ASURIS NORTHWEST HEALTH

Medicare Advantage Policy Manual **Policy ID:** M-LAB74

COVID-19 Testing

Published: 06/01/2024

Next Review: 03/2025

Last Review: 04/2024 ***Medicare Link(s) Revised:*** *06/01/2024*

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 may 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

COVID-19 testing includes molecular and antigen testing for active infection with the SARS-CoV-2 virus, as well as antibody testing (aka, serology testing), which measures antibodies that the immune system develops in response to the virus. Serology or antibody testing is not intended to diagnose active coronavirus infection.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: **One** COVID-19 or related test is covered **without** a physician order, but *repeat or subsequent* COVID-19, influenza or RSV testing **will** require a physician order after September 2, 2020. According to CMS, FDA-authorized COVID-19 serology (antibody) tests are **subject to the same order requirements.**[1] See "Policy Guidelines" below for additional

information. In addition, not all COVID-19 testing will meet Medicare's reasonable and necessary requirements for coverage. Finally, CMS has also published guidance for COVID-19 testing related to skilled nursing facility (SNF) residents, which also provides information regarding Medicare and COVID-19 testing in general.[2]

CMS Coverage Manuals*	For CPT codes ***0224U, 0226U, 0240U, 0241U, 86328, 86408, 86409, 86413, 86769, 87428, 87449, 87450, 87635, 87636, 87637, 87811, U0001, U0002***: Medicare Benefit Policy Manual, Pub. No. 100.02 Chapter 15 – Covered Medical and Other Health Services *See Section 80.1 in the following link:* §80.1 - Clinical Laboratory Services COVID-19 testing, including viral (molecular [PCR-based] and antigen) and antibody (serology) tests may be **medically necessary** to diagnose or manage a specific medical condition. **CPT codes 0240U, 0241U, 86328, 86413, 86769, 87428, 87449, 87450, 87635, 87636, 87637, 87811, and U0001-U0005 are such potentially covered tests**. See "Policy Guidelines" below for Medicare rules regarding physician orders for these tests. However, other tests are not eligible for coverage. *§1862(a)(1)(A) of the Social Security Act* states Medicare payment may not be made for services that are not reasonable and necessary to treat or diagnose an illness or condition. *42 CFR §410.32(a)* states, "All… diagnostic laboratory tests…must be ordered by… the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Therefore, COVID-19 testing (viral and antibody) is considered **not medically necessary** when performed for public health surveillance, epidemiologic, school, travel, recreational (e.g., for camp, sports, or social events), employer purposes, or to determine eligibility for plasma donation or the need for personal protective equipment (PPE), as these do not meet Medicare's medical necessity requirements for diagnostic laboratory services. Some of these testing scenarios may also be considered "screening" in nature, which are also generally non-covered under the Medicare program. **CPT codes 0226U, 86408 and 86409 are such non-covered tests**. See below for additional tests.

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	For ***0202U, 0223U, and 0225U***: For the BioFire® Respiratory Panel 2.1 (RP2.1; ***0202U***), the cQIAstat-Dx Respiratory SARS-CoV-2 Panel, (QIAGEN Sciences; ***0223U***), and the ePlex® Respiratory Pathogen Panel 2 (GenMark Dx; ***0225U***) tests:

MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	LCD L39003
Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Article A58726

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

To be eligible for Medicare coverage, Medicare requires diagnostic laboratory tests be ordered by the physician who is treating the beneficiary for a specific medical problem **and** who will use the test results in the management of that specific medical problem.[3,4] Testing that will not be used for patient management or for which the test results are **not** expected to improve health outcomes for that individual would **not** meet Medicare's medical necessity requirements.

However, during the public health emergency (PHE), for select COVID-19 and related influenza or respiratory syncytial virus (RSV) clinical diagnostic laboratory tests, Medicare removed the requirement that these specific diagnostic laboratory tests must be ordered by a treating physician or non-physician practitioner (NPP). Specifically, effective September 2, 2020, "the order of a physician or other practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis, when performed in conjunction with a COVID-19 diagnostic laboratory test in order to discount influenza virus or related diagnosis. This includes FDA-authorized COVID-19 serology tests, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection."[1] CMS published a list of COVID-19, influenza, and other respiratory testing to which these rules applied during the PHE.[5] With the ending of the PHE in May 2023, the requirement for a physician or NPP order for all COVID-19 testing has been reinstated.[6]

The CMS-3401-IFC Rule also states, "Medicare continues to cover other medically necessary clinical diagnostic laboratory tests when a treating physician or other practitioner orders them, and that other Medicare conditions of coverage and payment continue to apply, including any applicable local coverage determinations."[1] Therefore, other tests may continue to be subject to Medicare's physician order rules, as well as LCD and article coverage guidelines.

CLINICAL TRIALS

Clinical trials are only eligible for coverage by Medicare Advantage plans if the clinical trial is approved by Medicare. If a clinical trial is not approved by Medicare, then it is not considered a "qualifying clinical trial," which means the trial and its related services would not be covered by either Medicare or the Medicare Advantage plan. This Medicare-approval requirement is outlined in the member benefit contract or Evidence of Coverage (EOC). For qualifying clinical trials, Original Medicare would be the primary payor, and the Medicare Advantage plan would process as secondary. Therefore, if a claim is submitted to the Medicare Advantage Organization (MAO) for services that are part of a qualifying clinical trial, the claim must be accompanied with the Medicare Explanation of Benefits (MEOB). The MAO will then process the claim as the secondary carrier according to Medicare guidelines described above. Claims submitted without the MEOB will be denied, with a message instructing the provider to submit the claim to Original Medicare. A separate Medicare Advantage medical policy addresses clinical trial services in further detail (see Cross References).

CROSS REFERENCES

Genetic and Molecular Diagnostics – Next Generation Sequencing and Genetic Panel Testing, Genetic Testing, Policy No. M-64

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

REFERENCES

1. https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
2. CMS web page for *MEDICARE PAYMENT FOR COVID-19 VIRAL TESTING*; Available at: https://www.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf [accessed 4/22/2024]
3. 42 CFR 410.32 (a)
4. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services
5. CMS web page for *COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE**; Available at: https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf [accessed 4/22/2024]
6. https://www.cms.gov/files/document/what-do-i-need-know-cms-waivers-flexibilities-and-transition-forward-covid-19-public-health.pdf

CODING

Codes	Number	Description
CPT	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 *(Use for the BioFire® Respiratory Panel 2.1 (RP2.1) test; BioFire® Diagnostics)*

	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 *(Use for the QIAstat-Dx Respiratory SARS CoV-2 Panel; QIAGEN Sciences)*
	0224U	Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed *(Use for the COVID-19 Antibody Test; Mount Sinai Laboratory)*
	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 *(Use for the ePlex® Respiratory Pathogen Panel 2; GenMark Dx)*
	0226U	Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum *(Use for the Tru-Immune™, Ethos Laboratories)*
	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
	0408U	Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])
	86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
	86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); screen
	86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]); titer
	86413	Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative
	86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) Multi-step method
	87428	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B

	87449	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; not otherwise specified, each organism
	87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
	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
	87811	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])
HCPCS	U0001	CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel *(Effective for dates of service on or after February 4, 2020)*
	U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*