Payment Policy | Chromoendoscopy as an Adjunct to Colonoscopy

EFFECTIVE DATE: 02|19|2013
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OVERVIEW

Chromoendoscopy (also known as chromoscopy and chromocolonoscopy) refers to the application of dyes or stains during endoscopy to enhance tissue differentiation or characterization. When used with colonoscopy, the intent is to increase the sensitivity of the procedure by facilitating the identification of mucosal abnormalities.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Chromoendoscopy and virtual chromoendoscopy as an adjunct to diagnostic or surveillance colonoscopy is considered incidental to the colonoscopy and therefore is not separately reimbursed.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefit/coverage.

BACKGROUND

Chromoendoscopy refers to the application of dyes or stains during endoscopy to enhance tissue differentiation or characterization. When used with colonoscopy, the intent is to increase the sensitivity of the procedure by facilitating the identification of mucosal abnormalities. There are two types of chromoendoscopy; one involves actual spraying of dyes or stains through the working channel of an endoscope. The other type, known as virtual chromoendoscopy, uses a computer algorithm to simulate different colors of light that result from dye or stain spraying.

Colonoscopy, a procedure during which colonic and rectal polyps can be identified and removed, is considered the criterion standard test for colorectal cancer (CRC) screening and diagnosis of colorectal disease. However, colonoscopy is an imperfect test. A 2006 systematic review pooled findings from tandem (i.e., back-to-back) colonoscopy studies and found that 22% of polyps were missed on the first colonoscopy. However, most of the missed polyps, were small and, thus, lower risk of becoming cancerous. The pooled miss rate by polyp size was 2% for polyps 10 mm and larger, 13% for polyps 5-10 mm, and 26% for polyps 1-5 mm.

Several adjunct endoscopic techniques, including chromoendoscopy, could potentially enhance the sensitivity of colonoscopy. Chromoendoscopy, also known as chromoscopy and chromocolonoscopy, refers to the application of topical stains or dyes during endoscopy to enhance tissue differentiation or characterization and facilitate identification of mucosal abnormalities. Chromoendoscopy may be particularly useful for detecting flat or depressed lesions. Standard colonoscopy uses white light to view the colon. In chromoendoscopy, stains are applied resulting in color highlighting of areas of surface morphology of epithelial tissue. The dyes or stains are applied via a spray catheter that is inserted down the working channel

of the endoscope. Chromoendoscopy can be used in the whole colon (pan-colonic chromoendoscopy) on an untargeted basis or can be directed to a specific lesion or lesions (targeted chromoendoscopy). Chromoendoscopy differs from endoscopic tattooing in that the former uses transient stains, whereas tattooing involves the use of a long-lasting pigment for future localization of lesions.

Stains and dyes used in chromoendoscopy can be placed in the following categories:

- Absorptive stains are preferentially absorbed by certain types of epithelial cells.
- Contrast stains seep through mucosal crevices and highlight surface topography.
- Reactive stains undergo chemical reactions when in contact with specific cellular constituents, which results in a color change.

Indigo carmine, a contrast stain, is the most commonly used stain with colonoscopy to enhance the detection of colorectal neoplasms. Several absorptive stains are also used with colonoscopy. Methylene blue, which stains the normal absorptive epithelium of the small intestine and colon, has been used to detect colonic neoplasia and to aid in the detection of intraepithelial neoplasia in patients with chronic ulcerative colitis. In addition, crystal violet (also known as gentian violet) stains cell nuclei and has been applied in the colon to enhance visualization of pit patterns (ie, superficial mucosal detail). Reactive stains are primarily used to identify gastric abnormalities and are not used with colonoscopy

Potential applications of chromoendoscopy as an alternative to standard colonoscopy include:

- Diagnosis of colorectal neoplasia in symptomatic patients at increased risk of colorectal cancer due to family history of colorectal cancer, personal history of adenomas, etc.
- Identification of mucosal abnormalities for targeted biopsy as an alternative to multiple random biopsies in patients with inflammatory bowel disease (IBD)
- Screening the general population for colorectal cancer

The equipment used in regular chromoendoscopy is widely available. Several review articles and technology assessments have stated that, although the techniques are simple, the procedure (e.g., concentration of dye and amount of dye sprayed) is variable and thus classification of mucosal staining patterns for identifying specific conditions is not standardized.

