Molecular Diagnostic Infectious Disease Testing

Guideline Number: MPG373.28
Approval Date: April 10, 2024

➲ Terms and Conditions

Table of Contents **Page**

Related Medicare Advantage Policy Guidelines

- Clinical Diagnostic Laboratory Services
- Molecular Pathology/Molecular Diagnostics/Genetic Testing

Related Medicare Advantage Reimbursement Policies

- Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy, Professional
- Laboratory Services Policy, Professional
- Molecular Pathology Policy, Professional and Facility

Related Medicare Advantage Coverage Summaries

- Molecular Pathology/Molecular Diagnostics/Genetic Testing
- Laboratory Tests and Services

Policy Summary

➲ See Purpose

Overview

Molecular Panel tests for infectious diseases have changed the landscape of clinical microbiology. They play an important role in diagnostic testing, as they simultaneously detect several different pathogens associated with similar and overlapping clinical symptomatology. For this reason, they are also known as 'Syndromic Panel' tests. These Panels belong to a category of testing known as culture-independent diagnostic tests (CIDTs), which are tests that detect pathogens without the need to grow and isolate them in culture. These tests have shorter turnaround times, often have good test performance characteristics, and require limited technical expertise, making them appealing for use by clinicians as well as clinical laboratories.

Historically, physicians were required to select the specific pathogens most likely thought to be associated with a patient's disease. They often had to rely on empiric therapy until results from the laboratory could be used in identifying definitive or targeted antimicrobial therapy, with results taking days and sometimes weeks. In recent years, molecular Panel tests, including multiplex PCR, have become increasingly used for the detection of pathogens, and clinicians are no longer required to name (or separately test for) many of the bacterial, viral, fungal, and parasitic species sought for a given clinical 'syndrome'. As the use of multiplex molecular tests have decreased the need to perform multiple assays to diagnose a given infection, results are often available to the physician within minutes to hours. Though culture-based methods of diagnosis are still routinely utilized, and definitive antimicrobial therapy may still lag pending full culture and susceptibility information, these tests have revolutionized infectious disease diagnostics and have made the road from diagnosis to treatment very rapid, in some cases occurring at the point-of-care (POC).

Guidelines

Molecular Infectious Disease Panels for Infectious Disease Pathogen Identification Testing

Medicare provides limited coverage for outpatient testing with molecular Syndromic Panels for infectious disease pathogen identification testing.

Medicare differentiates (where appropriate) between small, targeted Panels (up to 5 pathogens) and larger, expanded Panels (≥ 6 pathogens). This distinction is primarily applied to the Respiratory and Gastrointestinal Panels.

Examples of Molecular Infectious Disease Panels addressed by Medicare include but are not limited to:

- Targeted Respiratory Panels (3-5 targets)
- Expanded Respiratory and Pneumonia Panels (> 5 targets)
- Targeted Gastrointestinal Panels (3-5 targets)
- Expanded Gastrointestinal Panels (> 5 targets)
- Meningoencephalitis Panels
- Bloodstream Infection Panels
- Urogenital/Anogenital Panels
- Arthropod Infection Panels
- Joint Infection Panels

Refer to the Local Coverage Determination (LCD) References section for coverage details. Coverage varies by LCD.

Documentation Guidelines

Documentation must be adequate to verify that coverage guidelines listed above have been met. Thus, the medical record must contain documentation that the testing is expected to influence treatment of the condition toward which the testing is directed. The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition that warrants the test(s).

Examples of documentation requirements of the ordering physician/nonphysician practitioner (NPP) include, but are not limited to, history and physical or exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing, imaging results).

Documentation requirements of the performing laboratory (when requested) include, but are not limited to, lab accreditation, test requisition, test record/procedures, reports (preliminary and final), and quality control record.

Documentation requirements for lab developed tests/protocols (when requested) include diagnostic test/assay, lab/manufacturer, names of comparable assays/services (if relevant), description of assay, analytical validity evidence, clinical validity evidence, and clinical utility.

Providers are required to code to specificity however, if an unlisted CPT code is used the documentation must clearly identify the unique procedure performed. When multiple procedure codes are submitted on a claim (unique and/or unlisted) the documentation supporting each code should be easily identifiable. If on review UnitedHealthcare cannot link a billed code to the documentation, these services will be denied.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act.

