



December 1, 2016

Earl Berman, MD
Attn: Medical Review
Two Vantage Way
Nashville, TN 37228
cmd.inquiry@cgsadmin.com

RE: MoIDX: APC and MUTYH Gene Testing (DL36910)

Dear Dr. Berman,

Thank you for the opportunity to comment on DL36910. 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.

The Association for Molecular Pathology (AMP) is an international medical and 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 medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

Members of both the CAP and AMP are experts in molecular pathology and the implementation of this coverage policy will directly affect access to testing for Medicare beneficiaries as well as the practice of pathology. We are submitting a joint comment letter because both our organizations have the same views regarding this draft LCD and, as such, we request that CGS consider the recommendations outlined in this letter.

We thank you for your decision to cover APC and MUTYH gene testing for individuals suspected of having Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP). The coverage parameters outlined in this draft policy are well supported by the evidence and published guidelines, as well as by recent peer reviewed literature. However, it is important to note that approximately 5% of individuals with AFAP or MAP may present with 10-19 polyps, and language should be incorporated in the LCD that covers testing when indicated in these cases.^{1,2}

dLCD Statement: This policy provides Medicare coverage for APC and MUTYH gene testing for individuals suspected to have Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP) who have a personal history of ≥ 20 adenomas over a lifetime.

Request: We request that CGS revise its policy to include the following language: "Coverage may be reasonable and necessary for individuals who have less than 20 polyps, when supported by family history or clinical presentation, as documented in the medical record."

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 Nonda Wilson, CAP's Manager,

Economic and Regulatory Affairs, at nwilson@amp.org or Tara Burke, AMP Policy Analyst, at tburke@amp.org

Sincerely,
College of American Pathologists
Association for Molecular Pathology

REFERENCES

1. Grover S, Kastrinos F, Steyerberg EW, Cook EF, Dewanwala A, Burbidge LA, Wenstrup RJ, Syngal S. Prevalence and phenotypes of APC and MUTYH mutations in patients with multiple colorectal adenomas. *JAMA*. 2012;308:485–92
2. Nielsen M, Morreau H, Vasen HF, Hes FJ. MUTYH-associated polyposis (MAP). *Crit Rev Oncol Hematol*. 2011;79:1–16