

# Medical Coverage Policy



## Chromoendoscopy as an Adjunct to Colonoscopy

Device/Equipment  Drug  Medical  Surgery  Test  Other

Effective Date:	12/5/2012	Policy Last Updated:	4/2/2013
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**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description

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 "gold standard" test for colorectal cancer screening and diagnosis of colorectal disease. However, colonoscopy is an imperfect test. A recent 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. (1) Most of the missed polyps, though, 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 in order to enhance and facilitate the 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: These stains are preferentially absorbed by certain types of epithelial cells.
- Contrast: These stains seep through mucosal crevices and highlight surface topography.
- Reactive: These stains undergo chemical reactions when in contact with specific cellular constituents, which results in a color change.

Reactive stains are primarily used to identify gastric abnormalities and are not used with colonoscopy.

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 individuals 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 (i.e. superficial mucosal detail).

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 authors of review articles and technology assessments have stated that, although the techniques are simple, procedure, e.g. concentration of dye and amount of dye sprayed, is variable and classification of mucosal staining patterns for identifying specific conditions is not standardized.

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

Chromoendoscopy is a technique that is intended to increase the sensitivity of colonoscopy by improving the polyp detection rate. Multiple randomized controlled trials and back-to-back colonoscopy studies have evaluated chromoendoscopy in patients at increased risk of colorectal cancer. A Cochrane review of trials comparing chromoendoscopy to standard colonoscopy in high-risk patients (but excluding those with inflammatory bowel disease) found a significantly higher rate of adenoma detection and rate of 3 or more adenomas with chromoendoscopy compared to standard colonoscopy. The evidence for detecting larger polyps, either defined as greater than 5 mm or greater than 10 mm, is less robust. While one study reported a significantly higher detection rate for polyps greater than 5 mm, no studies reported increased detection for polyps greater than 10 mm. Among patients with inflammatory bowel disease, a meta-analysis of clinical trials focusing on patients with inflammatory bowel disease found a statistically significantly higher yield of chromoendoscopy over white light colonoscopy for detecting dysplasia. This evidence establishes that chromoendoscopy improves the polyp detection rate, but it is unclear whether the additional polyps detected are clinically important, and therefore whether the improved polyp detection rate will translate to improved health outcomes. In addition, there are concerns about the comparison group in some of these trials. It is uncertain whether the control groups received optimal colonoscopy, therefore the improved detection rate by chromoendoscopy may be a function of suboptimal standard colonoscopy.

There is insufficient evidence on chromoendoscopy in an average-risk screening population. One large randomized controlled trial on chromoendoscopy with screening colonoscopies did not find that high-definition chromoendoscopy identified more clinically meaningful lesions than high-definition white light colonoscopy. In addition, about half of the participants in a recent trial from Germany were average-risk individuals seeking screening colonoscopy, but results of the trial were not stratified by indication for colonoscopy. As a result of these limitations in the evidence for both high-risk and average-risk individuals, as well as a lack of consistent support from clinical reviewers, chromoendoscopy is considered incidental to the colonoscopy as an adjunct colonoscopy for both of these populations.

There is also insufficient evidence that virtual chromoendoscopy improves the detection of clinically significant adenomas or improves health outcomes compared to standard colonoscopy or standard chromoendoscopy. In addition, virtual chromoendoscopy devices have been recalled by the FDA because they did not undergo the proper approval process. Thus, virtual chromoendoscopy is considered incidental to the colonoscopy.

**Medical Criteria:**

none

**Policy**

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

**Coverage:**

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

**Coding:**

There is no specific CPT coding for chromoendoscopy. If the chromoendoscopy is reported, it should be reported with the unlisted CPT code 44799.

**Also Known As:**

N/A

**Related Topics:**

None

**Published:**

Provider Update, May 2013

**References:****Medicare National Coverage:**

There is no national coverage determination.

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**History:**

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