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Medical Policies

Print

Policy Number:	M-5084		
Policy Name:	Chromoendoscopy as an Adjunct to Colonoscopy		
Policy Type:	Medical	**Policy Subtype:**	Diagnostic Medical
Effective Date:	09-15-2025	**End Date:**	11-02-2025

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 (CC) screening and diagnosis of colorectal disease. However, colonoscopy is an imperfect procedure.

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. A 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 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). 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 individuals at increased risk of CC due to a family history of CC, a personal history of adenomas, etc.
- Identification of mucosal abnormalities for targeted biopsy as an alternative to multiple random biopsies in individuals with inflammatory bowel disease.
- Screening the general population for CC.

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.

Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of service.

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

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.

Procedure Codes

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Summary of Evidence

Chromoendoscopy

For individuals who have an average risk of colorectal cancer (CC) who receive chromoendoscopy, the evidence includes RCTs and a meta-analysis of these RCTs. Relevant outcomes are overall survival (OS), disease-specific survival (DSS), test validity, and change in disease status. The meta-analysis demonstrated that dye-based chromoendoscopy increased the adenoma detection rate and adenomas per colonoscopy in individuals at average or increased risk of CC compared to standard or high-definition white light colonoscopy. However, limitations included unclear indication of colonoscopy in the studies (which included individuals with screening and surveillance), and some heterogeneity in mean adenomas per individual. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an increased risk of CC who receive chromoendoscopy, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are OS, DSS, test validity, and change in disease status. A Cochrane systematic review of trials comparing chromoendoscopy with standard colonoscopy in high-risk individuals (but excluding those with inflammatory bowel disease [IBD]) found significantly higher rates of adenoma detection and rates of three (3) or more adenomas with chromoendoscopy than with standard colonoscopy. The evidence for detecting larger polyps, defined as greater than five (5) mm or greater than 10 mm, is less robust. While one (1) study reported a significantly higher detection rate for polyps greater than five (5) mm, no studies reported increased detection of polyps greater than 10 mm. A recent RCT and systematic review involving individuals with Lynch syndrome also found equivocal results. Results from the RCT showed similar neoplasia detection rates with chromoendoscopy and conventional white-light colonoscopy, while the systematic review concluded that chromoendoscopy is associated with significantly improved detection of certain lesions; however, the odds of having an adenoma detected were not significantly different between the modalities. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have IBD who receive chromoendoscopy, the evidence includes meta-analyses and a recent RCT. Relevant outcomes are OS, DSS, test validity, and change in disease status. Several meta-analyses found a statistically significant higher yield of chromoendoscopy over standard white-light colonoscopy for detecting dysplasia. The evidence supported improved polyp detection rates with chromoendoscopy; however, the studies had limitations such as lack of information regarding the timing of the screening modalities. A recent RCT found increased detection of dysplasia with chromoendoscopy compared to white-light endoscopy, although the benefit was only observed in a a subgroup analysis in the second half of the study follow-up period. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Virtual Chromoendoscopy

For individuals who have an average risk of CC who receive virtual chromoendoscopy, the evidence includes several RCTs and systematic reviews. Relevant outcomes are OS, DSS, 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 CC incidence and mortality rates compared with standard colonoscopy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an increased risk of CC who receive virtual chromoendoscopy, the evidence includes RCTs. Relevant outcomes are OS, DSS, 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 CC incidence and mortality rates compared with standard colonoscopy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have IBD who receive virtual chromoendoscopy, the evidence includes two (2) meta-analyses and two (2) RCTs. Relevant outcomes are OS, DSS, test validity, and change in disease status. One (1) meta-analysis showed superiority of virtual chromoendoscopy over high-definition white light colonoscopy for dysplasia per biopsy, and ranked virtual chromoendoscopy as the best option for screening among the different modalities in comparison. The second meta-analysis found no difference between dye-based chromoendoscopy and virtual chromoendoscopy for dysplasia detection. One (1) 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. The other RCT found that there was no significant difference in the detection of neoplasia between high definition white light versus high-definition virtual chromoendoscopy in individuals with long-standing IBD. There is a lack of studies assessing the impact of virtual chromoendoscopy on CC incidence and mortality rates compared with standard colonoscopy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Professional Statements and Societal Positions Guidelines

Practice Guidelines and Position Statements

American Society for Gastrointestinal Endoscopy and American Gastroenterological Association

In 2015, the American Society for Gastrointestinal Endoscopy (ASGE) and the American Gastroenterological Association published the SCENIC consensus statement on surveillance and management of dysplasia in individuals with inflammatory bowel disease (IBD). The statement, developed by an international multidisciplinary group representing a variety of stakeholders, incorporated systematic reviews of the literature. Table 1 summarizes relevant recommendations.

