Multiplex Pathogen Identification Panels for Infectious Disease

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative	Applicable States/Territories

			Contractors (MACs)	
LCD LCA	MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	L39044 A58761	J5, J8 - Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
LCD LCA	Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) Billing and Coding: Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) Respiratory Pathogen Panel Testing Billing and Coding: Respiratory Pathogen Panel Testing	L39226 A58963 L39027 A58741	J6, JK - National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
LCD LCA	Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	L37364 A56596 L39038 A58747	J15 - CGS Administrators, LLC	KY, OH
LCD LCA	MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	L39001	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa,

	Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58720		Guam, Northern Mariana Islands
LCD LCA	MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	L39003 A58726	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Amplification Techniques (NAATs) Billing and Coding: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) Respiratory Pathogen Panel Testing Billing and Coding: Respiratory Pathogen Panel Testing	L38229 A56642 L38916 A58575	JH, JL - Novitas Solutions, Inc.	AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, D.C.
LCD LCA	MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	L38988 A58710	JJ, JM - Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
LCD	Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Amplification Techniques (NAATs) Billing and Coding: Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex	L38227 A56638		FL, PR, U.S. VI

LCA	Nucleic Acid Amplification Techniques (NAATs) Respiratory Pathogen Panel Testing Billing and Coding: Respiratory Pathogen Panel Testing	L38918 A58577	JN - First Coast Service Options, Inc.	

Description

Microbes (eg, bacteria, fungi, parasites, viruses) cause infections in humans. Testing methods for detecting microbes traditionally include detection by cultures or antibody testing. However, since microbes contain genetic material (DNA and RNA), genetic testing methods can be applied to detect pathogens. The genetic material in microbes differs from the genetic material in human cells. Samples used for genetic testing for infectious disease include aspirated fluid around joints, blood, cerebrospinal fluid, sputum, stool and urine. Genetic testing can be used to diagnose infections, identify and type the microbes causing an infection as well as determine if a microbe will respond to a specific treatment.

Nucleic acid amplification test (NAAT or NAT) is one type of genetic test used for infectious disease. This technique makes numerous copies (amplification) of any genetic material from the microbes present in a sample so that it can be more easily detected. One type of NAAT is polymerase chain reaction (PCR). These tests provide faster results than traditional methods and are more sensitive and specific.

Some newer genetic tests for infectious disease can analyze several different microbes simultaneously from a single sample. This is called panel testing, also known as molecular panels or multiplex testing. Panel tests may be used to identify infections that have similar signs and symptoms but can be caused by a variety of microbes. Currently, the most common panel tests are respiratory or gastrointestinal infection multiplex NAAT panels. For example, an individual may present with symptoms such as abdominal pain and diarrhea which can be caused by a virus, bacteria or parasite. Genetic testing panels may lead to a quicker diagnosis which can influence treatment decisions but may also include those with unclear medical management.

Multiplex panels have been suggested for the evaluation of many types of infections including, but may not be limited to, bloodstream, gastrointestinal, meningitis, respiratory, urinary tract and urogenital/anogenital infections.

Next-generation sequencing (NGS), also known as high-throughput sequencing or deep sequencing, has been proposed to identify microbial infections for several indications. There are two approaches to NGS: whole genome sequencing or targeted sequencing which includes PCR in the process.
Antibiotic resistance testing, also known as antimicrobial susceptibility testing, provides information that can be used to guide treatment decisions such as the selection of appropriate antibiotic regimens. There are different methods for testing, including conventional methods (phenotypic testing) and newer molecular (genotypic) techniques such as PCR, NAAT and NGS.

Some laboratories offer panels that include both pathogen identification and antibiotic resistance or sensitivity. Panels are used for many indications including, but may not be limited to, recurrent urinary tract infections (UTIs).

Differentiation between bacterial from viral infections is an emerging indication for multiplex pathogen testing.

Metagenomic NGS is an evolving, novel molecular technology proposed to detect pathogens for infectious disease and can potentially provide direct, unbiased analysis of microbial composition of specimens without reliance on traditional culture or targeted molecular tests.

Genetic testing for infectious disease differs from genetic tests for inherited conditions. Microbes associated with infectious disease contain genetic material but the genetic material contained within microbes differs from genetic material within human cells. Genetic testing for inherited conditions, also known as germline mutation testing, analyzes an individual's DNA and can identify genetic mutations to determine inherited risk of disease. An individual's germline DNA is constant and identical in all body tissue types. The DNA and RNA of microbes are present only in the tissue sampled, are not representative of an individual's germline DNA and are not inheritable.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS "reasonable and necessary" criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary's specific medical problem.

