KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chromoendoscopy
Narrow Band Imaging for Colonoscopy

- Barrett's Esophagus
- Colorectal Cancer
- Inflammatory Bowel Disease (IBD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"Chromoendoscopy, Narrow Band Imaging for Colonoscopy"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Chromoendoscopy: • Barrett's Esophagus • Colorectal Cancer Screening	There is insufficient evidence in the published medical literature to show that these procedures provide better long-term outcomes than current standard services/procedures during endoscopy.
Chromoendoscopy: • Inflammatory Bowel Disease	Medical necessity review is no longer required. **Please refer to Kaiser Permanente payment policy *Chromoendoscopy and Narrow Band Imaging* for reimbursement clarification (Not separately reimbursed).**

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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Background

Chromoendoscopy (also known as chromoscopy or chromocolonoscopy) is an image-enhanced endoscopic technique that has the potential of providing detailed contrast enhancement of the surface of gastrointestinal mucosa. It can be used during any endoscopic examination to improve detection and characterization of subtle mucosal abnormalities, circumscribed dysplastic lesions and malignant changes in the gastrointestinal tract. Chromoendoscopy however, requires optimal bowel preparation in order to provide adequate visualization (Bisschops 2019, Buchner 2017, Clarke 2019, Shukla 2017).

Types of chromoendoscopy:

1. Dye-based chromoendoscopy. This involves actual spraying of absorptive stains or contrast stains directly onto the GI mucosa, through a spray catheter inserted into the endoscope. Dye spraying, or chromoscopy techniques, were first described in the 1970s to provide visualization of the mucosal surface with more clarity and sharpness. It has been used to aid in the detection and evaluation dysplastic changes in the esophagus, stomach, small intestine, and large intestine. Several stains have been described and can broadly be categorized into three groups:
    - Contrast stains (e.g., indigo carmine) that permeate through mucosal crevices and highlights surface topography and mucosal irregularities. Indigo carmine is the most commonly used stain with colonoscopy to enhance the detection of colorectal neoplasms.
    - Absorptive stains (e.g. methylene blue and Lugol's solution) that diffuse or are preferentially absorbed across specific epithelial cell membranes. The normal epithelial cells absorb the methylene blue dye and stain blue while dysplastic and cancerous lesions remain unstained. Methylene blue has been used to detect colonic neoplasia and to aid in the detection of intraepithelial neoplasia in individuals with chronic ulcerative colitis. It has also been used for the detection of Barrett's esophagus and associated dysplasia and/or early cancer, and for the diagnosis of early gastric cancer.
    - Reactive stains (e.g., Congo red and phenol red) undergo chemical reactions with specific cellular constituents, resulting in a color change. These are primarily used to identify gastric abnormalities and are not used with colonoscopy.

    The stains used in chromoendoscopy are transient in contrast to endoscopic tattooing that involves the use of a long-lasting pigment for future localization of lesions (Bisschops 2019, Brown 2016**,** Buchner 2017, Clarke 2019, Shukla 2017).
2. Virtual chromoendoscopy, also called electronic chromoendoscopy (EC), involves imaging enhancements with endoscopy systems using a computer algorithm to simulate different colors of light resulting from dye or stain spraying. The EC techniques depend on finding lesion first with WLE and then using EC function to characterize it (Desai 2019)

    Electronic chromoendoscopy includes:
    - Narrow-band Imaging (NBI) (Olympus Medical Systems Tokyo, Japan),
    - Flexible spectral imaging color enhancement (FICE) (Fujinon, Fujifilm Medical Co, Saitama, Japan),
    - i-SCAN (PENTAX Endoscopy, Tokyo, Japan).

