

Local Coverage Determination (LCD): Debridement of Mycotic Nails (L35013)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	District of Columbia Delaware Maryland New Jersey Pennsylvania

LCD Information

Document Information

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L35013

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For services performed on or after 10/01/2015

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Revision Effective Date

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LCD Title

Debridement of Mycotic Nails

Revision Ending Date

N/A

Proposed LCD in Comment Period

N/A

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N/A

Source Proposed LCD

N/A

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N/A

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Notice Period End Date

N/A

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for mycotic nail debridement services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for mycotic nail debridement services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 290 Foot Care

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1862(a)(13)(C) addresses routine foot care.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis

and subsequent medical review audits.

History/Background and/or General Information

As with other Medicare covered services, Mycotic Nail Debridement must be reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare payment generally may be made for mycotic nail debridement in the two following circumstances:

1. As "routine foot care" under Medicare's national "Exceptions to Routine Foot Care Exclusions" provision when there is clinical evidence of mycosis of the toenail and the services and patient conditions meet national requirements for that exception.
2. When, whether or not the services and patient conditions meet national requirements for routine foot care, there is clinical evidence of mycosis of the toenail, and the patient has marked limitation of ambulation due solely to discomfort caused by the nails, (patients who are non-ambulatory for other reasons must have severe pain or impairment of some aspect of ADL) or has secondary soft tissue infection resulting from the thickening and dystrophy of the infected nail plate. The treatment of symptomatic mycotic nails in the absence of a qualifying covered systemic condition will not be covered after the acute symptoms caused by mycosis have abated. In the absence of a qualifying systemic condition, debridement of six or more nails in a single encounter is not payable without medical review of records associated with the service.

Onychomycosis may present as one or more nail findings, including hypertrophy/thickening, lysis, discoloration, brittleness or loosening of the nail plate. Fungal disease of the toenails is usually a relatively benign condition and may produce little or no symptoms beyond white opacities on the nails. Confirmation of mycotic nail infections by laboratory tests such as fungal cultures and/or stains is not necessary for Medicare coverage of debridement when clinical findings are strongly supportive of the diagnosis and treatment is not contraindicated. For coverage of mycotic nail debridement, mycologic confirmation by culture, potassium hydroxide examination, or dermatophyte testing is expected to differentiate fungal disease from other nail pathology in certain circumstances including but not limited to the following conditions: previous unsatisfactory treatment results (recurrent nail disease, unsuccessful treatment with FDA approved antifungal medications, long term - beyond 12 debridements per 24 months, etc.) and for patients whose debridement is prescribed absent of concomitant pharmacologic therapy.

Definitive treatment of mycotic nails involves the appropriate use of effective antifungal pharmacologic agents with or without periodic debridement of dystrophic nail plates to lessen the fungal load. Medicare will cover debridement of mycotic nails as an adjunct to pharmacologic treatment with a prescription antifungal agent indicated per its Food and Drug Administration (FDA) label for the treatment of fungal nail infections.

Debridement of nails, whether by electric grinder or manual method, is a temporary reduction in the length and thickness (short of avulsion) of an abnormal nail plate. This is usually performed without anesthesia. The debridement code should not be used if the only part of the nail removed is the distal nail border or other portion of nail not attached to the nailbed. Medicare expects debridement services reported for Medicare payment to include removal of maximal nail material possible (in consideration of the clinical condition of the nail and the patient's degree of comfort during the procedure) required for control of symptoms or infection.

It is performed most commonly without anesthesia to accomplish any or all of the following objectives:

- Relief of pain
- Treatment of infection (bacterial, fungal, and viral)
- Temporary removal of an anatomic deformity such as onychauxis (thickened nail), or certain types of onychocryptosis (ingrown nail)
- Exposure of subungual conditions for the purpose of treatment as well as diagnosis (biopsy, culture, etc.)
- As a prophylactic measure to prevent further problems, such as a subungual ulceration in an insensate patient

with onychauxis

Debridement of asymptomatic mycotic nails is considered to be routine foot care and not a covered service unless submitted with documentation of the complicating factor or condition required for Medicare reimbursement.