For jurisdictions with no Medicare guidance for a particular test, iCare will utilize the MolDX program and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare's reasonable and necessary requirement.
In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

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The scope of this medical coverage policy is limited to the outpatient setting and does not address coverage for the inpatient setting.

A multiplex panel is defined as a test that analyzes more than one pathogen simultaneously. Targeted panels analyze fewer pathogens than expanded (larger) panels. While testing should be limited to a targeted panel, an expanded panel may be warranted when a targeted panel will not provide sufficient information for the appropriate clinical management of the individual.

GENERAL CRITERIA FOR MULTIPLEX PATHOGEN IDENTIFICATION PANELS FOR INFECTIOUS DISEASE

Apply General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease when test specific criteria are not available on this medical coverage policy **IN ADDITION TO** specific criteria below, as indicated.

Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Individual to be tested has a clinical indication for infectious disease testing; **AND**
    - Individual is immunocompetent and any of the following:
        - Presumption of active infection; **OR**
        - Infection associated complications (which may include exacerbation of underlying disease) that require the identification of a causative organism for appropriate management; **OR**
        - Atypical clinical presentations of disease for special populations who may not present with classic symptoms of infection (ie, elderly); OR
    - Individual is immunocompromised (weakened immune system) defined as follows:
        - Diagnosed with human immunodeficiency virus (HIV); **OR**
        - Diagnosed with acquired immunodeficiency syndrome (AIDS); **OR**
        - Taking immunosuppressive medications (ie, chemotherapy, biologics, transplant-related immunosuppressive drugs, high-dose systemic corticosteroids); **OR**
        - Diagnosed with an inherited disease that affects the immune system (ie, congenital immunoglobulin deficiency); **OR**
        - Atypical clinical presentations of disease; **OR**
        - Pretransplant evaluation regardless of the presence of symptoms (may be performed one time only); **AND**

- Results of testing will impact clinical management in a manner demonstrated in the peer-reviewed, published literature to improve outcomes for the individual; **AND**

- Test is performed according to the intended use of the test in the intended patient population for which the test was developed and validated; **AND**

- Test is performed using the intended sample types along with parallel testing that must accompany the test (ie, bloodstream and meningoencephalitis pathogen tests requires parallel testing using conventional Gram stain and culture-based detection for correlation of results); **AND**

- Evaluation for more than one pathogen by molecular testing is necessary for clinical management of the individual (testing for a single pathogen is not reasonable and necessary for the specific infection, individual or indication); **AND**

- Panel includes at least the minimum pathogens required for clinical decision making for its intended use that can be reasonably detected by the test; **AND**

- An expanded panel testing is only indicated when a targeted panel testing is not appropriate (ie, will not provide sufficient information for appropriate clinical management); **AND**

- Analytic validity, clinical validity and clinical utility of the panel is supported by the MolDX program or US Food & Drug Administration (FDA) approved/cleared tests when performed by the intended-use labeling directions; **AND**

- Documentation of the following is clearly stated in the medical record:

    - Specific clinical indications for testing (ie, clinical suspicion of a pathogen as the cause of the individual's condition); **AND**

    - Specific reasons for performing panel testing; **AND**

    - Provider type/specialty and place of service; **AND**

- Testing must be performed according to Clinical Laboratory Improvement Amendments (CLIA) and/or FDA regulations (eg, CLIA-nonwaived tests may only be performed in certified laboratories and according to CLIA regulations. CLIA-waived tests may be performed in healthcare settings that operate under a CLIA Certificate of Waiver or Certificate of Compliance/Certificate of Accreditation).

CRITERIA FOR PANELS WITH SPECIFIC INDICATIONS

Gastrointestinal Pathogen Panels - Targeted

Gastrointestinal (GI) pathogen targeted panel (6 to 11 pathogens) will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Individual is immune-competent; **AND**
    - Clinical indication for GI panel testing is diarrhea; **AND**
        - Diarrheal illness must be acute or persistent with signs or risk factors for severe disease (ie, fever, bloody diarrhea, dysentery, dehydration, severe abdominal pain) that may warrant hospitalization; **AND/OR**
        - Diarrheal illness has not resolved after 7 days and the individual has not taken laxatives within 24 hours of the test

Gastrointestinal Pathogen - Expanded Panels

Gastrointestinal (GI) pathogen expanded panels (12 or more pathogens) will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Targeted testing is not appropriate; **AND**
- Meets requirements of General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease above; **AND**
    - Individual is immune-competent; **AND**
        - Is seriously or critically ill***** or at imminent risk of becoming seriously or critically ill as a result of a presumed GI infection; **AND**
        - Is being treated in an appropriate critical care facility********; **OR**
    - Individual is immune suppressed; **AND**
        - Has severe and established underlying GI pathology (ie, inflammatory bowel disease [IBD], paralytic ileus, radiation therapy to the intestine); AND
        - Identification of an infectious cause is necessary to determine next steps in clinical management; **OR**
        - Test is ordered by a clinician specialist****** in one of the following:
            - ❖ Gastroenterology
            - ❖ Infectious diseases

