



CLINICAL MEDICAL POLICY	
Policy Name:	Nail Disorder Infectious Disease Testing, Including Onychomycosis
Policy Number:	MP-111-MC-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	08/31/2026
Effective Date:	11/01/2026
Next Annual Review:	11/2027
Implementation Date:	04/15/2026
Products:	Pennsylvania Medicare Assured
Application:	All participating and nonparticipating practitioners and facilities unless contractually precluded
Page Number(s):	1 of 7

Policy History

Date	Activity
11/01/2026	Provider Effective date
04/15/2026	QI/UM Committee review
04/15/2026	Policy initially developed

Disclaimer

Highmark WholecareSM medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark WholecareSM may provide coverage under the laboratory benefits of the Company's Medicare products for medically necessary testing of nail disorder infectious disease.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

Definitions

Microscopy - a technique that allows for the observation and analysis of small objects or materials, often utilized in various scientific fields, including forensic science. It involves the use of instruments, such as microscopes, to magnify specimens and reveal detailed structures.

Onychomycosis - a common fungal infection of the nail unit, affects both fingernails and toenails, with toenail involvement occurring far more frequently.

Nail dystrophy - abnormal changes in the shape, color, texture, and growth of the fingernails or toenails. Nail dystrophy is often caused by infection or injury to the nail. It may also be caused by certain conditions, including psoriasis, eczema, warts, cysts, and some tumors. Changes in nails can also be a sign of chronic heart, lung, liver, or kidney disease. Treatment with certain drugs, including chemotherapy drugs, can also cause changes to the nails. Also called onychodystrophy.

Procedures

Requests for laboratory testing in the evaluation and management of infectious causes of nail disorders, including onychomycosis, are reviewed using the following criteria.

1. **Microscopy, Stains, and/or Culture** CPT code(s): 88304, 88305, 88312, 88313, 87101, 87107, 87205, 87206, 87220

Independent gross and microscopic examination may be medically necessary in the evaluation of nail or nailbed tissue for onychomycosis when onychomycosis or some other infectious cause of nail abnormalities is suspected based on clinical exam.

When testing is otherwise medically necessary, the following limitations may apply:

- Culture should be reserved for those cases that require confirming fungal viability and identifying the pathogenic species.
- Gross and microscopic examination of more than one (1) nail from the same extremity is not medically necessary.
- Direct microscopic examination is usually conducted using only one (1) of the following methods; exceptions may be considered when one method is not diagnostic, there is a high index of suspicion, and/or a positive result is necessary to direct therapy:
 - Periodic acid-Schiff (PAS) stain (CPT: 88312); OR
 - Grocott's methenamine silver (GMS) stain (CPT: 88312); OR
 - Potassium hydroxide (KOH) preparation (CPT: 87220 +/- 87205/87206).

2. **Nucleic Acid Tests** CPT code(s): 87149, 87150, 87153, 87480, 87481, 87482, 87640, 87650, 87651, 87652, 87653, 87500, 87797, 87798, 87799, 87800, 87801

The clinical utility of testing for any organism through nucleic acid-based methods has not been demonstrated for onychomycosis, nail dystrophy, or any other nail disorders. These tests are considered Experimental, Investigational, or Unproven.

3. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.

4. Place of Service

The proper place of service for nail disorder infectious disease testing is outpatient.

Governing Bodies Approval

FDA

In the case of laboratory testing, FDA approval or clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight. In addition, FDA approval or clearance often does not include an assessment of clinical utility.

CLIA

Nail disorder infectious disease tests are offered as laboratory-developed tests under Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories. Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratories offering such tests as a clinical service must meet general regulatory standards of CLIA and must be licensed by CLIA for high complexity testing.

CMS

The Centers for Medicare & Medicaid Services (CMS) has published no guidance on this topic.

