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Re: Respiratory Pathogen Panel Testing DL38918 (First Coast) and DL38916 (Novitas)

Dear Medical Directors:

The Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP) write to provide joint comments on the proposed coverage policy for Respiratory Pathogen Panel Testing. We appreciate the opportunity to review and provide joint comments because our organizations share the same position regarding this draft LCD, which First Coast and Novitas are proposing to implement in your respective Medicare Administrative Contractor jurisdictions.

The AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

The CAP is the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, physicians, hospitals and healthcare systems worldwide, fostering and advocating excellence in the practice of pathology and laboratory medicine.

Together, we would like to thank you for proposing coverage for testing using multi-pathogen panels in the outpatient setting. We believe thoughtful consideration was given to the published literature and the resulting proposed LCD will positively impact patient care through early detection and implementation of appropriate treatment therapy early in the illness when it is most effective. After reviewing the proposed policy's coverage criteria, we ask that Novitas and First Coast consider the following AMP and CAP recommendations.

#### **Covered Indications**

1. *The covered indications state that, "Panels with  $\leq 5$  respiratory pathogens are performed, and BOTH of the following criteria are met:*

- *The outpatient setting is equipped to deliver timely results AND,*
- *For patients where it is demonstrated that clinical management can result in an improved health outcome.*

**Comment:** The AMP and the CAP agree with the first bullet that test results should be timely, however, we do not

see how this statement as written can practically be interpreted in the context of an LCD. Any medically indicated patient care service, laboratory or otherwise, must be provided in such a way that it can contribute to improving the health outcome of the patient to qualify for coverage. It is therefore unclear to us how including this statement as written in the LCD contributes to ensuring that only clinically useful services are provided or billed for. Coverage parameters should be as specific and narrow as possible to help avoid situations in which claims are denied. The Centers for Medicare and Medicaid Services Program Integrity Manual, Chapter 13, states that an LCD should contain clear and concise language and describe only the services that are reasonable and necessary for coverage under 1862(a)(1)(A) of the Social Security Act.<sup>6</sup>

The second bullet requires that a panel test must demonstrate “that clinical management results in an improved health outcome.” In addition to improving health outcomes, the diagnostic and treatment values of respiratory pathogen panel testing cannot be overstated. They are an essential element of protocols that physicians use to start, adjust, or stop a course of treatment. These diagnostic tests help prevent unnecessary exposure to antibiotics, help rule out the need for hospitalization or cohort patients to make optimal use of healthcare facilities, and minimize disease transmission to healthcare personnel, and others. Minimizing the use of antibiotics by using respiratory pathogen panel testing will also decrease the development of antibiotic resistance which is a significant global issue.

Respiratory pathogen panels are also a critical tool for clinicians during the COVID-19 pandemic as well as during the standard flu season. In addition to providing a crucial adjunct in determining the etiology of patients’ symptoms who present with flu-like illnesses, utilization of respiratory panel tests is essential for preserving person protective equipment (PPE) and reducing adverse impacts on emergency department and hospital bed capacity. Testing using respiratory panels is especially important where COVID-19 tests and supplies are either limited or not rapidly available to laboratories. Additionally, panel tests are necessary for understanding the likelihood of co-infection with other viruses and/or bacteria in COVID-19 patients to help address potential new mortality risks.

**Recommendation: We recommend that First Coast and Novitas remove the first bullet that states, “the outpatient setting is equipped to deliver timely results.” Alternatively, we propose that the first bullet be replaced with the phrase, “test results are provided to the treating physician for timely management of the patient.” We recommend that First Coast and Novitas change the second bullet to read: “For patients for whom clinical management can result in an improved health outcome.”**

*2. The proposed policy limitations state, “Panels with >5 respiratory pathogens performed in the Part B outpatient setting”*

**Comment:** We agree that multiplex respiratory viral panel testing is not indicated in all clinical scenarios. However, the proposed policy’s blanket approach to limit testing to only five respiratory pathogens fails to recognize a vulnerable subset of patients, including the immunocompromised, who are particularly prone to complications. Signs and symptoms can be indistinguishable between a variety of respiratory viral and bacterial pathogens and testing with a panel that detects additional respiratory pathogens allows for a definitive diagnosis to improve clinical management and health outcomes in the outpatient setting.

