



July 15, 2021

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Contractor Medical Directors  
National Government Services Medical Policy Unit  
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[PartBLCDComments@anthem.com](mailto:PartBLCDComments@anthem.com)

Re: Respiratory Pathogen Panel Testing (DL39027)

Dear Dr. Boren and Dr. Cunningham,

The Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP) write to provide joint comments on National Government Services (NGS) proposed Local Coverage Determination (LCD) for Respiratory Pathogen Panel Testing (DL39027). We appreciate the opportunity to review and provide joint comments as our organizations share the same perspective regarding this draft LCD.

The Association for Molecular Pathology (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 College of American Pathologists (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, pathologists and the public by fostering and advocating for excellence in the practice of pathology and laboratory medicine worldwide.

The AMP and CAP respectfully request that NGS postpone implementing its proposed LCD for Respiratory Pathogen Panel Testing. Palmetto GBA Molecular Diagnostic Services (MoIDX) recently concluded a public comment period for its new draft LCD for Multiplex Nucleic Acid Amplification Techniques (NAATs) for Infectious Disease Testing.<sup>1</sup> Palmetto's LCD proposes limited coverage for expanded ( $\geq 6$  pathogens) panel testing for several panel types including, respiratory and pneumonia; gastrointestinal; urogenital/anogenital; meningoencephalitis; bloodstream infection; and urinary tract infection. Palmetto acknowledges that published evidence demonstrates larger panel tests are accurate and reliable, and that their results can positively impact patient care in certain patient populations, settings and beneficiary type.

Larger panels are now fully integrated into the standard testing practices of many clinical laboratories and are routinely used for a number of infection types, including respiratory. These panels provide rapid results and are often more sensitive than traditional testing for the various organisms included.<sup>2,3,4</sup> **We therefore urge NGS to postpone implementing its proposed LCD for Respiratory Pathogen Panel Testing pending the completion of Palmetto's proposed LCD so that NGS may consider further evidence and information relevant to larger panels for use within the framework of its own coverage policy for infectious disease testing in the outpatient setting.**

Thank you again for the opportunity to review and comment on this proposed policy. We are happy to provide additional information regarding our comments. Please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy, 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

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<sup>1</sup> Proposed Local Coverage Determination (LCD): MolDX: Multiplex Nucleic Acid Amplification Test (NAAT) Panels for Infectious Disease Testing (DL38988). Proposed LCD Posting Date May 20, 2021. Centers for Medicare & Medicaid Services Coverage Database. CMS.gov. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=38987&ver=11&contractorName=2&contractorNumber=378%7C1&proposedStatus=all&sortBy=title&bc=AAAAAQAAAAAA>

<sup>2</sup> Dien Bard J, McElvania E. Panels and syndromic testing in clinical microbiology. Clin Lab Med. 2020;40(4):393-420.

<sup>3</sup> Ramanan P, Bryson AL, Binnicker MJ, Pritt BS, Patel R. Syndromic panel-based testing in clinical microbiology. Clin Microbiol Rev. 2017;31(1):e00024-17.

<sup>4</sup> Cybulski RJ, Jr., Bateman AC, Bourassa L, et al. Clinical impact of a multiplex gastrointestinal polymerase chain reaction panel in patients with acute gastroenteritis. Clinical Infect Dis. 2018;67(11):1688-1696.