Nationally Non-Covered Indications

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that **"tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute"**.

Note: For certain Panels, such as the Urogenital/Anogenital Panel, epidemiologic indication or potential exposure to pathogens as a result of a high-risk experience is considered a covered clinical indication, even in the absence of clinical symptoms.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0097U	Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V]) (Deleted 03/31/2022)
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0151U	Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (DNA or RNA), 33 targets, real-time semi-quantitative PCR, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results (Deleted 03/31/2022) (Non-Covered)
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0240U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
0241U	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi (Effective 07/01/2022)
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab (Effective 07/01/2022)

CPT Code	Description
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected (Effective 10/01/2022)
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected (Effective 10/01/2022)
0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique (Effective 04/01/2023)
0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, wound swab (Effective 04/01/2023)
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine (Effective 04/01/2023)
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score (Effective 04/01/2023)
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen (Effective 04/01/2023) (Non-Covered)
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine (Effective 04/01/2023)
0402U	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected (Effective 10/01/2023)
0416U	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine (Effective 10/01/2023)
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis
81514	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported
87154	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe

CPT Code	Description
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (e.g., Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpesvirus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
87501	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype
87502	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types
87503	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (e.g., 6, 11, 42, 43, 44)
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87632	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
87636	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
87637	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 Code	Description
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87660	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, direct probe
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique
87662	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique
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
87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), mutation identification in targeted region(s) (Effective 02/21/2022)
87999	Unlisted microbiology procedure

Diagnosis Code	Description
For CPT Codes 81513, 81514, and 0352U	
A51.0	Primary genital syphilis
A51.1	Primary anal syphilis
A51.31	Condyloma latum
A52.76	Other genitourinary symptomatic late syphilis
A54.00	Gonococcal infection of lower genitourinary tract, unspecified
A54.01	Gonococcal cystitis and urethritis, unspecified
A54.02	Gonococcal vulvovaginitis, unspecified
A54.03	Gonococcal cervicitis, unspecified
A54.09	Other gonococcal infection of lower genitourinary tract
A54.1	Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess
A54.21	Gonococcal infection of kidney and ureter
A54.22	Gonococcal prostatitis
A54.23	Gonococcal infection of other male genital organs
A54.24	Gonococcal female pelvic inflammatory disease
A54.29	Other gonococcal genitourinary infections
A54.6	Gonococcal infection of anus and rectum
A56.00	Chlamydial infection of lower genitourinary tract, unspecified
A56.01	Chlamydial cystitis and urethritis
A56.02	Chlamydial vulvovaginitis
A56.09	Other chlamydial infection of lower genitourinary tract
A56.11	Chlamydial female pelvic inflammatory disease
A56.19	Other chlamydial genitourinary infection
A56.2	Chlamydial infection of genitourinary tract, unspecified
A56.3	Chlamydial infection of anus and rectum
A59.00	Urogenital trichomoniasis, unspecified

Diagnosis Code	Description
For CPT Codes 81513, 81514, and 0352U	
A59.01	Trichomonal vulvovaginitis
A59.02	Trichomonal prostatitis
A59.03	Trichomonal cystitis and urethritis
A59.09	Other urogenital trichomoniasis
A60.00	Herpesviral infection of urogenital system, unspecified
A60.01	Herpesviral infection of penis
A60.02	Herpesviral infection of other male genital organs
A60.03	Herpesviral cervicitis
A60.04	Herpesviral vulvovaginitis
A60.09	Herpesviral infection of other urogenital tract
A60.1	Herpesviral infection of perianal skin and rectum
A60.9	Anogenital herpesviral infection, unspecified
A63.0	Anogenital (venereal) warts
B20	Human immunodeficiency virus [HIV] disease
B37.31	Acute candidiasis of vulva and vagina
B37.32	Chronic candidiasis of vulva and vagina
B37.41	Candidal cystitis and urethritis
B37.42	Candidal balanitis
B37.49	Other urogenital candidiasis
B37.89	Other sites of candidiasis
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
D26.0	Other benign neoplasm of cervix uteri
L29.2	Pruritus vulvae
L29.3	Anogenital pruritus, unspecified
N34.1	Nonspecific urethritis
N34.2	Other urethritis
N41.0	Acute prostatitis
N41.3	Prostatocystitis
N48.5	Ulcer of penis
N76.0	Acute vaginitis
N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
N76.5	Ulceration of vagina
N76.6	Ulceration of vulva
N76.82	Fournier disease of vagina and vulva
N76.89	Other specified inflammation of vagina and vulva
N77.1	Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere
N89.8	Other specified noninflammatory disorders of vagina
N90.89	Other specified noninflammatory disorders of vulva and perineum
N93.0	Postcoital and contact bleeding

