Biofire® Respiratory Panel Coding and Coverage Update

Effective April 1, 2021, three proprietary CPT® codes for Biofire® respiratory panel lab tests will be deleted – 0098U, 0099U, and 0100U. The change was listed in the November 2020 CPT® Panel meeting agenda:

https://www.ama-assn.org/system/files/2021-01/cpt-pla-codes-short.pdf

CPT® Proprietary Laboratory Analyses (PLA) Codes: Short Descriptors

It is important to note that further CPT Editorial Panel (Panel) or Executive Committee actions may affect these codes and/or descriptors. For this reason, code numbers and/or descriptor language in the CPT code set may differ at the time of publication. In addition, further Panel actions may result in gaps in code number sequencing.

Most recent changes to the CPT® Proprietary Laboratory Analyses (PLA) Short Descriptor document

- Addition of 6 PLA codes (0242U-0247U) and deletion of 3 PLA codes (0098U-0100U) accepted by the CPT Editorial Panel.
- Deleted codes in this document appear with a ~~strikethrough~~.

Some have speculated that since COVID-19 was not among the targets tested in these three CPT®'s, Biofire® withdrew the codes from active use.

0202U Deemed Non-Covered -- Meanwhile, hospitals and laboratories across the US have found that the 22-target Biofire® respiratory panel HCPCS 0202U is non-covered by most MAC's through Local Coverage Determinations. This has confounded some purchasers of the test since the national Clinical Lab Fee Schedule rate was hefty $416.78.

In its response to comments received in the course of adopting LCD L37764, WPS offers the following rationale to a commenter who attempted to persuade the MAC that multiplex testing for more than 5 targets should be covered:

Local Coverage Article for Response to Comments: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (DL37764) (cms.gov)

> "The commenter makes a hypothetical argument pointing out that there potentially exists a clinical application for a respiratory viral panel in some patients so as to lead to a better outcome.
>
> However, the commenter does not provide evidence that any particular panel (where a panel is a specified group of tests which must be ordered together) or any group of panels has clinical utility for a particular population or for beneficiaries with well identified indications. For coverage purposes Palmetto GBA must make coverage decisions regarding specific panels or specific selections of pathogens for specific indications. As such, while we agree that it is conceivable that there exists a patient population who might benefit from a particular group of multiple respiratory viral tests, at this point no evidence has been brought to our attention regarding how a clinician is to identify such

a population for any specific available test. Moreover, the only virus group in the core set of pathogens for which treatment is widely (but still not universally) appropriate is influenza.

For those cases in which more than one causative virus could be related to the observed signs or symptoms (either due to overlap of typical symptoms or the presence of atypical symptoms), and diagnosis of a specific causative agent is expected to alter treatment in a way that improves the outcome, the clinician could order individual viral tests for which a result would be expected to lead to clinically actionable information.

If new evidence develops demonstrating that a particular panel or the use of a particular set of respiratory viral tests, which match the components of a panel, leads to enhanced patient outcomes we would be willing to reconsider this coverage determination.

Draft LCD's and established LCD's limiting coverage of multiplex testing have been adopted by most MACs. Multiplex PCR respiratory viral panels of 6 or more pathogens are deemed not medically necessary and therefore non-covered. Here are links to a few LCD's from MAC's across the country:

Novitas	Proposed Local Coverage Determination for Respiratory Pathogen Panel Testing (DL38916) (cms.gov)
WPS	Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37764) (cms.gov)
Noridian	Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315) (cms.gov)
CGS	Local Coverage Determination for MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37348) (cms.gov)
Palmetto	Local Coverage Article for Billing and Coding: MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (cms.gov)
First Coast	Proposed Local Coverage Determination for Respiratory Pathogen Panel Testing (DL38918) (cms.gov)

PARA inquired of CMS whether hospitals which had purchased the 0202U test could report a lower target-count CPT®, such as 87631, in lieu of 0202U in order to receive some reimbursement for the spent expense of the 22-target respiratory panel. CMS responded by referring the question to local MACs for guidance.

MACs tend to limit interaction to identified provider representatives within each jurisdiction; therefore, PARA recommends that hospitals and laboratories reach out to its regional MAC for this coding guidance.

A copy of the email from CMS is provided on the following page.

Tue 3/16/2021 3:18 AM

CMS MCD Feedback <MCDFeedback@cms.hhs.gov>

RE: 0202U vs 87631

To [redacted]

Thank you for your question. While we aren't able to provide you with guidance regarding the possible coding scenario you describe below we do recommend reaching out directly to each MAC representing the geographic area of your clients. At least some of the MACs may have previously encountered similar situations.

From: Monica Lelevich <mlelevich@para-hcfs.com>
Sent: Thursday, March 11, 2021 1:32 PM
To: CMS MCD Feedback <MCDFeedback@cms.hhs.gov>
Subject: 0202U vs 87631 - JOANNA

Greetings,

I represent a revenue cycle consulting firm with hospital clients across the US. Several of our clients have purchased Biofire laboratory equipment in order to perform multiplex testing, such as HCPCS 0202U, which tests a single specimen for 22 target organisms which may have caused a respiratory infection.

Most MAC's have adopted an LCD which does not deem multiplex testing for more than 5 targets to be supported by Medical Necessity, so our clients cannot be paid for testing done on the new equipment.

Since our clients have already invested in the technology to report 22 targets in one test, and since the test methodology is the same as that described by the HCPCS 87631, would it be acceptable for hospitals to report 87631 if the hospital agrees to accept that code as payment in full, even though more than 5 targets were evaluated?

HCPCS/CPT®	OPPS Status	Clinical Lab Fee Schedule
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	A	$416.78
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	Q4	$142.63