Medical Coverage Policy

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Chromoendoscopy

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses the use of chromoendoscopy for surveillance of Barrett's esophagus and for surveillance of colorectal cancer based on personal history of inflammatory bowel disease.

Coverage Policy

Chromoendoscopy with or without optical technologies such as narrow band imaging is considered medically necessary for surveillance for individuals:

- with Barrett's esophagus
- at increased risk for colorectal cancer based on personal history of inflammatory bowel disease (IBD)

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

The National Comprehensive Cancer Network® (NCCN®) defines chromoendoscopy as an "image-enhanced endoscopic procedure using dye or optical technologies (Buchner, 2017)". Buchner (2017) notes that chromoendoscopy is an image-enhanced endoscopic technique achieved either through dye-based chromoendoscopy or electronic chromoendoscopy, which includes optical technologies such as narrow-band imaging (NBI, Olympus), flexible spectral imaging color enhancement (FICE, Fujinon), and i-scan (Pentax). Chromoendoscopy provides detailed contrast enhancement of the surface of gastrointestinal mucosa.

Chromoendoscopy has been studied in a variety of clinical settings and throughout the gastrointestinal tract. Chromoendoscopy generally refers to the application of stains or pigments by spraying through a catheter to improve tissue localization, characterization, or diagnosis during endoscopy. Common staining agents used are Lugol solution, methylene blue, toluidine blue, crystal violet, indigo carmine, congo red, and phenol red.

The term electronic chromoendoscopy refers to endoscopic imaging technologies that provide detailed contrast enhancement of the mucosal surface and blood vessels. These technologies offer an alternative to dye-based chromoendoscopy. Electronic chromoendoscopy technologies (i.e.,

optical technologies) include narrow-band imaging (NBI) (Olympus Medical Systems Tokyo, Japan), flexible spectral imaging color enhancement (FICE) (Fujinon, Fujifilm Medical Co, Saitama, Japan), and i-SCAN (PENTAX Endoscopy, Tokyo, Japan). Enhancement of mucosal features with electronic chromoendoscopy is achieved by the observation of light transmission at selected wavelengths because the interaction of tissue structures with light is wavelength dependent. Selective light transmittance is accomplished by optical filtering of white light in NBI, whereas FICE and i-SCAN both accomplish this through software-driven post-image processing (American Society for Gastrointestinal Endoscopy).

- Narrow band imaging (NBI) (Olympus® NBI™ Technology utilizes red-green-and-blue filters to modify white-light endoscopy. The selected wavelengths are absorbed by hemoglobin in the blood vessels. The absorption of light by hemoglobin creates a higher contrast between blood vessels and the surrounding tissue than white light. NBI is the most widely studied electronic chromoendoscopy technique.

- Flexible spectral imaging color enhancement (Fujinon® Intelligent Color Enhancement [FICE®] (FICE, Fujinon Inc.), captures the entire white-light spectrum without optical filters. It uses computer algorithms to modify the captured images, enhancing certain combinations of wavelengths. FICE displays the image as if the mucosa were illuminated by the selected wavelength.

- i-scan (Pentax Medical) image processing includes three algorithms or modes of image enhancement: surface enhancement, contrast enhancement, and tone enhancement. Switching the levels or modes of enhancements can be done on a real-time basis during endoscopic observation.

Surveillance of Barrett's Esophagus

The use of chromoendoscopy in the surveillance of Barrett's esophagus is supported by professional societies:

Source	Recommendation
American Gastroenterological Association (AGA) 2024	AGA Clinical Practice Guideline on Endoscopic Eradication Therapy of Barrett's Esophagus and Related Neoplasia (Rubenstein, 2024) In the background, under Implementation Considerations, the AGA notes: When performing surveillance post endoscopic eradication therapy (EET), the esophagus and cardia should be examined under white light and virtual chromoendoscopy with near focus, particularly using a clear cap.
American Gastroenterological Association (AGA) 2022	AGA Clinical Practice Update on New Technology and Innovation for Surveillance and Screening in Barrett's Esophagus: Expert Review (Muthusamy, 2022) Endoscopic Examination of Barrett's Esophagus Best Practice Advice 3: Screening and surveillance endoscopic examination should be performed using high-definition white light endoscopy (HD-WLE) and virtual chromoendoscopy (VC), with endoscopists spending adequate time inspecting the Barrett's segment.