Diagnosis Code	Description
For CPT Codes 81513, 81514, and 0352U	
N93.8	Other specified abnormal uterine and vaginal bleeding
O98.711	Human immunodeficiency virus [HIV] disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus [HIV] disease complicating pregnancy, second trimester
O98.713	Human immunodeficiency virus [HIV] disease complicating pregnancy, third trimester
R10.2	Pelvic and perineal pain
R30.0	Dysuria
T74.21XA	Adult sexual abuse, confirmed, initial encounter
T74.21XD	Adult sexual abuse, confirmed, subsequent encounter
T74.21XS	Adult sexual abuse, confirmed, sequela
T74.51XA	Adult forced sexual exploitation, confirmed, initial encounter
T74.51XD	Adult forced sexual exploitation, confirmed, subsequent encounter
T74.51XS	Adult forced sexual exploitation, confirmed, sequela
T76.21XA	Adult sexual abuse, suspected, initial encounter
T76.21XD	Adult sexual abuse, suspected, subsequent encounter
T76.21XS	Adult sexual abuse, suspected, sequela
T76.51XA	Adult forced sexual exploitation, suspected, initial encounter
T76.51XD	Adult forced sexual exploitation, suspected, subsequent encounter
T76.51XS	Adult forced sexual exploitation, suspected, sequela
Z04.41	Encounter for examination and observation following alleged adult rape
Z04.71	Encounter for examination and observation following alleged adult physical abuse
Z04.81	Encounter for examination and observation of victim following forced sexual exploitation
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z33.1	Pregnant state, incidental
Z33.3	Pregnant state, gestational carrier
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior
Z72.89	Other problems related to lifestyle

Coding Clarifications:
The following coding clarifications apply to the Non-Covered Diagnosis Code List below:

- Diagnosis code **Z11.3** is excluded from Non-Coverage for CPT codes **0352U, 0353U, 0402U, 81513, 81514, 87480, 87510, 87660, 87661, 87800, 87801, and 87999.**
- Diagnosis code **Z36.89** is excluded from Non-Coverage for CPT codes **87662, 87798, and 87801** when reported for Zika Virus Testing by PCR.
- Diagnosis code **Z04.81** is excluded from Non-Coverage for CPT codes **0352U, 0353U, 0402U, 81513, 81514, 87800, 87801, and 87999.**

Non-Covered Diagnosis Code
Non-Covered Diagnosis Codes List

Non-Covered Diagnosis Code
This list contains diagnosis codes that are **never covered when given as the primary reason for the test.** If a code from this section is given as the reason for the test and you know or have reason to believe the service may not be covered, call UnitedHealthcare to issue an Integrated Denial Notice (IDN) to the member and you. The IDN informs the member of their liability for the non-covered service or item and appeal rights. You must make sure the member has received the IDN prior to rendering or referring for non-covered services or items in order to collect payment. ☐

Definitions

Panel: A test that detects > 1 pathogen.

Syndromic Panel: A test that simultaneously detects multiple different pathogens associated with similar and overlapping clinical symptomatology.

Questions and Answers

1	**Q:**	Did coverage for some of the respiratory viral Panel codes change?
	A:	Yes, Medicare coverage for Multiplex PCR respiratory viral Panels of 6 or more pathogens varies by jurisdiction. Please refer to the appropriate Local Coverage Determinations (LCDs)/Articles in the reference section for coverage information for the corresponding date of service.
2	**Q:**	The diagnosis code tables were removed for the Respiratory and Gastrointestinal panels. Where is that information located now?
	A:	This information may be found in the Local Coverage Determinations (LCDs) and Articles located in the reference section below. Please refer to the appropriate Medicare Administrative Contractor's LCD/Article and appropriate version corresponding to the date of service.

