



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

### Medical Policy

## Chromoendoscopy as an Adjunct to Colonoscopy

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### Policy Number: 904

BCBSA Reference Number: 2.01.84

NCD/LCD: N/A

### Related Policies

Computed Tomography (CT) CT Colonography (Virtual Colonoscopy), #[179](#)

Confocal Laser Endomicroscopy, #[618](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Chromoendoscopy is considered [INVESTIGATIONAL](#) as an adjunct to diagnostic or surveillance colonoscopy.

Virtual chromoendoscopy is considered [INVESTIGATIONAL](#) as an adjunct to diagnostic or surveillance colonoscopy.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

### CPT Codes

There is no specific CPT code for this service.

### ICD Diagnosis Codes

Investigational for all diagnoses.

## DESCRIPTION

### COLONOSCOPY

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 procedure. A systematic review by van Rijn et al (2006) pooled findings from tandem (ie, back-to-back) colonoscopy studies and found that 22% of polyps were missed on the first colonoscopy.<sup>1</sup> Most polyps missed were small and thus had a lower risk of becoming cancerous. The pooled miss rate by polyp size was 2% for polyps 10 mm and larger, 13% for polyps 5 to 10 mm, and 26% for polyps 1 to 5 mm.

### Adjunctive Procedures

Several adjunct endoscopic techniques, including chromoendoscopy, could 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 (pancolonic 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 adjunct to standard colonoscopy include:

- Diagnosis of colorectal neoplasia in symptomatic patients at increased risk of CRC due to family history of CRC, 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.
- Screening the general population for CRC.

The equipment used in regular chromoendoscopy is widely available. Several review articles and technology assessments have indicated that, although the techniques are simple, the procedure (eg, the 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 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.

## Summary

Chromoendoscopy refers to the use 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 2 types of chromoendoscopy: one involves actual spraying of dyes or stains through the working channel of an endoscope; the other, known as virtual chromoendoscopy, uses a computer algorithm to simulate different colors of light that result from dye or stain spraying.

## Chromoendoscopy

For individuals who have an average risk of colorectal cancer (CRC) who receive chromoendoscopy, the evidence includes a randomized controlled trial (RCT) evaluating this population. Relevant outcomes are overall survival, disease-specific survival, test 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 CRC 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 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 rate 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 who receive chromoendoscopy, the evidence includes observational studies and meta-analyses of observational data. Relevant outcomes are overall survival, disease-specific survival, test validity, and change in disease status. One 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; however, it is unclear whether the additional polyps detected are clinically important and, therefore, whether improved polyp detection rates will translate into improved health outcomes. Moreover, 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 might have

been a function of suboptimal standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Virtual Chromoendoscopy**

For individuals who have an average risk of CRC who receive virtual chromoendoscopy, the evidence includes several RCTs and a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test 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 of studies assessing the impact of virtual chromoendoscopy on CRC incidence and mortality rates 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 CRC who receive virtual chromoendoscopy, the evidence includes several RCTs and a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test 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 of studies assessing the impact of virtual chromoendoscopy on CRC incidence and mortality rates 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 who receive virtual chromoendoscopy, the evidence includes an RCT and nonrandomized comparative study. Relevant outcomes are overall survival, disease-specific survival, test 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 the endoscopy method used. There is a lack of studies assessing the impact of virtual chromoendoscopy CRC incidence and mortality rates compared with standard colonoscopy. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Policy History**

<b>Date</b>	<b>Action</b>
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2018	New references added from BCBSA National medical policy.
7/2017	New references added from BCBSA National medical policy.
12/2016	New references added from BCBSA National medical policy.
1/2016	New references added from BCBSA National medical policy.
5/2015	New references added from BCBSA National medical policy.
5/2014	New references from BCBSA National medical policy.
5/2013	New references from BCBSA National medical policy.
2/2013	New policy describing non-coverage

### **Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

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