



August 8, 2018

National Government  
Virginia Muir  
LCD Comments  
P.O. Box 7108  
Indianapolis, IN 46207-7108  
PartBLCDComments@anthem.com

Re: Draft Local Coverage Determination - Biomarker Testing for Prostate Cancer Diagnosis (DL37733)

Dear Ms. Muir:

Thank you for the opportunity to review and comment on National Government Services' proposed coverage policy for Biomarker Testing for Prostate Cancer Diagnosis (DL37733). The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 2,300 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 and commercial clinical laboratories, community hospitals, and the in vitro diagnostics industry.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

We appreciate NGS' willingness to provide limited coverage for biomarker testing as part of emerging efforts to both improve detection of prostate cancer and help guide treatment decisions. Given the limited evidence at this time for the clinical use of these assays, we agree with the coverage limitations that are outlined in NGS' proposed policy.

Thank you again for the opportunity to provide you with our comments. Please direct any questions you may have to Tara Burke, AMP Senior Policy Analyst, at [tburke@amp.org](mailto:tburke@amp.org) or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at [nwilson@amp.org](mailto:nwilson@amp.org).

Sincerely,

Association for Molecular Pathology  
College of American Pathologists