August 8, 2025

VIA Electronic Mail

Dr. Joshua Ardise, Senior Executive Medical Director
Dr. Eric J. Berman, Senior Executive Medical Director
Dr. Eliane Schwartz, Medical Director
Horizon Blue Cross Blue Shield of New Jersey
Three Penn Plaza East
Newark, New Jersey 07105

RE: Response to Change in Coverage for COVID and Respiratory Point of Care Tests

Dear Drs. Ardise, Berman, and Schwartz:

On behalf of the Point of Care Testing Association (POCTA),[1] the Infectious Diseases Society of America (IDSA), AdvaMedDx, and the Urgent Care Association, we are writing in response to the "Update: Coverage and Reimbursement for COVID-19 Testing to change" published on your website on November 15, 2023, 00:48 a.m. ET[2] (hereafter, referred to as the "Update Policy").

The Update Policy applies to tests for COVID-19, as well as to multiplex panels for multiple viral pathogens (e.g., COVID-19, Influenza and Respiratory Syncytial Virus.) These tests provide valuable information to healthcare providers, especially in the POC setting. POC respiratory pathogen testing gives clinicians information needed to identify the right therapy for the right patient at the right time. Furthermore, POC tests performed in non-laboratory settings, especially in more sparsely populated settings where access to care may be more challenging, may substantially expand access to accurate, timely results.

Notwithstanding the above, the Update Policy only allows professional providers to perform a single type of COVID test – the single-step antigen test described by CPT code 87811 – in-office. As such, if a clinician believes it is

[1] POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the POC benefits patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients in a variety of care settings, from clinics to pharmacies to community centers to non-hospital facilities (e.g., assisted living). POCTA is comprised of Abbott Rapid Dx, Abbott Point of Care, Beckman Coulter Diagnostics, Becton, Dickinson and Company (BD), bioMérieux, Cepheid, and Roche Diagnostics Corporation.

[2] https://www.horizonblue.com/providers/news/news-legal-notices/update-coverage-and-reimbursement-covid-19-testing-change

appropriate to request COVID testing using instrumented antigen (87426) or amplified probe methods (87635), or multiplex testing using the same methods (87428 (antigen), 87636, 87637, 0202U, 0240U, 0241U (amplified probe)), such tests must be sent to an off-site reference laboratory for analysis.

For the reasons outlined below, we are requesting that Horizon amend the Update Policy to re-establish reimbursement for professional providers performing tests described with the following CPT codes in a POC setting: CPT codes 87426, 87428, 87635, 87636, 87637, and 0202U[3].

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1. Introduction to POC *In Vitro* Diagnostics (IVDs)

IVDs contribute to nearly 70% of all health care decisions. As demonstrated during the COVID-19 pandemic, POC testing quickly and accurately identifies infected individuals to facilitate appropriate treatment and limit further spread of disease. IVDs utilize different techniques (e.g. Polymerase Chain Reaction (PCR), immunoassay) to identify different pathogen targets (e.g., nucleic acid, antigen).

We understand and support policies that encourage the efficient use of limited healthcare resources. However, we believe the Update Policy unduly restricts access to medically necessary POC tests that can be furnished and used in patient management in real time when such use is in the best interests of patient care. POC testing is needed to timely diagnose disease or monitor conditions when rapid turnaround time is important to reduce time to diagnosis and/or time to treat.

It is widely acknowledged that POC testing can be a valuable tool in a physician's ability to rapidly diagnose disease and to prevent its spread through the community. POC testing provides "rapid actionable information for patient care at the time and site of an encounter with the health care system", "reduce[s] the need for multiple visits", and "facilitate[s] the containment of infectious disease outbreaks."[4] Similarly, the Infectious Diseases Society of America (IDSA) notes the importance of quick diagnostic

[3] Extended long descriptors listed in Appendix. Our request does not reference codes 0240U or 0241U because those codes have been deleted effective July 1, 2025.

[4] Kozel TR, Burnham-Marusich AR. Point-of-care testing for infectious diseases: past, present, and future." *J Clin Microbiol* 2017;55(8):2313-2320. doi:10.1128/JCM.00476-17

methods, since "rapid isolation of contagious patients is expected to reduce SARS-CoV-2 transmission."[5]

POC testing is widely available (e.g., not requiring access to a microscope or specific expertise/training to successfully perform). Recent advances have the potential to make POC testing even simpler, more accurate and have a faster turnaround time, thus enhancing providers' ability to detect and treat health risks. Studies have demonstrated that POC testing increases diagnostic certainty and reduces transfers from rural providers to more centralized hospitals, producing cost savings.[6]

The quality of testing in the POC setting is assured through the appropriate level of certification required under the Clinical Laboratory Improvement Amendments (CLIA) for the type of testing performed in the POC setting. Many POC tests have met the high accuracy bar required for CLIA waiver. For those POC tests that are not waived, CLIA certification as a non-waived laboratory and requirements for proficiency testing and for inspection assure the quality of testing furnished in the POC setting.

By denying access to POC testing for a number of respiratory conditions where POC testing has been shown to be accurate and reliable, the guideline will have a chilling effect on physicians' willingness to adopt POC testing.

