



December 2, 2016

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

Re: Draft Local Coverage Determination - Genomic Sequence Analysis Panels in the Treatment of Acute Myelogenous Leukemia (AML) (DL36926)

Dear Drs. Clark and Cunningham:

Thank you for this opportunity to respond to your draft local coverage determination regarding Genomic Sequence Analysis Panels in the Treatment of Acute Myelogenous Leukemia (AML) (DL36926). 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 would like to thank you for your proposal to provide expansive coverage, including genomic sequence analysis panels, for patients with AML. Please consider adding coverage for ICD-10 codes C92.Z0 (Other myeloid leukemia not having achieved remission) and C92.Z2 (Other myeloid leukemia, in relapse). These codes are used for normal karyotype AML which is a group of patients for which testing is also indicated. Please also consider adding coverage for C92.30 (Myeloid sarcoma, not having achieved remission) and C92.32 (Myeloid sarcoma, in relapse). Coverage for these codes is necessary since AML sometimes presents as an extramedullary solid tumor-like "myeloid sarcoma" in addition to or instead of its presence in the bone marrow.

We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Tara Burke, AMP Senior Policy Analyst, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@amp.org.

Sincerely,

Association for Molecular Pathology College of American Pathologists