    Selective light transmittance is accomplished by optical filtering of white light in NBI, and by software driven post-image processing in FICE and i-SCAN (Buchner 2017)

    Narrow-band Imaging technology is the most studied in clinical trials. It is a blue light technology that enhances visualization of superficial mucosal structures, especially superficial microcapillaries. The technology is based on the penetration properties of light that is directly proportional to wavelength. Short wavelengths penetrate only superficially into the mucosa, whereas longer wavelengths are capable of penetrating more deeply in the mucosa. In contrast to conventional white-light endoscopy (WLE) that uses the full visible wavelength range (400-700 nm) to produce a red-green-blue image, NBI illuminates the tissue surface using special filters that narrow the red-green-blue bands and simultaneously increase the relative intensity of the blue band. The resulting narrow-band blue-green light improves visualization of mucosal patterns due to the limited optical scattering and shallow penetration depth; therefore, the color contrast is enhanced between the neoplastic lesions and adjacent normal mucosa. The blue light is also absorbed by hemoglobin for optimal detection of mucosal, glandular, and vascular patterns as well as the presence of abnormal blood vessels that are associated with the development of dysplasia. It is hypothesized that as adenomas have increased vascularity and look brown with NBI against a blue-green normal background mucosa, this increased

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contrast might improve visualization in wide-field observation (Thosani 2016, Buchner 2017, Atkinson 2019).

Chromoendoscopy has been evaluated for its use with or without standard white light colonoscopy for screening, diagnosis, and/or surveillance of gastrointestinal dysplasia or cancer including the following:

- As an adjunct to colonoscopy for colorectal cancer (CRC) screening to increase the sensitivity of the procedure by facilitating the identification of mucosal abnormalities. The traditional colonoscopy using white light is considered the gold standard method for screening the general population for colon cancer, detection of precursor lesions, and for the diagnosis of colorectal neoplasia in symptomatic patients. However, it is not a perfect imaging test and has been found to miss polyps in 1 of 5 cases with an estimated polyp miss rate of up to 22% especially with very small adenomas. This may lead to an increase in the interval CRC rates. Potential explanations for these missing lesions include the small size or flatness of lesions, difficulty in finding lesions such as those hidden behind folds or flexures, shorter withdrawal time, and poor bowel preparation Over the years, several modifications have been made in the imaging modalities to enhance the traditional colonoscopy and improve its sensitivity in polyp detection. The introduction of High-definition (HD) imaging in the last decade have improved the detection of more adenomas and sessile lesions that may have been missed with the standard colonoscopy. Chromoendoscopy is another technique introduced to potentially improve polyp detection and characterization particularly the flat or nonpolypoid colonic adenomas. The technology can be used for the whole colon (pan-colonic chromoendoscopy) or directed to a specific lesion or lesions (targeted chromoendoscopy). Chromoendoscopy however may to be time consuming and labor intensive (Buchner 2017, Desai 2019, Kim 2020).
- Endoscopic surveillance of patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease) with the goal of early detection of dysplasia and identification of mucosal abnormalities for targeted biopsy as an alternative to multiple random biopsies (Shukla 2017, Clarke 2019).
- Endoscopic surveillance of Barrett's esophagus to potentially improve the image quality and the diagnostic accuracy of white light endoscopy. It can also potentially allow visualization of advanced esophageal neoplasms and identifying any subtle changes in the esophageal mucosa that may correspond to early stages of the disease or abnormalities that may not be seen in upper gastrointestinal endoscopy (Morita 2017, Cerrone 2019).

Medical Technology Assessment Committee (MTAC)

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus

Date: 01/11/2021

Evidence Conclusion:

- The published literature suggests that using acetic acid chromoendoscopy or NBI electronic endoscopy for BO surveillance may have a higher diagnostic yield compared to WLE and standard Seattle protocol when performed by experienced endoscopists (considering all limitations discussed earlier).
- There is insufficient published evidence on the long-term benefit of the using chromoendoscopy and targeted biopsy as a replacement to or in adjunct to the current standard of WLE and Seattle protocol on reducing the rate of biopsy, improving patient QoL or reducing the BO-related morbidity and mortality.

Articles: The literature search for recent of studies and meta-analyses of studies evaluating the accuracy and /or efficacy of chromoendoscopy versus WLE in detecting and characterizing dysplastic lesions and reducing the rate of unnecessary biopsies identified three meta-analyses published in the last 5 years, as well as the protocol and feasibility study for the ABBA trial on the use of acetic acid targeted biopsies in Barrett's surveillance. The search did not reveal ant recently published RCTs or prospective longitudinal studies that compared the efficacy of chromoendoscopy versus WLE in the detection and characterization of dysplastic lesions during surveillance of BO. The more recent and /or relevant meta-analysis comparing chromoendoscopy versus WLE and the standard surveillance protocol were selected for critical appraisal. See Evidence Table