- ❖ Oncology
- ❖ Transplant; **OR**

- Individual is being managed in an appropriate critical care facility****

Respiratory or Pneumonia Pathogen Panels - Targeted

Respiratory and pneumonia pathogen targeted panels* (up to and including 5 pathogens)[38,39,40] will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Individual is immune-competent; **AND**
- Has severe and established underlying respiratory pathology (ie, severe asthma, chronic obstructive pulmonary disease [COPD], cystic fibrosis, pulmonary fibrosis, radiation therapy to the lung); **AND**
- Treatment with antibiotics may be indicated according to established guidelines. Specific examples that do not meet coverage criteria according to established guidelines include the following:
  - Asthma exacerbations without the additional presence of either fever and purulent sputum or radiographic evidence of pneumonia
  - Uncomplicated community acquired pneumonia (CAP)

Respiratory or Pneumonia Pathogen Panels - Expanded

Respiratory and pneumonia pathogen expanded panels* (6 or more pathogens)[38,39,40] will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Targeted testing is not appropriate or does not provide adequate information to treat the individual; **AND**
- Meets requirements of General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease above; **AND**
- Individual is immune-competent; **AND**
  - Is seriously or critically ill* or at imminent risk of becoming seriously or critically ill as a result of a presumed respiratory infection; **AND**
  - Is being treated in an appropriate critical care facility****
- Individual is immune-suppressed; **AND**
  - Test is ordered by a clinician specialist** in one of the following:
    - Infectious diseases

- Oncology
- Pulmonology
- Transplant; **OR**

- Is being managed in an appropriate critical care facility

***Seriously ill is defined as vital signs may be unstable and not within normal limits. Individual is acutely ill. Indicators are questionable. Critically ill is defined as vital signs are unstable and not within normal limits. Individual may be unconscious. Indicators are unfavorable.[4]

****For ALL patients, exceptions to the limitation on medical specialists who can order expanded panel tests are provided in the accompanying Billing and Coding Article, such that patient geography and access to care do not preclude the receipt of appropriate diagnostic testing when indicated.[32,33,34,35,36]

*****For respiratory or pneumonia panels, only one will be covered for a given individual for the same clinical indication.[32,33,34,35,36]

******Appropriate clinical care facility is defined as any of the following:[20,21,22,23,24,41]

- Off campus – outpatient hospital
- Inpatient hospital
- On-campus – outpatient hospital
- Emergency room - hospital

Bloodstream Infection Pathogen Panels

Bloodstream infection pathogen panels will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Meets General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease; **AND**
- There is clinical concern for bacteremia or sepsis; **AND**
- Microbe(s) were seen on a Gram stain from the individual's blood; **AND**
- Individual is being managed in an appropriate critical care facility******; **AND**
- Personnel (ie, an antimicrobial stewardship team [ASP]) are equipped for rapid (within 24 hours) tailoring of antimicrobial therapy as a result of rapid testing

Meningoencephalitis Pathogen Panels

Meningoencephalitis pathogen panels will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Meets General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease; **AND**
- Testing is from a sample collected via lumbar puncture, and NOT an indwelling medical device (ie, cerebrospinal fluid [CSF] shunts); **AND**
- Immune-competent individual has at least two of the following indicators of central nervous system (CNS) infection OR immune-compromised individual with at least one of the following indicators of CNS infection:
    - CSF markers
    - Radiology, clinical signs and symptoms consistent with meningitis or encephalitis
    - Epidemiologic indication or exposure

Urinary Tract Infection Panels

Urinary tract infection (UTI) panels will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Meets General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease; **AND**
- Individual is symptomatic; **AND**
- At higher risk for UTI complications (ie, elderly, recurrent UTIs and/or complicated urinary tract anatomy; **AND/OR**
- Managed in urogynecology or urology specialty care setting

Urogenital/Anogenital Infection Panels

Urogenital/anogenital infection panels will be considered medically reasonable and necessary when the following requirements are met:[32,33,34,35,36]