Virtual chromoendoscopy (also called electronic chromoendoscopy) involves imaging enhancements with endoscopy systems that could be an alternative to dye spraying. One system is the Fujinon® Intelligent Color Enhancement (FICE®) feature (Fujinon Inc.). This technology uses postprocessing computer algorithms to modify the light reflected from the mucosa from conventional white light to various other wavelengths.

Regulatory Status

In August 2014, the Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA documents state that FICE can be used to supplement white-light endoscopy but is not intended to replace histopathologic sampling as a means of diagnosis.

In April 2013, the i-SCAN™ (Pentax [Tokyo, Japan]), used for virtual chromoendoscopy, was cleared for marketing by FDA through the 510(k) process. This digital image enhancement technology is part of the Pentax EPK-i5010 Video Processor. The i-SCAN™ has several modes that digitally enhance images in real time during endoscopy. The FDA documents stated that i-SCAN™ is intended as an adjunct following white-light endoscopy but not intended to replace histopathologic analysis.

No dye or stain product has been specifically approved by FDA for use in chromoendoscopy.

For individuals who have an average risk of colorectal cancer undergoing colonoscopy who receive chromoendoscopy, the evidence includes 1 randomized controlled trial (RCT) focused on this population. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. The single RCT did not find that high-definition chromoendoscopy identified more clinically meaningful lesions than high-definition white-light colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have an increased risk of colorectal cancer undergoing colonoscopy who receive chromoendoscopy, the evidence includes multiple RCTs, back-to-back colonoscopy studies, and systematic reviews. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. A Cochrane systematic review of trials comparing chromoendoscopy with standard colonoscopy in high-risk patients (but excluding those with inflammatory bowel disease) found significantly higher rates of adenoma detection and rates of 3 or more adenomas with chromoendoscopy than with standard colonoscopy. The evidence for detecting larger polyps, defined as greater than 5 mm or greater than 10 mm, is less robust. While 1 study reported a significantly higher detection rates for polyps greater than 5 mm, no studies reported increased detection of polyps greater than 10 mm. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have inflammatory bowel disease undergoing colonoscopy who receive chromoendoscopy, the evidence includes observational studies and meta-analyses of observational data. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. The meta-analysis found a statistically significant higher yield of chromoendoscopy over white-light colonoscopy for detecting dysplasia. This evidence established that chromoendoscopy improves polyp detection rates, but it is unclear whether the additional polyps detected are clinically important and, therefore, whether improved polyp detection rates will translate into improved health outcomes. In addition, there are concerns about comparison groups used in some of these trials. It is uncertain whether the control groups received optimal colonoscopy; therefore, the improved detection rates by chromoendoscopy may be a function of suboptimal standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have an average risk of colorectal cancer undergoing colonoscopy who receive virtual chromoendoscopy, the evidence includes several RCTs and a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. The available RCTs have not found that virtual chromoendoscopy improves the detection of clinically important polyps compared with standard white-light colonoscopy. Moreover, there is a lack studies on the impact of virtual chromoendoscopy on colorectal cancer (CRC) incidence or mortality compared with standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have an increased risk of colorectal cancer undergoing colonoscopy who receive virtual chromoendoscopy, the evidence includes several RCTs and a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. The available RCTs have not found that virtual chromoendoscopy improves the detection of clinically important polyps compared with standard white-light colonoscopy. Moreover, we lack studies on the impact of virtual chromoendoscopy on CRC incidence or mortality compared with standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have inflammatory bowel disease undergoing colonoscopy who receive virtual chromoendoscopy, the evidence includes an RCT and nonrandomized comparative study. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and change in disease status. The RCT found a significantly greater likelihood that virtual chromoendoscopy would correctly identify the extent of disease inflammation than standard colonoscopy but no significant difference in the likelihood of identifying disease activity. A retrospective cohort study found that targeted biopsy resulted in a higher rate of neoplasia

detection regardless of endoscopy method used. We lack studies on the impact of virtual chromoendoscopy CRC incidence or mortality compared with standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

BlueCHiP for Medicare and Commercial Products

There is no specific CPT coding for chromoendoscopy.

If the chromoendoscopy is reported, use the unlisted CPT code 44799, unlisted procedure, intestine.

RELATED POLICIES

None

PUBLISHED

Provider Update, March 2018
Provider Update, March 2017
Provider Update, March 2016
Provider Update, June 2015
Provider Update, Aug 2014
Provider Update, May 2013

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