

CONCERT GENETIC TESTING: DERMATOLOGY

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

OVERVIEW

This policy addresses the use of tests for fungal infection of the nails (onychomycosis), which can sometimes affect surrounding skin. These criteria are intended for use in the outpatient setting.

For additional information see the [Rationale](#) section.

POLICY REFERENCE TABLE

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 2024, 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.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage.

CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	REF
Onychomycosis (Nail Fungus) Tests			

Microscopy/Peroxidase Tests for Onychomycosis	Fungus Stain (LabCorp)	87206, 87220	1, 2
	KOH Prep (Pacific Medical)		
Fungal Culture for Onychomycosis	Culture, Fungus, Miscellaneous (Quest Diagnostics)	87101, 87102, 87106, 87107, 87143, 87149	
	Fungus (Mycology)		
	Culture/Dermatophyte Culture (LabCorp)		
	Fungal Isolate Identification (Quest Diagnostics)		
Culture-Independent Molecular Tests (NAAT/PCR) for Onychomycosis	Nail-ID (Vikor Scientific)	87481, 87500, 87641, 87652, 87653, 87798	

RELATED POLICIES

This policy document provides criteria for infectious dermatologic disorders. Please refer to:

- ***General Approach to Laboratory Testing*** for criteria related to dermatologic conditions, including known familial variant testing, that is not specifically discussed in this or another non-general policy

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CRITERIA

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

ONYCHOMYCOSIS (NAIL FUNGUS) TESTS

Microscopy/Peroxidase Tests for Onychomycosis

- I. Microscopy/oxidase tests for onychomycosis are 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/enrollee's clinical management.
- II. Current evidence does not support microscopy/oxidase tests for all other indications.

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Fungal Culture for Onychomycosis

- I. Fungal culture for onychomycosis (presumptive and/or definitive) is 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/enrollee's clinical management.
- II. Current evidence does not support fungal culture for onychomycosis (presumptive and/or definitive) for all other indications.

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

- I. Current evidence does not support culture-independent molecular tests (NAAT/PCR) for onychomycosis for all indications.

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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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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	03/23	03/23
Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced “coverage criteria” with “criteria. For Other Related Policies: added “Molecular”. For Congenital Ichthyosis Multigene Panels: removed “81252” throughout. For Epidermolysis Bullosa Multigene Panels: in I.A. replaced “AND” with “OR”; in I.B.1 replaced with “May be” with “Is”; in I.B.4. replaced “Can lead” with “Leads”; in I.B.5. replaced “AND” with “OR”; in I.C. added “4. Natal teeth, OR”. For Other Covered Dermatologic Conditions: added “and Molecular”. For Background and Rationale: replaced “inheritance patterns” with “genetic testing”.	10/23	10/23
Semi-annual review. Updated title to reflect V2.2024 version. In Known Familial Variant Analysis for Dermatologic Conditions criteria, moved criteria to policy “Genetic Testing: General Approach to Genetic and Molecular Testing” to consolidate criteria for known familial variant tests. In Epidermolysis Bullosa Multigene Panels criteria, retired criteria set based on rarity of testing (low order volume and low claim volume). In Congenital Ichthyosis Multigene Panels criteria, removed minimum gene list; at present there is limited rationale for inclusion. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	04/24	04/24
RASA1 and EPHB4 Sequencing and/or Deletion/Duplication Analysis or Multigene Panel: Updated title in Background and Rationale from 'Capillary Malformation-Arteriovenous Malformation Syndrome (CM-AVM)' to 'RASA1 and EPHB4 Sequencing and/or Deletion/Duplication Analysis or Multigene Panel' to align with criteria set name; Updated dates in References. Congenital Ichthyosis Multigene Panel: Updated GeneReviews copyright dates in Reference list. Other Covered Dermatologic Conditions: Added one disorder to list (Epidermolysis Bullosa).	11/24	11/24
Annual review. Policy title changed from Concert Genetic Testing: Dermatologic Conditions to Concert Genetic Testing: Dermatology. Minor wording changes throughout without clinical significance. Other Covered Dermatologic Conditions: Added gene names for each condition listed in the criteria. “Investigational” policy statements changed to note that “current evidence does not support...” Coding table, rationale and references updated.	11/25	12/25

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.

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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 developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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