Source	Recommendation
	The goal of endoscopic screening and surveillance in BE is early detection of BE-related dysplasia and early esophageal adenocarcinoma (EAC). Consistent with recent guidelines (ASGE/Qumseya 2019) (ACG/Shaheen, 2022), the panel agrees with the routine use of HD-WE and VC during screening and surveillance endoscopy in patients with BE.
American College of Gastroenterology (ACG) 2022	Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline (Shaheen, 2022). Surveillance: 8. We recommend both white light endoscopy and chromoendoscopy in patients undergoing endoscopic surveillance of BE Quality of evidence: Moderate Strength of Recommendation: Strong
American Society for Gastrointestinal Endoscopy 2019	ASGE 2019 Guideline on screening and surveillance of Barrett's Esophagus (Qumseya, 2019) Question 3: In patients with BE who are undergoing surveillance for dysplasia, what is the role of chromoendoscopy in increasing the rate of dysplasia detection? Recommendation: In patients with BE undergoing surveillance, we recommend using chromoendoscopy or virtual chromoendoscopy, in addition to white-light endoscopy (WLE) and biopsy specimens obtained using the Seattle protocol compared with WLE and biopsy specimens obtained using the Seattle protocol alone. Strength of Recommendation: Strong Quality of evidence: Moderate

The use of chromoendoscopy in the surveillance of Barrett's esophagus is supported in the peer-reviewed literature (Jukema et al., 2024; Chis, et al., 2021; Everson 2019; Qumseya, et al., 2013). Based on a meta-analysis, Qumseya et al. (2013) concluded that advanced imaging techniques such as chromoendoscopy or virtual chromoendoscopy significantly increase diagnostic yield for identification of dysplasia or cancer in patients with Barrett's esophagus.

Surveillance of Inflammatory Bowel Disease

The use of chromoendoscopy in the surveillance of inflammatory bowel disease is supported by professional societies:

Source	Recommendation

Source	Recommendation
National Comprehensive Cancer Network® (NCCN®) 2024	NCCN® Colorectal Cancer Screening Clinical Practice Guidelines™ (Version 1.2024 — February 27, 2024) Personal History of Inflammatory Bowel Disease It is well-recognized that individuals with a personal history of IBD (ie, ulcerative colitis, Crohn's colitis) are at an increased risk for CRC, because chronic inflammation can lead to dysplasia and subsequent malignant conversion. Evidence shows that endoscopic surveillance can detect CRC at earlier stages in patients with extensive colitis, and that it may reduce the risk of death from CRC in these patients (MS-21). Colonoscopic surveillance in patients with IBD should be performed during quiescent disease. Colonoscopic surveillance may be performed by chromoendoscopy (dye spray or high-definition virtual) with targeted biopsy. If using standard-definition white light endoscopy (SD-WLE), performing the colonoscopy in conjunction with chromoendoscopy is recommended. If HD-WLE or chromoendoscopy is not available, the panel recommends referral to institutions with expertise in these modalities (MS-22). Evaluation of Surveillance Findings in IBD Biopsies can be better targeted to abnormal-appearing mucosa using chromoendoscopy or confocal endomicroscopy, and several studies indicate increased sensitivity of chromoendoscopy in detecting dysplastic lesions; however, the natural history of these lesions is unclear (MS-22). The presence of invisible dysplasia may be confirmed with chromoendoscopy, if this procedure has not already been performed (MS-23).
National Comprehensive Cancer Network® (NCCN®) 2024	NCCN® Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric. (Version 3.2024 — October 31, 2024) High-quality colonoscopy is advised for colon Cancer Surveillance. If Lynch syndrome is confirmed, chromoendoscopy may also be used during colonoscopy in which dye spray is used to enhance visualization. Chromoendoscopy may be considered in patients with Lynch syndrome, but larger prospective randomized trials are needed to better understand its role in Lynch syndrome (MS-10,11).
American Gastroenterological Association (AGA) 2024	AGA 2024 Clinical Practice Update on Appropriate and Tailored Polypectomy: Expert Review (Copland, 2024) Best Practice Advice: A structured visual assessment using high-definition white light and/or electronic chromoendoscopy and with photodocumentation should be conducted for all polyps found during routine colonoscopy. Closely inspect colorectal polyps for features of submucosally invasive cancer (SMIC).

