

Medical Policy Manual **Approved: Do Not Implement Until 12/12/09**

In Vivo Analysis of Colorectal Polyps

DESCRIPTION

During a colonoscopy or sigmoidoscopy as a screening test for colorectal cancer, the physician must often decide which polyp should be removed for histologic diagnosis. While hyperplastic polyps are considered benign without malignant potential, adenomatous polyps are thought to represent one of the earliest stages in the progression to a malignancy. Identification of these premalignant lesions is considered one of the cornerstones of colorectal cancer prevention. Recently a spectrophotometry technique has been developed as an adjunct to colonoscopy that is intended to distinguish between normal and precancerous tissue. This system is based on the observation that benign and malignant tissue emits different patterns and wavelengths of fluorescence after exposure to a laser light. One such device was approved by the U.S. Food and Drug Administration (FDA) in 2000, the Optical Biopsy System (SpectraScience, Minneapolis MN). This system consists of an optical fiber emitting a laser that is directed against 3 different regions of the same polyp. The subsequent fluorescent signal is collected, measured, and analyzed by a proprietary system software, and classifies a polyp as "suspicious" (i.e., adenomatous) or "not suspicious" (i.e., hyperplastic).

Narrow band imaging (NBI) is another new technique that allows visualization of the mucosal surface and capillary vessels and thus may assist in the differentiation of abnormal from normal mucosa during colonoscopy. Two NBI systems are available. The NBI color chip system is used in the United States; in this system a single filter with a 2-band pass characteristic is used to generate central wavelengths at 415 nm (blue) and 540 nm (green and red). The NBI red-green-blue sequential illumination system uses narrow spectra of red, green, and blue light and a video endoscopic system with a frame sequential lighting method. The light source unit consists of a xenon lamp and a rotation disk with 3 optical filters. The rotation disk and monochrome charge-coupled device are synchronized and sequentially generate image in 3 optical filter bands. By use of all 3 band images, a single color endoscopic image is synthesized by the video processor. NBI has limited penetration into the mucosal surface and has enhanced visualization of capillary vessels and their fine structure on the surface layer of colonic tissue.

The FDA-labeled indication for the Optical Biopsy System reads as follows: "The SpectraScience Optical Biopsy System is indicated for use as an adjunct to lower gastrointestinal endoscopy. The device is intended for the evaluation of polyps less than 1 cm in diameter that the physician has not already elected to remove. The device is only to be used in deciding whether such polyps should be removed (which includes submission for histological examination)."

NBI received FDA clearance through the 510K process in 2005. This clearance (K051645) added NBI with the EVIS EXERA 160A System (Olympus Medical Systems Corp) to existing endoscopic equipment. FDA indications are for endoscopic diagnosis, treatment, and video observation.

POLICY

- In vivo analysis of colorectal polyps for the identification of pre-cancerous tissue is considered **investigational**.

ADDITIONAL INFORMATION

In the absence of any well-designed randomized controlled trials, no conclusions can be drawn about whether in vivo analysis of colorectal polyps has an effect on health outcomes.

SOURCES

BlueCross BlueShield Association. Medical Policy Reference Manual. (4:2008). *In vivo analysis of colorectal polyps*. (2.01.51). Retrieved April 1, 2009 from BlueWeb.



BlueCross BlueShield
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Policy

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National Guideline Clearinghouse. (2006, May). *Guidelines for colonoscopy surveillance after polypectomy: A consensus update by the US Multi-Society Task force on Colorectal Cancer and the American Cancer Society*. Retrieved April 1, 2009 from

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