Summary of Literature

Onychomycosis is a common nail disorder caused mostly by the dermatophytic fungi *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Clinical features of onychomycosis include nail thickening and discoloration, onycholysis (separation of the nail plate), and subungual hyperkeratosis. As noted by a consumer survey, these features are not uncommonly met with self-diagnosis and self-treatment with topical anti-fungal medications, highlighting the importance of public health measures. Early fungal invasion of the nail may be present without apparent clinical findings. The infection may be present in multiple extremities, affecting fingernails and/or toenails. Although the majority of cases of onychomycosis are chronic and non-threatening, the risk of complications from onychomycosis is increased in the immunocompromised and those with peripheral vascular disease or diabetes.

Diagnostic accuracy of onychomycosis based on clinical findings approaches 75%. The differential diagnosis for onychomycosis is broad, and includes skin disorders, other infectious conditions, onychodystrophy as a result of trauma, and tumors such as melanoma.

Therapeutic options strike a fine balance between mycologic cure and the untoward side effects of systemic therapy, and the poor response to topical medications. Clinical trials have shown only moderate success of clinical cure, and a high relapse rate.

Coding Requirements

Microscopy, Stains, and/or Culture CPT code(s): 88304, 88305, 88312, 88313, 87101, 87107, 87205, 87206, 87220

Gross examination and microscopy of nail plate is reimbursable with CPT 88304.

- CPT 88304 is reimbursable for one (1) unit per extremity per date of service, for a maximum of four (4) units per date of service. Exceptions will be considered on a case by case basis.

In the evaluation of nail clippings, CPT 88305 is not appropriate for billing of specimens consisting entirely of nail plate with no underlying tissue.

Special stains relevant to this medical policy are billed with CPT 88312. The following limits apply:

- CPT 88312 is reimbursable for one (1) unit per extremity per date of service, for a maximum of four (4) units per date of service. Exceptions will be considered on a case by case basis.
- CPT 88312 should not exceed four (4) dates of service in any 12 month period. Exceptions will be considered on a case by case basis.

The following limits apply to direct microscopic examination methods:

- Typically, only one (1) direct microscopic examination, either by PAS stain (CPT 88312) or GMS stain (CPT 88312) or KOH preparation (CPT 87220) is reimbursable for the same clinical episode. Exceptions may be considered on a case-by-case basis.

Procedure Codes

CPT Code	Description
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
87107	Culture, fungi, definitive identification, each organism; mold
87101	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
88304	Level III – Surgical pathology, gross and microscopic examination
88305	Level IV - Surgical pathology, gross and microscopic examination
87205	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87206	Smear, primary source with interpretation; fluorescent and/or acid fast stain for bacteria, fungi, parasites, viruses or cell types
88312	Special stain including interpretation and report; Group I for microorganisms (eg, acid fast, methenamine silver)
88313	Special stain including interpretation and report; Group II, all other (eg, iron, trichrome), except stain for microorganisms, stains for enzyme constituents, or immunocytochemistry and immunohistochemistry
87220	Tissue examination by KOH slide of samples from skin, hair, or nails for fungi or ectoparasite ova or mites (eg, scabies)

Diagnosis Codes

ICD-10 Code	Description
B35.1	Tinea unguium
L60.0	Tinea unguium
L60.1	Onycholysis
L60.2	Onychogryphosis
L60.3	Nail dystrophy
L60.4	Beau's lines
L60.5	Yellow nail syndrome
L60.6	Other nail disorders
L60.9	Nail disorder, unspecified

Nucleic Acid Tests CPT code(s): 87149, 87150, 87153, 87480, 87481, 87482, 87640, 87650, 87651, 87652, 87653, 87500, 87797, 87798, 87799, 87800, 87801

The clinical utility of testing for any organism through nucleic acid-based methods has not been demonstrated for onychomycosis, nail dystrophy, or any other nail disorders. These tests are considered Experimental, Investigational, or Unproven.