Source	Recommendation
U.S. Preventive Services Task Force (USPSTF) 2021	Screening for Colorectal Cancer: Updated Evidence Report and Systematic Review for the USPSTF (JAMA/Lin, et al., 2021) There is a growing body of evidence, NOT included in this review, that evaluates whether technological advancements in colonoscopy to improve adenoma detection, namely chromoendoscopy or digital/virtual chromoendoscopy (e.g., narrow band imaging, flexible spectral imaging color enhancement), endoscopic technologies to increase mucosal surface area inspection (e.g., wide-angle lens or full-spectrum endoscopy, through-the-scope retrograde viewing device), and computer aided detection using artificial intelligence can improve detection, but data are limited to support widespread adoption in screening or average-risk populations.
American Gastroenterological Association (AGA) 2021	Clinical Practice Update on Endoscopic Surveillance and Management of Colorectal Dysplasia in Inflammatory Bowel Diseases: Expert Review (Murthy, 2021). The Best Practice Advice regarding endoscopic surveillance and management of colorectal dysplasia in inflammatory bowel diseases, specific to chromoendoscopy, includes: Dye spray chromoendoscopy, performed by appropriately trained endoscopists, should be considered in all persons with colonic inflammatory bowel disease undergoing surveillance colonoscopy, particularly if a standard definition endoscope is used or if there is a history of dysplasia. (#1) Virtual chromoendoscopy is a suitable alternative to dye spray chromoendoscopy for dysplasia detection in persons with colonic inflammatory bowel disease when using high definition endoscopy. (#2) A finding of invisible dysplasia should prompt repeat examination by an experienced endoscopist using high-definition dye spray chromoendoscopy under optimized viewing conditions, with extensive nontargeted biopsies in the area of prior dysplasia if no lesion is seen. A finding of unresectable visible dysplasia or of invisible multifocal or high-grade dysplasia on histology should prompt colectomy. For visible lesions that can be resected or if histologic dysplasia is not confirmed on a high-quality dye spray chromoendoscopy examination, continued endoscopic surveillance at frequent intervals is appropriate. (#5) Targeted biopsies of representative or concerning pseudopolyps is appropriate during colonoscopy. Removal and sampling of all lesions is neither required nor practical. Surgery should be a last resort to manage colorectal cancer risk in the setting of severe pseudopolyposis. Dye spray chromoendoscopy should not be used to detect flat or subtle lesions within a field of pseudopolyps. (#8)

