of Tennessee

Policy

Reimbursement Policy

Onychomycosis Testing

I. Policy Description

Onychomycosis, also known as tinea unguium,[1] is a fungal infection of the nail typically caused by pathogenic fungal dermatophytes, such as *Trichophyton rubrum*, *Trichophyton mentagrophytes,* and *Epidermophyton floccossum;* onychomycosis may also be caused by yeasts, including *Candida parapsilosis* and *Candida guilliermondii*, or non-dermatophyte molds, including *Neoscytalidium dimidiatum, Onychocola canadensis,* the *Aspergillus* species, *Scopulariopsis* species, *Alternaria* species, *Acremonium* species, and *Fusarium* species.[1-3]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals with signs of onychomycosis, direct microscopic examination with potassium hydroxide, fungal culture of desquamated subungual material, or fungal stain of a nail clipping(s) **MEETS COVERAGE CRITERIA**.

2) For individuals with onychomycosis and for whom anti-fungal therapy has failed to resolve infection, nucleic acid amplification testing (NAAT) **MEETS COVERAGE CRITERIA.**

3) To screen for, diagnose, or confirm onychomycosis, NAAT (see Note 1) **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

4) To screen for, diagnose, or confirm onychomycosis, attenuated total-reflectance fourier transform infrared (ATR-FTIR) spectroscopy **DOES NOT MEET COVERAGE CRITERIA**.

5) Testing for the presence of fungal-derived sterols (e.g., ergosterol) **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: Nucleic acid testing (e.g., PCR, PCR-RFLP, and next-generation sequencing [NGS]) of the following microorganisms: *Candida* species, *Aspergillus* species, *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccossum, Neoscytalidium dimidiatum, Onychocola canadensis, Scopulariopsis* species, *Alternaria* species, *Acremonium* species, and *Fusarium* species.[1-3]

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82542	Column chromatography, includes mass spectrometry, if performed (e.g., 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
87101	Culture, fungi (mold or yeast) isolation, with presumptive identification of isolates; skin, hair, or nail
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 (e.g., sequencing of the 16S rRNA gene)
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
87220	Tissue examination by KOH slide of samples from skin, hair, or nails for fungi or ectoparasite ova or mites (e.g., scabies)
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,
87798	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), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
88312	Special stain including interpretation and report; Group I for microorganisms (e.g., acid fast, methenamine silver)
88749	Unlisted in vivo (e.g., transcutaneous) laboratory service

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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