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Medicare Advantage Policy Manual **Policy ID:** M-GT85

Molecular Panel Testing for Identification of Microorganisms

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Syndromic pathogen panels are diagnostic tools used in medical laboratories to identify the cause of an infection based on the symptoms a patient is experiencing. These panels are designed to detect multiple pathogens (such as bacteria, viruses, and fungi) that can cause similar symptoms, all in a single test. This approach has the potential to help healthcare providers to diagnose infections more accurately. These panels vary in size from small, targeted panels to larger "expanded" panels.

MEDICARE ADVANTAGE POLICY CRITERIA

Notes: The Medicare references in this policy represent the guidance available at publication; please see the Medicare Coverage Database for the latest guidance. This policy includes links to external webpages that are not maintained by the health plan.

Nucleic acid testing specific to the SARS-CoV-2 virus (COVID-19) is addressed in a separate policy (see Cross References).

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- ✓ MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39003) *(Companion article A58726, see "Associated Documents" in the LCD)*

Links to prior versions can be found at the bottom of the LCD.

Additional research may be needed to determine coverage for tests or indications not addressed in the LCD and article.

LCDs and Articles for Other Jurisdictions

Note: The health plan is required to use LCDs and articles published by the contractor with jurisdiction over the service area in which the tests are performed.[1,2] See below for contractor guidance in other jurisdictions:

Laboratories in CA and NV:

- ✓ MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39001) and associated article

Laboratories in AL, GA, TN, SC, NC, VA, WV:

- ✓ MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988) and associated article

Laboratories in IA, KS, MO, NE, IN, MI:

- ✓ MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39004) and associated article

Laboratories in KY, OH:

- ✓ MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39038) and associated article

Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:

- ✓ Respiratory Pathogen Panel Testing (L38916) and associated article

- ✓ Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (L38229) and associated article

Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:

- ✓ Respiratory Pathogen Panel Testing (L39027) and associated article
- ✓ Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) (L39226) and associated article

Laboratories in FL, PR, and VI:

- ✓ Respiratory Pathogen Panel Testing (L38918) and associated article
- ✓ Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (L38227) and associated article

Additional research may be needed to determine coverage for tests or indications not addressed in the LCD and article.

Additional Information

The MolDX program requires that tests complete a technical assessment (TA) for coverage.

The following tests have completed a MolDX TA and are listed as "**covered**":

- Alinity® m STI Assay [0455U] (Abbott Molecular)
- Alinity™ m HSV1&2/VZV Assay [0527U] (Abbot Molecular)
- ePlex® Respiratory Pathogen Panel 2 [0225U] (GenMark Diagnostics)
- FilmArray® Gastrointestinal (GI) Panel [0097U] (BioFire)
- FilmArray® Respiratory Panel (RP) 2.1 [0202U] (BioFire)
- FilmArray® Respiratory Panel [0528U] (BioFire)

The following tests have completed a TA and are listed as "**not covered**":

- Bridge Urinary Tract Infection Detection and Resistance Test [0321U] (Bridge Diagnostics)
- HealthTrackRx Bronchitis [0556U] (HealthTrackRx)
- HealthTrackRx Vaginitis [0557U] (HealthTrackRx)
- Karius® Test [0152U] (Karius)
- Respiratory Pathogen Panel (NxGen MDx)
- Taq Card Urinary Tract Infection PCR Panel [0593U] (Soft Cell Laboratories)
- Urinary Tract Infection Testing [0504U] NxGen MDx

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The following information is required in order to determine medical necessity and potential Medicare coverage for a genetic or molecular diagnostic test. *[See Title XVIII of the Social Security Act, §1833(e), which states no payment may be made unless information necessary to determine payment has been submitted].*

1. The specific name of the panel;
2. Name and location of the performing laboratory;
3. Applicable CPT and/or HCPCS code(s);
4. Brief explanation of how the results of pathogen panel testing are necessary to guide treatment decisions relevant to the member's personal medical history.
5. Medical records relevant to the testing being performed. This includes:
   - History and physical examinations by the referring physician;
   - Conventional testing and outcomes; and
   - Conservative treatment provided, if applicable.

CROSS REFERENCES

1. Genetic and Molecular Diagnostics – Next Generation Sequencing, Genetic Panels, and Biomarker Testing, Genetic Testing, Policy No. 64

REFERENCES

1. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 - MAC with Exclusive Jurisdiction over a Medicare Item or Service

CODING

Codes	Number	Description
CPT	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), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms 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 (SARSCoV-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
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinarypathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative 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
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
0429U	Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified probe

	technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
0480U	Infectious disease (bacteria, viruses, fungi and parasites), cerebrospinal fluid (CSF), metagenomic next generation sequencing (DNA and RNA), bioinformatic analysis, with positive pathogen identification
0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral/rectal/vaginal swab, algorithm reported as probability of fluoroquinolone resistance
0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity, (23S rRNA point mutation), oral/rectal/vaginal swab, algorithm reported as probability of macrolide resistance
0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism
0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism
0527U	Herpes simplex virus (HSV) types 1 and 2 and Varicella zoster virus (VZV), amplified probe technique, each pathogen reported as detected or not detected
0528U	Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria
0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma
0556U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0557U	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism
0563U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
0564U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
0590U	Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism
0593U	Infectious disease (genitourinary pathogens), DNA, 46 targets (28 pathogens, 18 resistance genes), RT-PCR amplified probe technique, urine, each analyte reported as detected or not detected

	0595U	Infectious disease (tropical fever pathogens), vector borne and zoonotic pathogens, including 2 viruses (Chikungunya virus and Dengue virus serotypes 1, 2, 3, and 4), 1 bacterium (Leptospira species), and 1 parasite with species differentiation (Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale), real-time RTPCR, whole blood, each pathogen reported as detected or not detected
	87523	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta), quantification, including reverse transcription, when performed
HCPCS	None	