Covered Indications

Whether by manual method or by electrical grinder, debridement is a modality used as part of the definitive antifungal treatment of onychomycosis.

Payment may be made for the debridement of a mycotic nail (whether by manual method or by electrical grinder) when definitive antifungal treatment options have been reviewed and discussed with the patient at the initial visit and the physician attending the mycotic condition documents that the following criteria are met:

I. In the absence of a systemic condition, the following criteria **must** be met:

A. In the case of ambulatory patients there exist both:

1. Clinical evidence of mycosis of the toenail **AND**
2. Marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

B. In the case of non-ambulatory patients there exist both:

1. Clinical evidence of mycosis of the toenail **AND**
2. The patient suffers from pain or secondary infection or the condition compromises the patient's ADL or care resulting from the thickening and dystrophy of the infected toenail plate.

II. For patients with a systemic condition and clinical evidence of mycosis of the toenail, but who do not meet the above criteria, refer to Local Coverage Determination (LCD) L35138, Routine Foot Care.

Medicare does not routinely cover fungus cultures, KOH preparations, or dermatophyte testing performed on toenail clippings in the doctor's office. Identification of cultures of fungi, potassium hydroxide examination, or dermatophyte testing of the toenail clippings is medically necessary only:

- When it is required to differentiate fungal disease from psoriatic nails or other nail pathology.
- When a definitive treatment for a prolonged period of time is being planned involving the use of a prescription medication which could pose health issues.

Debridement of nails is considered reasonable and necessary when performed by physicians, doctors of osteopathy, podiatrists and non-physician practitioners (NPPs) when performed within their state scope of practice or when performed under the direction of a qualified provider.

Limitations

Whirlpool treatment prior to the debridement of mycotic nails to soften the nails or the skin is not eligible for separate reimbursement.

Debridement codes should not be used to report the simple trimming, cutting, or clipping of the distal nail plate.

For frequency limitations please refer to the Utilization Guidelines section below.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
 - Furnished in a setting appropriate to the patient's medical needs and condition.
 - Ordered and furnished by qualified personnel.
 - One that meets, but does not exceed, the patient's medical needs.
 - At least as beneficial as an existing and available medically appropriate alternative.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

N/A

**Analysis of Evidence
(Rationale for Determination)**

N/A

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally

to all claims.

CODE	DESCRIPTION
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients
018x	Hospital - Swing Beds
021x	Skilled Nursing - Inpatient (Including Medicare Part A)
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
028x	Skilled Nursing - Swing Beds
083x	Ambulatory Surgery Center
085x	Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, Claims Processing Manual, for further guidance.

CODE	DESCRIPTION
99999	Not Applicable

CPT/HCPCS Codes

Group 1 Paragraph:

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

Group 1 Codes:

CODE	DESCRIPTION
11720	Debride nail 1-5
11721	Debride nail 6 or more

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
B35.1*	Tinea unguium
L02.611	Cutaneous abscess of right foot
L02.612	Cutaneous abscess of left foot
L03.031	Cellulitis of right toe
L03.032	Cellulitis of left toe
L60.0	Ingrowing nail
M79.604	Pain in right leg
M79.605	Pain in left leg
M79.661	Pain in right lower leg
M79.662	Pain in left lower leg
M79.671	Pain in right foot
M79.672	Pain in left foot
M79.674	Pain in right toe(s)
M79.675	Pain in left toe(s)
R26.2	Difficulty in walking, not elsewhere classified
R26.89	Other abnormalities of gait and mobility
R26.9	Unspecified abnormalities of gait and mobility

Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation:

*Note: ICD-10-CM code B35.1 must appear on each claim in addition to one of the other above ICD-10-CM codes that indicates secondary infection, pain, or difficulty in ambulation.

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

All those not listed under the "ICD-10 Codes that Support Medical Necessity" section of this policy.

