Medicare Medical Policy

Respiratory Viral Panels

MEDICARE MEDICAL POLICY NUMBER: 255

Effective Date: 8/1/2026

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Next Annual Review: 7/2027

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Molecular Syndromic Respiratory Viral Panels	• **Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, HI, and NV**: LCD: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39001) • **Testing performed in VA, WV, NC, SC, GA, TN, and AL**: LCD: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988) **NOTES:** • While the above LCDs address testing for various types of infectious disease pathogens, this medical policy is **specific to respiratory conditions and panels only**. • The above LCDs state, "Services that do not have Food and Drug Administration (FDA)-cleared/approved indicated uses, as well as FDA-approved tests performed in ways not consistent with their intended-use labeling directions, will require registration with Molecular Diagnostic Services Program (MolDX®) and a Technical Assessment (TA) to demonstrate compliance of the service with this policy." To identify services with FDA approval or clearance, please use the FDA website. *(The web page appears specific to influenza tests, but tests for other respiratory viral illnesses are also included.)* • The test reported with 0556U has **not** been FDA approved or cleared, nor has it met the required MolDX TA requirements, so it is considered **not medically necessary** until the local MAC for this laboratory's jurisdiction indicates otherwise.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization

determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

None

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Table 1 below includes a list of proprietary tests with their associated billing CPT proprietary laboratory analysis (PLA) code.

Table 1: Proprietary Tests and Associated PLA codes

Test	CPT Code
ePlex® Respiratory Pathogen (RP) Panel (ePlex RP® panel) (GenMark Diagnostics, Inc.)	0115U
BioFire® FilmArray® Respiratory Panel 2.1 (RP2.1) (bioMérieux)	0202U
QIAstat–Dx® Respiratory SARS CoV–2 Panel (QIAGEN Sciences)	0223U
ePlex® Respiratory Pathogen Panel 2 (GenMark Dx) (GenMark Diagnostics, Inc.)	0225U
BIOFIRE® FILMARRAY® Pneumonia (PN) Panel (bioMérieux)	0528U
HealthTrackRx Bronchitis (HealthTrackRx or Thermo Fisher Scientific)	0556U
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel (code used when test is selected from the Respiratory Menu) (bioMérieux)*	0563U
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel (code used when test is selected from the Sore Throat menu) (bioMérieux)*	0564U

* BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel: Organism types and subtypes differ, depending on what "menu" the SPOTFIRE R/ST test is selected from.

Medical Necessity

CPT codes 87631, 87636, 87637, and 87812 are potentially medically necessary only when billed with an ICD-10 code that supports medical necessity, as outlined in the local coverage article (LCA) A58720 (see the diagnosis code list for **Group 1** codes).

CPT codes 87632, 87633, 0115U, 0202U, 0223U, 0225U, 0528U, 0563U and 0564U are also only potentially medically necessary when billed with an ICD-10 code that supports medical necessity, as found in the LCA A58720 (see the diagnosis code list for **Group 6** codes). Note that these CPT codes require a diagnosis code from *two* different diagnosis code lists within the LCA, **or** a place of service (POS) that would warrant the medical need of such tests.

The test reported with 0556U has not been FDA approved or cleared, nor has it met the MolDX TA requirements, so it is considered **not medically necessary**.

CODES*		
CPT	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
	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
	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
	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
	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
	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
	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
	87812	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification. Dated 11/9/2018. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K180966. Accessed 6/3/2026.
2. U.S. FDA. Influenza Diagnostic Tests. Updated 10/15/2024. https://www.fda.gov/medical-devices/in-vitro-diagnostics/influenza-diagnostic-tests. Accessed 6/3/2026.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
10/2022	Q4 2022 code updates (converted to new format 2/2023)
8/2023	Annual review; no changes
6/2024	Interim update to diagnosis code configuration based on LCA A58726 updates
8/2024	Annual review; no changes
12/2024	Interim update to diagnosis code configuration based on LCA A58726 updates; add reference to FDA website due to LCD language
1/2025	Q1 2025 code updates
3/2025	Interim update to criteria regarding the BIOFIRE® FILMARRAY® Pneumonia Panel test (add reference to LCAs A59055/A59056)
5/2025	Interim update to criteria regarding the BIOFIRE® FILMARRAY® Pneumonia Panel test (change reference to LCDs for other infectious disease panels)
7/2025	Q3 2025 code updates
8/2025	Annual review; no changes
10/2025	Interim update; update coverage for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel. Replaced A59056 with A59055 due to Noridian JF consolidation with JE LCD policies)
1/2026	Q1 2026 code updates (2/13/2026: Replaced LCD L39003 with LCD L39001 due to Noridian JF consolidation with JE LCD policies) (4/10/2026: Replaced LCA A58726 with A58720 due to Noridian JF consolidation with JE LCA articles)
5/2026	Interim update; removed reference to A59055 due to retroactive retirement to 1/31/26
8/2026	Annual review; no changes