2. Clinical guidelines support the availability of POC testing for these analytes.

As currently drafted, the Policy Update only authorizes coverage for one specific test – visually read antigen testing reported with code 87811 – when offered in a POC setting. We are not aware of any clinical practice guideline, consensus statement, or other evidence-based third-party document that supports limiting access to respiratory pathogen testing to this specific type of test in the POC setting. Indeed, the Centers for Disease Control and Prevention (CDC) recommend testing for both COVID and flu in outpatient clinic patients presenting with acute respiratory illness symptoms when both viruses are circulating:

SARS-CoV-2 Testing

- *Test for SARS-CoV-2 by nucleic acid detection OR SARS-CoV-2 antigen detection assay, especially in persons at increased risk for progression to severe COVID-19. (Note: Because antigen detection*

[5] IDSA Guidelines on the Diagnosis of COVID-19: Antigen Testing (Dec. 20, 2022), IDSA Guidelines on the Diagnosis of COVID-19: Antigen Testing (idsociety.org).

[6] Nichols JH, Alter D, Chen Y, *et al*. AACC guidance document on management of point-of-care testing. [Epub] J Appl Lab Med June 4, 2020, as doi:10.1093/jalm/jfaa059.

assays have lower sensitivity than nucleic acid detection assays, a negative SARS-CoV-2 antigen detection assay result does not necessarily exclude SARS-CoV-2 infection. This should be confirmed by SARS-CoV-2 nucleic acid detection assay or repeat antigen testing 48 hours later, if clinical suspicion for COVID-19 is high – such as in the setting of high SARS-CoV-2 community prevalence or recent close exposure to a person with COVID-19.) If the second antigen test is negative, per FDA guidance, a third antigen test could be considered if there is a high clinical suspicion of COVID-19.

Influenza Testing

- *Test for influenza if results will change clinical management or for infection control decisions (e.g. long-term care facility resident returning to a facility, or a person of any age returning to a congregate setting): order rapid influenza nucleic acid detection assay; if a rapid influenza nucleic acid detection assay is not available on-site, order rapid influenza antigen detection assay. If available, multiplex nucleic acid detection assay for SARS-CoV-2, influenza A and B viruses can be performed on-site, or at an offsite clinical laboratory.*

  (Note: Because SARS-CoV-2 and influenza virus co-infection can occur, a positive influenza test result without SARS-CoV-2 testing does not exclude SARS-CoV-2 infection, and a positive SARS-CoV-2 test result without influenza testing does not exclude influenza virus infection).[7]

Furthermore, in situations where amplified probe testing is not available with timely results, IDSA guidelines support the use of rapid antigen testing for COVID, and are generally agreed to have comparable specificity to molecular methods.[8]

The CDC identifies both PCR and antigen tests as "effective methods for diagnosing RSV"[9] without suggesting that access should be limited to any particular site of care.

3. Necessity of accurately identifying the specific respiratory condition(s) causing patients symptoms – but clinicians are unable

[7] CDC, Clinical Guidance for Hospitalized and Non-Hospitalized Patients When SARS-Cov-2 and Influenza Viruses are Co-Circulating (Sept. 17, 2024), Clinical Guidance for Hospitalized and Non-Hospitalized Patients When SARS-CoV-2 and Influenza Viruses are Co-Circulating | Influenza (Flu) | CDC.

[8] IDSA Guidelines on the Diagnosis of COVID-19: Antigen Testing (Dec. 20, 2022), IDSA Guidelines on the Diagnosis of COVID-19: Antigen Testing (idsociety.org).

[9] CDC, Diagnostic Testing for RSV August 30, 2024), Diagnostic Testing for RSV | RSV | CDC.

to reliably do so at the time of prescribing, without access to accurate test results.

Clinician ability to accurately identify any individual respiratory pathogen remains poor. In one study, Hansen *et al.* reported that emergency department physician diagnoses of influenza had a sensitivity of just 36% (95% CI, 10.8-38.5%).[10]

Poor clinician empiric performance may be explained, at least in part, since it is often not possible for health care providers to distinguish potential respiratory viral conditions based on signs and symptoms alone:

> *Both adult and pediatric patients infected with RSV often present with nonspecific, overlapping symptoms that can lead to difficulty in distinguishing it from influenza, coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or other respiratory illnesses. Thus, empiric diagnosis is often insufficient and should be supported by viral diagnostic testing to facilitate appropriate treatment, improved surveillance, and timely infection control.*[11]

Notwithstanding this difficulty, it remains critically important to correctly identify the underlying cause(s) of a patient's symptoms, as there are significant differences in recommended treatment options for each etiology. As summarized below, there is no overlap between the Centers for Disease Control and Prevention (CDC)-recommended treatments for COVID-19, influenza, and RSV:

Test	CDC-recommended therapy
Influenza[12]	Tamiflu, Relenza, Rapivab, Xofluza
COVID-19[13]	Paxlovid, Veklury, Lagrevio
RSV[14]	No specific treatment. Antiviral medication is not routinely recommended to fight RSV.

