

Dr. Steve Phurrough, MD MPA
Centers for Medicare and Medicaid Services
OCSQ-CAG
7500 Security Blvd
MS-C10906
Baltimore, Maryland 21244

12 June 2007

Dear Dr. Phurrough:

Our thanks to you and the members of the Coverage and Analysis Group for meeting with us on May 15, 2007 to discuss the CAG's requests for information concerning the national coverage decision (NCD) application for colorectal cancer through stool-based human DNA analysis.

This package of documents responds to the questions you and your staff raised at our May 15th meeting. Specifically, this set of documents, also provided electronically on the enclosed compact disk, includes the following:

1. Answers to questions and discussion of questions raised by the CAG during our May 15th meeting. Please note, the reference numbers for the citations refer to the reference section of the NCD submission document (#3 below). Full texts of the references are also provided on the accompanying compact disk (CD).
2. Evidence provided by Laboratory Corporation of America ® Holdings of CLIA compliance including: (i) an overview of the LCA process, (ii) current CLIA and College of American Pathologists Accreditation certificates, and (iii) reference material describing the standards which must be met to acquire and maintain such accreditation. (Addendum D of this document)
3. An updated NCD application document with accompanying references dated 12 June 2007, formally requesting an NCD (previously submitted 16 August 2006). The letter making the formal request remains unchanged, a copy of which is included as page 13-14. William Larson of your office has the signed original copy. (Materials on the enclosed CD).
4. A copy of the materials that were provided to the American Cancer Society - Multi-Society Task Force (MSTF) to inform its colorectal cancer screening guidelines process. The MSTF published national colorectal cancer screening guidelines in 1997 and again in 2003. Their current process should result in a guidelines update in 2007. The USPSTF published an updated guideline in 2002

and there is no indication that USPSTF will be meeting soon to update their colorectal cancer screening guideline. (Reference #79 on the enclosed CD).

- a. Note: The MSTF primarily includes the American Gastroenterological Association, the American College of Gastroenterology, the American Society of GI Endoscopy, the American College of Radiology, and representatives of other primary care medical societies. The ACS, rather than issuing its own guidelines as it had in the past, joined the MSTF and participates in that process.

This letter, with its attachments, is a formal request to CMS for a national coverage decision on:

Colorectal cancer screening through the identification of specific colorectal cancer associated DNA mutations and alterations by the analysis of human DNA isolated from stool

In accordance with the NCD request process published in the Federal Register, September 26, 2003 (FR Vol. 68, number 187, pages 55634-55641), we request that CMS uses the collaborative NCD development track, track one (pg 55638, IV E).

We look forward to continuing to work with the CAG throughout its deliberations on this NCD request and answering any questions or providing additional documentation to support your efforts. We remain hopeful that CMS will respond favorably to our request for a NCD so as to provide Medicare beneficiaries with another colorectal cancer screening option to both facilitate and enhance utilization of what remains a woefully underutilized congressionally mandated benefit.

Sincerely yours,

Barry M. Berger, MD FCAP
Senior Vice-President for Medical Affairs
EXACT Sciences Corporation