Source	Recommendation
	A finding of invisible dysplasia should prompt repeat examination by an experienced endoscopist using high-definition dye spray chromoendoscopy under optimized viewing conditions, with extensive nontargeted biopsies in the area of prior dysplasia if no lesion is seen. A finding of unresectable visible dysplasia or of invisible multifocal or high-grade dysplasia on histology should prompt colectomy. For visible lesions that can be resected or if histologic dysplasia is not confirmed on a high-quality dye spray chromoendoscopy examination, continued endoscopic surveillance at frequent intervals is appropriate. (#10)
U.S. Multi-Society Task Force (MSTF) on Colorectal Cancer 2020	Endoscopic Removal of Colorectal Lesions: Recommendations by the US Multi-Society Task Force on Colorectal Cancer (Kaltenbach 2020). Some Statements of Best Practice include: Statement 1: Lesion assessment and description • We suggest proficiency in the use of electronic (eg, NBI, i-scan, 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) Statement 4: Surveillance • To assess for local recurrence, we suggest 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)
American College of Gastroenterology (ACG) 2019	ACG Clinical Guideline: Ulcerative Colitis in Adults (Rubin 2019) Colorectal cancer prevention in ulcerative colitis: 47. We suggest colonoscopic screening and surveillance to identify neoplasia in patients with UC of any extent beyond the rectum (conditional recommendation, very low quality of evidence). 48. When using standard-definition colonoscopes in patients with UC undergoing surveillance, we recommend dye spray chromoendoscopy with methylene blue or indigo carmine to identify dysplasia (strong recommendation, low quality of evidence). 49. When using high-definition colonoscopes in patients with UC undergoing surveillance, we suggest white-light endoscopy with narrow-band imaging or dye spray chromoendoscopy with methylene blue or indigo carmine to identify dysplasia (conditional recommendation, low quality of evidence).

Source	Recommendation
American Society of Clinical Oncology (ASCO) 2019	Early Detection for Colorectal Cancer: ASCO Resource-Stratified Guideline (Lopes 2019) Include some recommendations regarding chromoendoscopy: For people with positive premalignant polyps or other abnormal screening results—pedunculated, enhanced/maximal, overarching—refer patients to endoscopy if available and feasible; otherwise, refer to surgery: • Colonoscopy should be performed always with therapeutic intent (Evidence quality: insufficient; Strength of recommendation: strong), and it should be performed by endoscopist with training in polypectomy (Evidence quality: low; Strength of recommendation: strong) For nonpedunculated, enhanced/maximal (term used to define sessile and flat colonic lesions): • Colonoscopy should be performed by endoscopists with training in large complex polyps (Evidence quality: low; Strength of recommendation: weak) always with therapeutic intent; endoscopic resection is first-line therapy for large nonpedunculated colorectal polyps with no suspicion of malignancy (Intent, Evidence quality: insufficient; Strength of recommendation: strong; Resection, Evidence quality: intermediate; Strength of recommendation: strong) • Lesions should be removed with polypectomy; removal of lesions is dependent on the low likelihood of malignancy (Evidence quality: intermediate, Strength of recommendation: strong) • Endoscopic assessment of lesion using enhanced endoscopy methods (if available, may include chromoendoscopy); clinicians should follow the British Society of Gastroenterology/Association of Coloproctologists of Great Britain and Ireland (BSGACGB) guideline (Evidence quality: insufficient; Strength of recommendation: strong)

The use of chromoendoscopy in the surveillance of inflammatory bowel disease is supported in the peer-reviewed literature (Virk, et al., 2024; Rabago, et al., 2024; Alexandersson, et al., 2020; Resende, et al., 2020; Iannone, et al., 2017; Brown, et al., 2016).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found.	
LCD		No Determination found.	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when used to report chromoendoscopy with or without optical technologies such as narrow band imaging for surveillance of individuals with Barrett's esophagus or at increased risk for colorectal cancer based on personal history of inflammatory bowel disease (IBD)

CPT®* Codes	Description
44799	Unlisted procedure, intestine
45399	Unlisted procedure, colon
45999	Unlisted procedure, rectum

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Removed policy statements and content except for chromoendoscopy. • Added surveillance of Barrett’s esophagus to the chromoendoscopy policy statement.	12/15/2024
Annual Revision	• Removed narrow band imaging and confocal fluorescent endomicroscopy from the policy statement.	11/15/2023