A broad spectrum of respiratory pathogens can cause significant morbidity and mortality in patients with a weakened immune system. This is especially true for hematopoietic stem cell or solid organ transplant recipients, as well as for patients receiving high-dose chemotherapy and/or steroids. Early diagnosis is essential for optimal patient management to direct antiviral therapy, initiate or discontinue antibiotic therapy, guide decisions about chemotherapy or timing of transplant, and for informing optimized infection control practices. Current U.S. and international guidelines endorse upfront, simultaneous testing for multiple respiratory viruses (i.e., testing beyond influenza A/B and RSV only) in transplant and cancer patients.<sup>1,2,3,4</sup>

The misuse of antibiotics, as when used inappropriately for viral infections, can lead to severe adverse effects in patients. A recent study by Tamma et al.,<sup>5</sup> demonstrated that a large proportion of hospitalized patients experience antibiotic-associated adverse effects. The authors drew several conclusions from this research, including that 20% of patients experienced one or more adverse effects and with each additional 10 days of antibiotics the adverse effects increased by 3%. It was also noted that 4% of patients developed *Clostridium difficile* infections, 6% of patients developed infections with multidrug-resistant organisms, and 24% of patients had prolonged hospital stays as a result of their adverse effects. In addition, the authors concluded that 19% of antibiotics prescribed in this study were unnecessary.

Additionally, broader testing may be necessary for recognition of the possibility of co-infection in patients. This is even more important in the current pandemic where co-infections with SARS-CoV-2 have been reported. The risk of co-infections is pressuring clinicians and hospitals to broaden their patient testing portfolios to address new mortality risks. Laboratories are experiencing an exponential increase in the number of requests for respiratory viral panels (RVPs) by clinicians during this SARS-CoV-2 outbreak. Multiplex PCR is a highly sensitive, highly specific test for the detection of viral and bacterial infections, including influenza, parainfluenza, respiratory syncytial virus, metapneumovirus, adenovirus, and several common non-SARS coronaviruses. Utilization of RVPs during this pandemic provides important clinical information such as providing fast turnaround times for persons under investigation, preserving person protective equipment (PPE); and rapid triaging to assign appropriate levels of care and minimize disease transmission to patients, healthcare personnel, and others, while reducing adverse impacts on emergency department and hospital bed capacity.

**Recommendation: We request that First Coast and Novitas allow for coverage of panels with more than five pathogens when they are determined to be clinically warranted, especially in the clinical scenarios detailed in this letter.**

3. *The following CPT codes are effective January 01, 2021. At the time of publication, the new codes have not been loaded to the system. The codes will be added to the Group 1 Code table upon finalization of the article: 87428, 87636, 87637, 0240U, 0241U.*

**Comment:** We appreciate your acknowledgement of the additional codes and for adding them to the list of Group 1 (covered) codes when the final LCD Billing & Coding Guideline Article is issued.

6. *ICD-10 codes.*

**Comment:** We request that the following additional ICD-10 codes be added to the associated coverage article:

B20	Human immunodeficiency virus [HIV] disease
D80.7	Transient hypogammaglobulinemia of infancy
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81.30	Adenosine deaminase deficiency, unspecified
D81.819	Biotin-dependent carboxylase deficiency, unspecified
D81.9	Combined immunodeficiency, unspecified
D82.9	Immunodeficiency associated with major defect, unspecified
D83.9	Common variable immunodeficiency, unspecified
D84.89	Other immunodeficiencies
D84.9	Immunodeficiency, unspecified
D89.9	Disorder involving the immune mechanism, unspecified
J12.0	Adenoviral pneumonia
J12.1	Respiratory syncytial virus pneumonia
J12.3	Human metapneumovirus pneumonia
J12.0	Adenoviral pneumonia
J12.1	Respiratory syncytial virus pneumonia
J12.3	Human metapneumovirus pneumonia
J12.82	Pneumonia due to coronavirus disease 2019
M35.81	Multisystem inflammatory syndrome
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z11.52	Encounter for screening for COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z86.16	Personal history of COVID-19
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status

Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
D70*	Neutropenia
D70.1*	Agranulocytosis secondary to cancer chemotherapy
D70.2*	Other drug-induced agranulocytosis

\* Chemotherapy can cause reduced white cells/leukopenia/neutropenia resulting in immunosuppression which increases the risk for infections.

In closing, we thank First Coast and Novitas for considering our recommendations for their Respiratory Pathogen Panel Testing local coverage determination. As new evidence emerges demonstrating the clinical utility underlying multi-pathogen panel testing, we urge First Coast and Novitas to remain open to future expansion of this coverage policy.

Should you have any questions or require additional information, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at [tburke@amp.org](mailto:tburke@amp.org) or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at [nwilson@cap.org](mailto:nwilson@cap.org).

Sincerely,

Association for Molecular Pathology  
College of American Pathologists

## References

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