- Meets General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease; **AND**
    - Epidemiologic indication or potential exposure to sexually transmitted pathogens (ie, in the case of clinical concern for multiple sexually transmitted infections [STIs] due to a high-risk experience), even in the absence of clinical symptoms (documentation of the high-risk reason for panel testing must be clearly stated in the medical record); **OR**
    - In the absence of a high-risk experience, the primary clinical concern is for a few specific pathogens due to specific signs and symptoms (ie, lesions suggestive of herpes simplex virus [HSV]) (targeted panel only [less than 5 pathogens] [eg, HSV-1 and HSV-2]); OR

- Diagnosis of infectious vaginosis/vaginitis targeted or expanded panel that includes a combination of at least two of the following:
  - *Gardnerella vaginalis*
  - Other bacterial vaginosis (BV)-associated bacteria (BVAB) (such as *Atopobium vaginae* and/or *Megasphaera* types)
  - *Trichomonas vaginalis*
  - *Candida* species

REPEAT MULTIPLEX PATHOGEN IDENTIFICATION PANELS FOR INFECTIOUS DISEASE

Repeat multiplex pathogen panels for infectious disease will be considered medically reasonable and necessary when the following requirements are met (limited to one additional panel test):[32,33,34,35,36]

- Previous panel analyzed the same pathogens within 14 days for the same clinical indication; **AND**
- Meets General Criteria for Multiplex Pathogen Identification Panels for Infectious Disease AND specific criteria, if available, established within this medical coverage policy; **AND**
- The first panel yielded a negative result; **AND**
- There is a high index of suspicion for a pathogen as the cause of symptoms; **AND**
- The clinical condition of the individual is not improving or is deteriorating after a clinically appropriate length of time

Note: Tests that demonstrate similar indicated uses and equivalent or superior performance to standard of care (SOC) or other covered tests, as demonstrated in a technology assessment, may similarly be covered under this policy.[32,33,34,35,36]

Note: Additional syndromic panel types and indications may also be covered according to the established criteria outlined in this policy.[32,33,34,35,36]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following tests may not be considered a benefit (statutory exclusion):

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law (exception: individual at high risk for urogenital/anogenital infection);[32,33,34,35,36,77] **OR**
- Tests that confirm a diagnosis or known information;[77] **OR**
- Tests to determine risk for developing a disease or condition (exception: individual at high risk for urogenital/anogenital infection);[32,33,34,35,36,77] **OR**
- Tests performed to measure the quality of a process;[77] **OR**
- Tests without diagnosis specific indications;[77] **OR**
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial[77]

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment.

The following items will not be considered medically reasonable and necessary:

- Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the MolDX Program
- More than 1 panel performed on the same date of service for the same clinical indication (exception: a second panel may be performed for bloodstream and meningoencephalitis panels for nonduplicative content)[32,33,34,35,36]
- Panel does not include at least the minimum pathogens required for clinical decision making for its intended use that can be reasonably detected by the test[32,33,34,35,36]
- Panels intended for home use (including those that have been FDA-approved/cleared)[32,33,34,35,36]
- Repeat respiratory or pneumonia pathogen panels (exception: repeat respiratory or pneumonia pathogen panels will be considered medically necessary for the same clinical indication if the requirements of the criteria above are met. Respiratory and pneumonia panels will be considered as

equivalent tests, such that if criteria for repeat testing are met, a clinician may choose to perform the repeat test using the pneumonia panel, even if the original test was a respiratory panel.[32,33,34,35,36]

- Test for a single pathogen for the specific infection, individual or indication[32,33,34,35,36]
- Test is performed as a test of cure[32,33,34,35,36]
- Urogenital/anogenital infection expanded panels if the primary clinical concern is for a few specific pathogens due to specific signs and symptoms[32,33,34,35,36]

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81479	Unlisted molecular pathology procedure	
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	
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique	
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, 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 (eg, 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 (eg, 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	
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, 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 (eg, 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 (eg, 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	
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	
0086U	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility	
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	
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	

0140U	Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected	
0141U	Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected	
0142U	Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected	
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, plasma, untargeted next-generation sequencing, report for significant positive pathogens	
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	
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)–based antimicrobial susceptibility for each organisms identified	
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique	

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	
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	
0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP-10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection	
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	
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	
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 viaquantitative polymerase chain reaction (qPCR), urine	
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	
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	
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	
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	

CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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4. American Hospital Association (AHA). Guidelines for releasing information on the condition of patients. https://www.mahprm.org. Accessed October 23, 2023.

5. American Thoracic Society (ATS). American Thoracic Society Documents. Microbiological laboratory testing in the diagnosis of fungal infections in pulmonary and critical care practice: an official American Thoracic Society clinical practice guideline. https://www.thoracic.org. Published September 1, 2019. Accessed November 15, 2022.

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Change Summary

- 01/01/2024 New Policy.