Table 1. Recommendations on Surveillance and Management of Dysplasia in Individuals With Inflammatory Bowel Disease

Populations	Interventions	Comparators	Outcomes
Individuals: • With average risk of colorectal cancer	Interventions of interest are: • Chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status
Individuals: • With increased risk of colorectal cancer	Interventions of interest are: • Chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status
Individuals: • With inflammatory bowel disease	Interventions of interest are: • Chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status

Populations	Interventions	Comparators	Outcomes
Individuals: • With average risk of colorectal cancer	Interventions of interest are: • Virtual chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status
Individuals: • With increased risk of colorectal cancer	Interventions of interest are: • Virtual chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status
Individuals: • With inflammatory bowel disease	Interventions of interest are: • Virtual chromoendoscopy	Comparators of interest are: • Standard white-light colonoscopy	Relevant outcomes include: • Overall survival • Disease-specific survival • Test validity • Change in disease status

Populations	Interventions	Comparators	Outcomes
Recommendation	LOA	SOR	QOE
'When performing surveillance with white-light colonoscopy, high definition is recommended rather than standard definition.'	80%	Strong	Low
'When performing surveillance with standard-definition colonoscopy, chromoendoscopy is recommended rather than white-light colonoscopy.'	85%	Strong	Moderate
'When performing surveillance with high-definition colonoscopy, chromoendoscopy is suggested rather than white-light colonoscopy.'	84%	Conditional	Low

LOA: level of agreement; QOE: quality of evidence; SOR: strength of recommendation.

Panelists did not reach consensus on the use of chromoendoscopy in random biopsies of individuals with IBD undergoing surveillance.

Commentaries in two (2) gastroenterology journals questioned whether the SCENIC guidelines would be accepted as the standard of care in IBD surveillance. Both commentaries noted that the guidelines considered the outcome of the detection of dysplasia and not disease progression or survival. Moreover, the commentators noted the lack of longitudinal data on clinical outcomes in individuals with dysplastic lesions detected using chromoendoscopy.

The ASGE (2015) issued guidelines on endoscopy in the diagnosis and treatment of IBD, which made the following recommendations about chromoendoscopy: 'Chromoendoscopy with pancolonic dye spraying and targeted biopsies is sufficient for surveillance in inflammatory bowel disease; consider 2 biopsies from each colon segment for histologic staging.'

The ASGE (2015) also published a systematic review and meta-analysis assessing narrow-band imaging, i-SCAN, and Fujinon Intelligent Color Enhancement for predicting adenomatous polyp histology of small or diminutive colorectal polyps to determine whether they have met previously established criteria or thresholds to incorporate into clinical practice. The ASGE assessment confirmed that:

'The thresholds have been met for narrow-band imaging with endoscopists who are experts in using these advanced imaging technologies and when assessments are made with high confidence. The ASGE Technology Committee endorsed the use of NBI for both the 'diagnose-and-leave' strategy for diminutive (5 mm) rectosigmoid hyperplastic polyps and the 'resect-and-discard' strategy for diminutive (5 mm) adenomatous polyps.'

The report addressed the 'trepidation' of individuals, endoscopists, and pathologists with the 'diagnose-and-leave' strategy, indicating there are challenges for implementation for the use of these strategies in clinical

practice.

U.S. Multi-Society Task Force on Colorectal Cancer

In 2020, the Multi-Society Task Force issued guidelines on the endoscopic removal of colorectal lesions. Regarding lesion assessment and description, the Task Force suggested 'proficiency in the use of electronic- (e.g., NBI, i-SCAN, and Fuji Intelligent Chromoendoscopy, or blue light imaging) or dye (chromoendoscopy)-based image-enhanced endoscopy techniques to apply optical diagnosis classifications for colorectal lesion histology [conditional recommendation, moderate-quality evidence).' The Task Force also suggested 'careful examination of the post-mucosectomy scar site using enhanced imaging, such as dye-based (chromoendoscopy) or electronic-based methods, as well as obtaining targeted biopsies of the site. Post-resection scar sites that show both normal macroscopic and microscopic (biopsy) findings have the highest predictive value for long-term eradication [conditional recommendation, moderate-quality evidence].'

In 2012, the Multi-Society Task Force guidelines on colonoscopy surveillance after screening and polypectomy (consensus update) stated that chromoendoscopy and narrow-band imaging might enable endoscopists to accurately determine if lesions are neoplastic and if there is a need to remove them and send specimens to pathology. The guidelines noted that these technologies currently do not have an impact on surveillance intervals.

Diagnosis Codes

Not Applicable

CURRENT CODING

CPT:

44799	UNLISTED PROCEDURE SMALL INTESTINE	Commercial
44799	UNLISTED PROCEDURE SMALL INTESTINE	Medicaid Expansion

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ND Committee Review

Internal Medical Policy Committee 3-17-2021 New Policy for North Dakota *Effective May 3, 2021*

Internal Medical Policy Committee 3-23-2022 Annual Review, no changes in criteria *Effective May 2, 2022*

Internal Medical Policy Committee 3-23-2023 Revision- *Effective May 01, 2023*

- *Added* Summary of Evidence
- *Updated* References

Internal Medical Policy Committee 5-14-2024 Annual Review, no changes in criteria *Effective July 1, 2024*

- *Added* Policy Application

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.