[10] Hansen GT, Moore J, Herding E, *et al*. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE study group. *J Clin Virol* 2018;102:42-49.

[11] Bernstein DI, Mejias A, Rath B, *et al*. Summarizing study characteristics and diagnostic performance of commercially available tests for respiratory syncytial virus: a scoping literature review in the COVID-19 era. *J Appl Labor Med* 2022:jfac058.

[12] Treating Flu with Antiviral Drugs (Sept. 11, 2024), Treating Flu with Antiviral Drugs | Influenza (Flu) | CDC.

[13] Types of COVID-19 Treatments (May 8, 2025), Types of COVID-19 Treatment | COVID-19 | CDC.

[14] Symptoms and Care of RSV (August 30, 2024), Symptoms and Care of RSV | RSV | CDC.

If diagnosed incorrectly, patients may experience continuation of symptoms due to inappropriate treatment, and increased health care utilization (e.g., need for follow-up visits).

4. **Accurate diagnosis facilitated by POC testing increases appropriate antiviral therapy prescriptions and saves costs.**

POC tests can accurately identify respiratory condition(s) – and clinicians can use such information to inform appropriate prescribing decisions. For example, in a retrospective study, Benirschke et al. found that that as compared to other rapid testing methods, the use of a highly sensitive and specific POC PCR test for influenza detection led to higher antiviral prescribing in positive patients (82.4% versus 69.9%, $p<0.05$) and decreased use in negative patients (2.3% versus 13.1%, $p<0.005$).[15]

Access to POC tests may also lead to meaningful cost savings/more efficient resource utilization. In a prospective study assessing the impact of rapid RT-PCR influenza testing on physician decision-making in the emergency department, ED, Hansen et al. estimated that "[o]verall costs savings associated with access to RT-PCR testing in the ED resulted in $200.40/patient/ED visit. Projections over an extended influenza season (2000 ED visits) including estimated cost of providing testing resulted in net cost savings of $578,627 to $678,627."[16]

Furthermore, a 2023 cost effectiveness study by Diehl found, "Using highly sensitive and specific PCR-POCT in patients suspected of COVID-19 infection at German ERs may significantly reduce hospital expenditures."[17]

5. **The Update Policy leaves Horizon BCBS commercial beneficiaries without comparable access to POC test compared to Medicare and other commercial plan's beneficiaries.**

The legal notice referenced above leaves your patients without access to the POC Tests, even though their neighbors with commercial insurance may have such access. For example, Novitas (the Medicare Administrative Contractor for New Jersey) identifies several of these tests as covered services

[15] Benirschke RC, McElvania E, Thomson RB, *et al*. Clinical impact of rapid point-of-care PCR influenza testing in an urgent care setting: a single-center study. *J Clin Microbiol* 2019;57(3):e01281-18.

[16] Hansen GT, Moore J, Herding E, et al. Clinical decision making in the emergency department setting using rapid PCR: Results of the CLADE study group. J Clin Virol 2018;102:42-49.

[17] Diel R, Nienhaus A. Cost-Benefit of Real-Time Multiplex PCR Testing of SARS-CoV-2 in German Hospitals. Int J Environ Res Public Health. 2023;20(4):3447. Published 2023 Feb 15. doi:10.3390/ijerph20043447

in its "Respiratory Pathogen Panel Testing" coding article,[18] and the underlying LCD explicitly notes that such services may be performed in a physician's office.[19]

Similarly, Aetna coverage policies explicitly identify many of these tests as covered services when applicable criteria have been met, without limiting access to a particular site of service.[20] Furthermore, New Jersey Medicaid maintains fee schedule amounts for several of these codes – again, without limiting access to a particular site of service.[21]

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We thank you in advance for your consideration of these comments and our request to provide equitable access to testing at professional office settings. We value Horizon's ongoing efforts to provide members access to these technologies . **In furtherance of these recommendations, we are requesting a teleconference to walk through this information, and to answer any questions you may have.** Please contact Mike Ryan at 202.756.8088, or via e-mail to mryan@mwe.com, if we can be helpful in any way.

Sincerely yours,

Point of Care Testing Association
Infectious Diseases Society of America
AdvaMedDx
Urgent Care Association

[18]CMS, Billing and Coding: Respiratory Pathogen Panel Testing, A58575. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58575&ver=32 (identifying 87636, 87637, 0240U, and 0241U as covered services).

[19]CMS, Respiratory Pathogen Panel Testing, L38916. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38916 ("Respiratory pathogen panel testing in the outpatient setting by a Part B provider (e.g., physician's office, independent clinical laboratory) will be considered medically reasonable and necessary when all of the following are met…".)

[20] *See* Aetna Medical Policy; Polymerase Chain Reaction Testing: Selected Indications Reviewed 06/17/2025, Polymerase Chain Reaction Testing: Selected Indications - Medical Clinical Policy Bulletins | Aetna (identifying 87635-87637, 0202U as covered "if selection criteria are met").

[21] Medicaid Fee For Services: update June 1, 2025, CPTHCPCSCODES2025.pdf

Appendix

Code	Descriptor
87426	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])
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
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
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