrollee shows signs or symptoms of onychomycosis (e.g., nails that are discolored, deformed, brittle, and/or foul-smelling; subungual debris; separation of the nail from the nail bed), **AND**
 - B. Results of testing would influence the member’s/enrollee’s clinical management.
- II. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of Microscopy/Peroxidase tests for any additional indications except onychomycosis.

Fungal Culture for Onychomycosis

- I. Fungal culture for onychomycosis (presumptive and/or definitive) may be considered **medically necessary** when:
 - A. The member/enrollee shows signs or symptoms of onychomycosis (e.g., nails that are discolored, deformed, brittle, and/or foul-smelling; subungual debris; separation of the nail from the nail bed), **AND**
 - B. Results of testing would influence the member's/enrollee's clinical management.
- II. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of fungal culture for any additional indications except onychomycosis (presumptive and/or definitive).

Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis

- I. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of culture-independent molecular tests (NAAT/PCR) for onychomycosis.

BACKGROUND AND RATIONALE

Microscopy/Peroxidase Tests for Onychomycosis

British Association of Dermatologists

In their 2014 onychomycosis guidelines, the British Association of Dermatologists state the following:

“Laboratory confirmation of a clinical diagnosis of tinea unguium should be obtained before starting treatment. This is important for several reasons: to eliminate nonfungal dermatological conditions from the diagnosis; to detect mixed infections; and to diagnose patients with less responsive forms of onychomycosis, such as toenail infections due to *T. rubrum*.” (p. 942)

“Traditionally, laboratory detection and identification of dermatophytes consists of culture and microscopy.” (p. 942)

American Academy of Family Physicians

In their 2021 rapid evidence review of onychomycosis, the AAFP listed the common signs and symptoms of onychomycosis, including: nails that are discolored, deformed, hypertrophic, or

hyperkeratotic; subungual debris; separation from the nail bed; brittle nails that break easily or crumble; and nails that are foul smelling. (p. 360)

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Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis

British Association of Dermatologists

In their 2014 onychomycosis guidelines, the British Association of Dermatologists state the following:

“It appears that real-time PCR significantly increased the detection rate of dermatophytes compared with culture. However, PCR may detect nonpathogenic or dead fungus, which could limit its use in identifying the true pathogen. Restriction fragment length polymorphism analysis, which identifies fungal ribosomal DNA, is very helpful for defining whether the disease is caused by repeat infection or another fungal strain when there is a lack of response to treatment. However, this technique has not been implemented into routine clinical practice.” (p. 942)

American Academy of Family Physicians

In their 2021 rapid evidence review of onychomycosis, the AAFP states the following:

“A potassium hydroxide (KOH) preparation with direct microscopy is the preferred diagnostic method [for onychomycosis] because it is highly specific, has rapid results, and is cost-effective. Diagnosis by KOH preparation alone is sufficient for treatment initiation. However, if KOH results are negative and there is high clinical suspicion for onychomycosis, other testing may be performed to confirm the diagnosis.” (p. 361)

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Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
87101	Culture, bacterial; with isolation and presumptive identification of each isolate, urine
87102	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
87106	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; blood
87107	Culture, fungi, definitive identification, each organism; yeast
87143	Culture, typing; immunofluorescent method, each antiserum
87147	Culture, typing; gas liquid chromatography (GLC) or high pressure liquid chromatography (HPLC) method
87149	Culture, typing; immunologic method, other than immunofluorescence (eg, agglutination grouping), per antiserum
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87206	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87220	Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps)
87480	Infectious agent detection by nucleic acid (DNA or RNA); <i>Borrelia miyamotoi</i> , amplified probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, direct probe technique
87482	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, amplified probe technique
87500	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87640	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique

CPT® Codes	Description
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	02/24
Added “Lab” to policy title. Removed CPT and ICD-10 codes from policy reference table. Added CPT code table and moved the “coding implications” section.	02/24	

REFERENCES

1. Ameen M, Lear JT, Madan V, Mohd Mustapa MF, Richardson M. British Association of Dermatologists’ guidelines for the management of onychomycosis 2014. Br J Dermatol. 2014;171(5):937-958.
2. Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: rapid evidence review. Am Fam Physician. 2021;104(4):359-367.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable

NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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