References

CMS National Coverage Determinations (NCDs)

Refer to NCD 210.10 Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs for additional information on the CPT codes **0353U, 0402U,** and **87800**.

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing				
L39038 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58747 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	CGS	KY, OH	KY, OH
L39001 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58720 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L39003 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58726 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38988 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58710 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L39044 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58761 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
Gastrointestinal Panels				
L37364 Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs)	A56596 Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs)	CGS	KY, OH	KY, OH
L38227 Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs)	A56638 Billing and Coding: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs)	First Coast	FL, PR, VI	FL, PR, VI
L39226 Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE)	A58963 Billing and Coding: Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE)	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L38229 Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs)	A56642 Billing and Coding: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs)	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L37350 Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) **Retired 06/01/2022; See L39001**	A56706 Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) **Retired 06/01/2022; See A58720**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37368 Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) **Retired 06/01/2022; See L39003**	A56711 Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) **Retired 06/01/2022; See A58726**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37709 Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) **Retired 04/17/2022; See L38988**	A56593 Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) **Retired 04/17/2022; See A58710**	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L37766 Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) **Retired 04/16/2022; See L39044**	A56637 Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) **Retired 04/16/2022; See A58761**	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
Respiratory Viral Panels				
L38918 Respiratory Pathogen Panel Testing	A58577 Billing and Coding: Respiratory Pathogen Panel Testing	First Coast		FL, PR, VI
L39027 Respiratory Pathogen Panel Testing	A58741 Billing and Coding: Respiratory Pathogen Panel Testing	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L38916 Respiratory Pathogen Panel Testing	A58575 Billing and Coding: Respiratory Pathogen Panel Testing	Novitas		AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L37348 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See L39038**	A56974 Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See A58747**	CGS	KY, OH	KY, OH
L37301 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See L39001**	A57338 Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See A58720**	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37315 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See L39003**	A57340 Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 06/01/2022; See A58726**	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L37713 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 04/17/2022; See L38988**	A56851 Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 04/17/2022; See A58710**	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L37764 MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 04/16/2022; See L39044**	A57579 Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels **Retired 04/16/2022; See A58761**	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
General Molecular Diagnostic Tests				
L36021 Molecular Diagnostic Tests (MDT)	A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A57526 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
General Molecular Diagnostic Tests				
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A57527 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	WPS	IA, IN, KS, MI, MO, NE	IA, IN, KS, MI, MO, NE
L34519 Molecular Pathology Procedures	A58918 Billing and Coding: Molecular Pathology and Genetic Testing	First Coast	FL, PR, VI	FL, PR, VI
L35062 Biomarkers Overview	A58917 Billing and Coding: Molecular Pathology and Genetic Testing	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
Influenza Diagnostic Tests				
N/A	A58817 Billing and Coding: Influenza Diagnostic Tests	CGS	KY, OH	KY, OH
N/A	A59055 Billing and Coding: Influenza Diagnostic Tests	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A59056 Billing and Coding: Influenza Diagnostic Tests	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A54769 Billing and Coding: Influenza Diagnostic Tests	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
CPT Code 87641 Medical Policy Article				
N/A	A52379 Billing and Coding: CPT Code 87641 (Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique)	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
Zika Virus Testing				
N/A	A55326 Billing and Coding: Zika Virus Testing by PCR and ELISA Methods)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A55327 Billing and Coding: Zika Virus Testing by PCR and ELISA Methods	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

CMS Benefit Policy Manual

Chapter 15; § 80.1-80.1.3 Clinical Laboratory Services

CMS Claims Processing Manual

Chapter 12; § 60 Payment for Pathology Services
Chapter 16; § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates-Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests
Chapter 18; § 170-170.5 Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs

CMS Transmittal(s)

Transmittal 11676, Change Request 12960, Dated 11/04/2022 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–April 2023 Update)
Transmittal 12318, Change Request 13390, Dated 10/19/2023 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–April 2024 Update–CR 1 of 2

Other(s)

CMS Lab NCDs - ICD-10; CMS.gov
Palmetto GBA MolDx Website
Palmetto GBA MolDx Manual, Palmetto GBA MolDx Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/10/2024	**Applicable Codes** ***Non-Covered Diagnosis Codes*** • Added Z02.84 **Administrative** • Archived previous policy version MPG373.27

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section above to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage

requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.