Respiratory Pathogen Panel Testing

CPT: 87636

CMS Policy for Illinois, Minnesota, and Wisconsin

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Diagnostic testing for identification of pathogens that are causative for respiratory infections has evolved over the years. The aim is for rapid, accurate, and sensitive identification in an effort to improve patient outcomes through improved clinical decision making. These new technologies include nucleic acid-based amplification techniques. The focus of this LCD is respiratory pathogen panel testing, which typically includes detection for multiple virus pathogens by amplification of target DNA and is currently the most popular technique that can provide rapid, accurate, and sensitive results.1

Even with the widespread use of respiratory pathogen panel testing, only a few methods are available that not only detect respiratory pathogens but are also U.S. Food and Drug Administration (FDA) approved. Please see the FDA link for approved/cleared respiratory pathogen panel tests. https://www.fda.gov/.2 It is recognized that labs may not have FDA approval/clearance of their products, i.e. laboratory developed tests (LDTs). At the time of this publication, tests are not limited to FDA approved/cleared products only. Coverage for tests is based on demonstration of analytical and clinical validity and clinical utility at a level that meets the Medicare medically reasonable and necessary requirement.

Covered Indications

Respiratory pathogen panel testing in the outpatient 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:

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CMS Policy for Illinois, Minnesota, and Wisconsin (continued)

1. Panels with ≤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 the test result aids clinical management with the goal of an improved health outcome for the patient.

Limitations

The following is considered not medically reasonable and necessary:

1. Panels with >5 respiratory pathogens performed in the Part B outpatient setting.[3]

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

Introduction

This evidence review focuses on respiratory pathogen panel testing in the outpatient setting and whether the evidence is adequate to draw conclusions about improved health outcomes for the Medicare population. In general, improved health outcomes of interest include patient mortality and morbidity, as well as patient quality of life and function. The current clinical evidence is based on guideline recommendations and clinical studies that demonstrate the clinical utility of this testing. Specific outcomes of these trials in the outpatient setting are focused on accurate detection and identification of the pathogens in an effort to help guide clinical decision making. In other words, does performance of this test in the outpatient setting affect patient care, and ultimately, lead to reduced morbidity and mortality from respiratory infections in the Medicare population. Accurate, rapid test results have the potential to alter clinical management, such as initial medication prescription and safe medication de-escalation, which will result in improved patient health outcomes.

Internal Technology Assessment

PubMed® was searched for prospective clinical trials that included the terms molecular and respiratory. The studies that were found using these terms were then screened for applicability to the adult outpatient population. Only two studies were found that met the inclusion criteria. A search utilizing the terms molecular and pneumonia found no new studies. The terms panel and respiratory had 121 results and respiratory and immunocompromised had 59 results. The studies were then screened for inclusion of adults and outpatient settings. Guidelines were searched for respiratory infections, especially those which included patients who are immunocompromised. Additional studies were found upon review of the bibliographies within other search criteria. For inclusion in review, studies must be published in the English language and be specific to the human population. All countries of origin were included if broad inclusion for the clinical studies met the criteria. Ultimately, prospective studies that included adults, had identifiable outpatients, and had clinical utility outcomes for respiratory pathogen panel tests that primarily change the clinician decision making as the surrogate for patient outcomes of morbidity and mortality were included.