Audits of Respiratory (CPT Code 87633) / Gastro (CPT Code 87507) Panels are Ongoing.

(January 3, 2021): In recent months, we have seen a significant rise in the number of Medicare and Medicaid audits focusing on the medical necessity of certain outpatient Respiratory Viral Panels (CPT Code 87633) and Gastrointestinal Pathogen Panels (CPT Code 87507). Unfortunately, many of these audits seem to be merely the latest example where payors have conflated the issues of **"Medical Necessity"** and **"Coverage."** In this article, we examine a number of the laboratory tests currently being audited by Medicare and Medicaid payors and we discuss why the government's crack-down on respiratory and gastrointestinal testing may be ill-advised. Specific respiratory tests currently being scrutinized include:

CPT Code 87631 (Respiratory Virus Panel. 3-5 Targets)

CPT Code 87632 (Respiratory Virus Panel. 6-12 Targets)

CPT Code 87633 (Respiratory Virus Panel. 12-20 Targets)

Specific gastrointestinal tests currently being audited include:

CPT Code 87505 (Infectious agent detection by nucleic acid (DNA or RNA) Gastrointestinal Pathogen Panel (PCR). 3-5 Targets)

CPT Code 87506 (Infectious agent detection by nucleic acid (DNA or RNA) Gastrointestinal Pathogen Panel (PCR). 6-11 Targets)

CPT Code 87507 (Infectious agent detection by nucleic acid (DNA or RNA) Gastrointestinal Pathogen Panel (PCR). 12-25 Targets)

I. Clinical Laboratory Testing for Viral Respiratory Infections:

Prior to the development of low-cost, outpatient multiplex laboratory testing technologies, clinicians diagnosed viral respiratory track infections with the assistance of direct fluorescent-antibody assay (DFA) and culture testing. With this approach, clinicians were able to detect only a little more than a handful of commonly seen respiratory viruses. DFA testing was labor intensive, required

qualified laboratory staff and specific monoclonal antibodies. As technology has advanced, the ability to detect new respiratory viruses also increased. From 2000 to 2007, five new human respiratory viruses were discovered. The emergence of five new respiratory viruses since 2000, including metapneumovirus (MPV), severe acute respiratory syndrome coronavirus (SARS-CoV), avian influenza virus H5N1, CoVs NL63 and HKU1, and human bocavirus really amplified the limitations of relying on DFA and culture testing. It became more important than ever that clinicians have the ability to readily detect both traditional and emerging respiratory viruses. **[1]**

Since 2000, a number of laboratory polymerase chain reaction (PCR) testing technologies were developed that enabled the rapid processing of 20 or more respiratory tests simultaneously, using a single sample. As this technology has developed, the use of these multiplex testing systems has grown. Today, a number of physician practices and clinics have integrated multiplex PCR testing systems into their outpatient practices. The benefits of using multiplex PCR respiratory viral panel tests are well established and are discussed below.

II. Benefits of Multiplex PCR Respiratory Viral Panels -- CPT Code 87631 / CPT Code 87632 and CPT Code 87633:

The specific respiratory lab tests being audited include: **CPT Code 87631 / CPT Code 87632 and CPT Code 87633.** As you would expect, payors are quite concerned with the proliferation of CPT Code 87633, which involves the testing and billing for 12-20 targets. Despite these concerns, proponents of broad respiratory testing can point to a wide variety of benefits that have been realized through the use of multiplex PCR respiratory viral panel systems. These benefits include, but are not limited to:

PCR testing platforms cover a broader scope of viral agents. PCR respiratory viral panel testing platforms can automatically process 22 (or more) viral tests at one time. DFA testing systems were typically limited to conducting 6 or 7 concurrent tests.

PCR test results are faster. PCR respiratory viral panel test results are typically available within an hour. In contrast, old-school DFA and culture testing is both labor intensive and more time consuming.

PCR respiratory viral panels have been shown to significantly reduce ICU days.**[2]**

PCR respiratory viral panels have been shown to reduce the duration of a patient's antibiotic use. **[3]**

Perhaps most importantly, PCR respiratory viral panels just work better.

> **PCR respiratory viral panels identified significantly more pathogens than traditional testing platforms.** Christine Ginocchio, Ph.D.[4] presented a poster at the recent Seasonal and Pandemic Influenza meeting in Washington, DC, that emphasized the assay's reproducibility and its ability to detect mixed infections. *"Overall, we detected a variety of respiratory viruses in **29 percent of specimens tested by direct immunofluorescence [DFA**], in **49.9 percent of the specimens by rapid viral culture using R-Mix cells** [Diagnostic Hybrids, Athens, Ohio], and in **64 percent of the specimens by the RVP [respiratory viral panel] assay**," she says. "The increase in identifying specimens positive for a respiratory virus was due to the fact that we are detecting viruses we normally do not culture for or grow routinely in the laboratory—the rhinoviruses, parainfluenza, and coronaviruses."*

Despite the fact that the benefits to using multiplex testing are numerous, a number of payors have taken a hard line when it comes to covering these tests. Several of the payors concerns are discussed below.