Non-covered Procedure Codes

CPT/HCPCS Code	Description
87149	Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed
87150	Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed
87153	Culture, typing; identification by nucleic acid sequencing method, each isolate (eg, sequencing of the 16S rRNA gene)
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification
87640	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
87500	Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique

87797	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique

Reimbursement

Participating facilities will be reimbursed per their Highmark WholecareSM contract.

Reference Sources

Ghannoum MA, Hajjeh RA, Scher R, et al. A large-scale North American study of fungal isolates from nails: the frequency of onychomycosis, fungal distribution, and antifungal susceptibility patterns. J Am Acad Dermatol. 2000. Accessed on February 13, 2026.

de Berker D. Clinical Practice. Fungal Nail Disease. NEJM. 2009. Accessed on February 13, 2026.

Leung AKC, Lam JM, Leong KF, et al. Onychomycosis: an updated review. Recent Pat Inflamm Allergy Drug Discov. 2020. Accessed on February 13, 2026.

Benedict K, Gold JAW, Wu K, et al. High frequency of self-diagnosis and self-treatment in a nationally representative survey about superficial fungal infections in adults. J Fungi (Basel). 2022. Accessed on February 13, 2026.

Angulo-Rodriguez A, Hernandez-Ramirez H, Vega-Memije ME, et al. Subclinical onychomycosis in apparently healthy adults. Skin Appendage Disord. 2021. Accessed on February 13, 2026.

Shemer A, Gupta AK, Farhi R, et al. When is onychomycosis onychomycosis? A cross-sectional study of fungi in normal-appearing nails. Br J Dermatol. 2015. Accessed on February 13, 2026.

Elewski BE, Leyden J, Rinaldi MG, Atillasoy E. Office practice-based confirmation of onychomycosis. Arch Intern Med. 2002. Accessed on February 13, 2026.

Frazier WT, Santiago-Delgado ZM, Stupka KC. Onychomycosis: rapid evidence review. Am Fam Physician. 2021. Accessed on February 13, 2026.

Nenoff P, Reinell D, Mayser P, et al. S1 Guideline onychomycosis. J Dtsch Dermatol Ges. 2023. Accessed on February 13, 2026.

Kreijkamp-Kaspers S, Hawke K, Guo L, et al. Oral antifungal medication for toenail onychomycosis. Cochrane Database Syst Rev. 2017. Accessed on February 13, 2026.

Christensen JK, Peterson GM, Naunton M, et al. Challenges and opportunities in the management of onychomycosis. J Fungi (Basel). 2018. Accessed on February 13, 2026.

Li DG, Cohen JM, Mikailov A, et al. Clinical diagnostic accuracy of onychomycosis: A multispecialty comparison study. Dermatol Res Pract. 2018. Accessed on February 13, 2026.

Ameen M, Lear JT, Madan V, et al. British Association of Dermatologists' guidelines for the management of onychomycosis. 2014. Accessed on February 13, 2026.

Hassab-El-Naby HMM, Shaheen I, Abdo HM, El-Shafey H. Comparative study for the reliability of potassium hydroxide mount versus nail clipping biopsy in diagnosis of onychomycosis. The Gulf Journal of Dermatology and Venereology. 2011. Accessed on February 13, 2026.

Amichai B, B, Davidovici B, Trau H, et al. A rationale for systemic treatment in onychomycosis with negative results on fungal examination. Clin Exp Dermatol. 2011. Accessed on February 13, 2026.

Jeelani S, Ahmed QM, Lanker AM, et al. Histopathological examination of nail clippings using PAS staining (HPE-PAS): gold standard in diagnosis of onychomycosis. Mycoses. 2015. Accessed on February 13, 2026.

Houck MM, Siegel JA. Chapter 4 – Microscopy, Fundamentals of Forensic Science (Second Edition). Academic Press. 2010. Accessed on February 13, 2026.

Bodman MA, Syed HA, Krishnamurthy K. Onychomycosis. November 6, 2025. Accessed on February 13, 2026.

National Institutes of Health (NIH). National Cancer Institute. Nail Dystrophy. 2025. Accessed on February 13, 2026.