Group 1 Codes: N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. For each service encounter, the medical record should contain the number of nails debrided and a description of each nail, which requires debridement. This should include, but is not limited to, the size (including thickness) and color of each affected nail. In addition, the local pathology caused by each affected nail resulting in the need for debridement must be documented. For CPT code 11721, complete documentation must be provided for at least 6 nails. (In situations where several nails are identical in characteristics, it may be appropriate to combine those nails into the description.)
5. The medical record must demonstrate the necessity of debridement of each debrided nail considering the patient's usual activities. Clinical rationale for treatment of mycotic nails with less than definitive care (i.e., debridement without pharmacologic intervention) must be explained in the record. For coverage of mycotic nail debridement by reason of the presence of specified conditions (i.e., in the absence of a qualifying covered systemic condition), the record should contain a description of the specified condition beyond mention that the particular condition is present (e.g., painful nails, limited ambulation, infection). The medical record must clearly document which nails were treated at every visit.
6. Routine identification of cultures of fungi, potassium hydroxide examination, or dermatophyte testing in the toenail is medically indicated when necessary to differentiate fungal disease from other nail pathology, or when definitive treatment for prolonged oral or topical antifungal therapy has been planned. If fungal testing is performed and billed, documentation of the testing, results, and the need for the prolonged oral or topical antifungal therapy must be in the patient record and available to Medicare upon request.
7. Services for debridement of more than five nails in a single day may be subject to special review. Documentation to support the medical necessity of such services must be in the patient's record and available to Medicare upon request.
8. Documentation of mycotic nail debridement services to residents of nursing homes must include a current nursing facility order (dated and signed with date of signature) for mycotic nail debridement services issued by the patient's supervising physician. Such orders must meet the following requirements:
 - The order must be dated and must have been issued by the supervising physician prior to mycotic nail debridement services being rendered.
 - Telephone or verbal orders not written personally by the supervising physician must be authenticated by the dated physician's signature within a reasonable period of time following issuance of the order.
 - The order must be consistent with the attending physician's overall plan of care.
 - The order must be for medically necessary services to address a specific patient complaint of physical finding.
 - Routinely issued or "standing" facility orders for mycotic nail debridement services that do not meet the above requirements are insufficient.
9. Documentation of mycotic nail debridement services to residents of nursing homes performed at the request of the patient or patient's family/conservator should indicate if the request was from the patient or the patient's family/conservator. When the request is from someone other than the patient, the documentation should identify the requesting person's relationship to the patient.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

- Medicare will cover CPT code 11720 and/or 11721 mycotic nail debridement no more often than every 60 days.
- Medicare will cover no more than six (6) sessions (CPT code[s] 11720/11721) per patient per 12 months absent medical review of patient records demonstrating medical necessity.

Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient's condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient's medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Contractor's Policies

Contractor Medical Directors

"Routine Foot Care/Mycotic Nail Debridement," Trailblazer LCD, (00400) L12481, (00900) L23770.

"Treatment of Ulcers and Symptomatic Hyperkeratoses," Noridian Administrative Services, LLC LCD, (CO) L23770.

"Routine Foot Care," Noridian Administrative Services, LLC, (CO) L23756.

"Routine Foot Care," Arkansas BlueCross BlueShield (Pinnacle) LCD, (NM, OK) L11701 and L11826.

Original JH source; LCD L32634, Mycotic Nail Debridement

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/16/2018	R3	LCD revised and published on 08/16/2018 to add clarifying language regarding culture, potassium hydroxide examination, or dermatophyte testing and mycotic nail debridement. Policy also updated with standard LCD language.	<ul style="list-style-type: none">• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2015	R2	LCD revised and published on 04/14/2016 to change the reference from ICD-9 to ICD-10 in documentation requirement #3 and Group 1 under ICD-10 Codes that DO NOT Support the Medical Necessity. The Routine Foot Care LCD number was changed from L27486 (ICD-9) to L35138 (ICD-10).	<ul style="list-style-type: none"> • Typographical Error
10/01/2015	R1	LCD revised and published on 06/25/2015.	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

N/A

Related National Coverage Documents

N/A

Public Version(s)

Updated on 08/10/2018 with effective dates 08/16/2018 - N/A

Updated on 04/08/2016 with effective dates 10/01/2015 - 08/15/2018

Updated on 06/23/2015 with effective dates 10/01/2015 - N/A

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