III. Problems with Multiplex PCR Respiratory Viral Panels:

> **Testing platform manufacturers have programmed their machines to test for organisms that are not common.** One the one hand, manufacturers have covered their bases when it comes to commonly identified viral infections. However, as the number of emerging respiratory viral organisms has grown, the manufacturers have expanded the scope of testing to include these organisms, despite the fact that they infrequently seen.
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> **Testing platforms have a "fixed" testing protocol.** For example, one of the more common PCR respiratory viral panel testing platforms is set up to test for 22 different organisms using a single sample, regardless of whether the ordering physician believes that a patient should be tested for all 22 of these viral organisms.
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> **Medicare takes the position that multiplex PCR respiratory platforms do not meet the payor's "reasonable and necessary" requirements.** Essentially, Medicare takes the position that fixed testing platforms, where a sample is automatically tested for 22 pathogens, regardless of whether or not they are needed, does not meet the payor's

reasonable and necessary requirements. As such, checking for pathogens where there is no identified need for testing would be medically unnecessary. As Palmetto has argued *"The multiplex PCR respiratory viral panels are effectively a 'one size fits all' diagnostic approach, and do not meet Medicare's 'reasonable and necessary' criteria. Non-coverage of these multiplex PCR respiratory viral panels does not deny patient access because appropriate clinician directed testing is available."*

The Emergence of COVID-19 has Heightened the Government's Concerns Regarding Multiplex Testing. Earlier this year, the OIG added "COVID-19 Add-on Testing" to its list Work Plan projects. As the OIG noted at the time, the ***OIG has program integrity concerns related to add-on tests in conjunction with COVID-19 testing, particularly related to potentially fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests, or genetic tests***.

IV. Coverage Concerns with Respect to Gastrointestinal Multiplex Testing -- CPT Code 87505 / CPT Code 87506 and CPT Code 87507:

The specific gastrointestinal lab tests being audited include: **CPT Code 87505 / CPT Code 87506 and CPT Code 87507.** As you would expect, payors are quite concerned with the proliferation of CPT Code 87507, which involves the testing and billing for 12-25 targets. Proponents of broad, multiplex testing can point to a number of benefits that have been identified in connection with this approach. Several of these benefits include:

Reduced antibiotic use.[5]

Reduced time to antimicrobial therapy.[6]

Led to more targeted therapy.[7]

Reduced downstream procedures such as endoscopies and abdominal imaging.[8]

Medicare, Medicaid and private payors have approached both respiratory and gastrointestinal multiplex testing in a similar fashion. For example, both Noridian has issued Local Coverage Determination guidance providing that it would only cover multiplex gastrointestinal pathogen molecular assays in limited circumstances:

"In immune competent beneficiaries, coverage is limited to no more than 5 bacterial targets (when not testing for Clostridium difficile). Testing for 6-11 pathogens is covered when there is a clinical concern for Clostridium Difficile colitis, and Clostridium difficile is one of the pathogens being tested.

Testing for 12 or more organisms will only be covered in critically ill or immunosuppressed patients." **[9]**

V. Responding to an Audit Respiratory and Gastrointestinal Multiplex Laboratory Tests:

Arguably, there has been a disconnect between the technology being developed by industry and payor policies. A number of the multiplex lab testing technologies currently being sold are not set up to test for only a limited number of specified pathogens. When conducting respiratory and gastrointestinal multiplex tests, the maximum number of targets are automatically tested. In other words, a provider can't use some of these machines to only test for 3-5 targets even if that is all the provider wanted to test. While payors like to base their denials of higher level multiplex testing on lack of medical necessity grounds, there have been a number of studies which suggest that in the long run, it is both better for the patient and more economical to conduct broad-based multiplex testing.

If your respiratory and / or gastrointestinal laboratory testing practices are audited (especially **CPT Code 87633** and **CPT Code 87507),** you will need to be able to show that the level of testing billed was medical necessary and appropriate given the clinical profile of each patient.

Liles Parker health law attorneys [10] are experienced in defending claims audits of this type. In addition to being experienced health lawyers, many of our attorneys have also achieved recognition as Certified Professional Coders (CPCs). Are your laboratory claims for CPT Code 87633 and CPT Code 87507 being audited? Give us a call for a free consultation: 1 (800) 475-1906.

[1] Journal of Clinical Microbiology, Development of a Respiratory Virus Panel Test for Detection of Twenty Human Respiratory Viruses by Use of Multiplex PCR and a Fluid Microbead-Based Assay Sept. 2007, p. 2965–2970.

[2] Martinez R, et al. Clinical Virology Symposium, Poster #C-368, May 2016.

[3] Rogers B, et al. Arch. Path. & Lab. Med. 2015;139(5): 636-41.

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[5] Axelrad JE, Freedberg DE, Whittier S, Greendyke W, Lebwohl B, Green DA. Impact of Gastrointestinal Panel Implementation on Healthcare Utilization and Outcomes. J of Clin. Microbiology. 2019; 27;57(3). e01775-18.

[6] Cybulski R, Bateman A, Bourassa L, Bryan A, Beail B, Matsumoto J, Cookson B, Fang FC; Clinical impact of a Multiplex Gastrointestinal PCR Panel in Patients with Acute Gastroenteritis. 2018. Clinical Infectious Diseases, ciy357, https://doi.org/10.1093/cid/ciy357.

[7] Id.

[8] Axelrad JE, Freedberg DE, Whittier S, Greendyke W, Lebwohl B, Green DA. Impact of Gastrointestinal Panel Implementation on Healthcare Utilization and Outcomes. J of Clin. Microbiology. 2019; 27;57(3). e01775-18.

[9] Noridian Local Coverage Article**:** Billing and Coding: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs) (A56711)

[10] For an overview of our attorney team, please see the following link**.**