The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance

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Date: 01/11/2021

Evidence Conclusion:

- The overall results of the published trials and meta-analyses suggest that dye-based chromoendoscopy marginally improves the detection of the adenoma as well as small polyps and flat lesions per subject when compared to standard colonoscopy. There were no significant differences between the two imaging modalities in the detection rate of advanced adenomas, advanced neoplasia, or cancer. The duration of withdrawal time is known to be directly associated with the adenoma detection rate (ADR), and thus the higher detection rates of adenomas, flat, and diminutive lesions with chromoendoscopy may be attributed to the increased withdrawal time with the dye-spray techniques.
- Electronic chromoendoscopy using NBI may modestly improve the adenoma detection rate compared with standard white-light colonoscopy, but the observed difference was only significant with optimal bowel preparation and use of NBI second generation. There were no significant differences in polyp or adenoma detection was observed between high definition white-light colonoscopy and high definition NBI.
- There is a lack of long-term studies to determine whether the use of chromoendoscopy would reduce rates of colorectal interval cancers.
- There is a lack of published studies comparing the effect of chromoendoscopy versus standard or high definition white light endoscopy in reducing the incidence of CRC or the associated morbidity and mortality.
- There is no published evidence, to date, to determine the effects of technology on net health outcome.

Articles: The literature search identified over 40 RCTs and more than 20 meta-analyses (dating back to the year 2012) that examined the impact of different dyes or electronic chromoendoscopy modalities on increasing the detection rate of colonic lesions when compared to one another or to white light colonoscopy.
Due to the large number of published studies and meta-analyses, the most recent meta-analyses of RCTs, that were more inclusive of trials, and had valid methodology were selected for the current review as well as recently published RCTs that compared neoplasia detection rates with chromoendoscopy (dye -based or NBI) versus standard white light (WL) of high-definition white light (HDWL) colonoscopy used for screening or diagnosis of colorectal cancer. The use of chromoendoscopy for the surveillance of Barrett's esophagus and the surveillance of irritable bowel disease will be reviewed separately in different reports. See Evidence Table**.**

The use of Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD)

Date: 01/11/2021

Evidence Conclusion:

- There is strong evidence that dye chromoendoscopy (DCE) is superior to standard white light endoscopy (SD-WLE) in detecting dysplastic lesions in patients with IBD.
- There is moderate to high strength evidence indicating that DCE does not provide any additive benefit over HD-WLE in the overall ability to detect dysplasia in patients with IBD. Randomized controlled trials, meta-analyses of RCT, and a recent US-based case control sturdy (Clarke et al 2020) showed no significant difference in dysplasia detection rate between DCE and HD-WLE. The studies that showed higher dysplasia detection rate with of DCE were mainly observational studies (with the exception of Alexandersson et al's 2020 RCT).
- Narrow band imaging (NBI) is not superior to SD or HD-WLE. Other technologies such as i-scan and Fujifilm Intelligent Chromoendoscopy have not been sufficiently studied in dysplasia surveillance.
- There is insufficient evidence to determine the safety of dye-chromoendoscopy.
- There are no published long-term longitudinal studies to date, to determine the impact of chromoendoscopy on treatment decisions for patients with IBD, patient health outcomes, e.g. reducing colectomy, reducing interval cancer and CRC-related morbidity and mortality, improving the quality of life and other patient-oriented outcomes.

Articles: The literature search identified four RCTs published in the last two years, one case control study , and nine meta-analyses of RCTs and /or prospective studies that examined the impact of dye or electronic chromoendoscopy modalities on increasing the dysplasia detection rates when compared to one another or to the standard or high definition white light colonoscopy. Three of the meta-analyses were network meta-analyses, two MAs compared dye chromoendoscopy versus white light endoscopy, and five compared different modalities of WLE and chromoendoscopy. See Evidence Table

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The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes-*commonly submitted with CPT code 43499 or 45399*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
7/10/2020	08/03/2021 MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC	10/03/2023

MPC Medical Policy Committee

Revision History	Description
08/04/2020	MPC approved to adopt non-coverage policy. Requires 60-day notice, effective date 01/01/2021.
05/04/2021	Added MTAC reviews for BE, CRC, and IBD. MPC approved to adopt MTAC's recommendation of non-coverage for chromoendoscopy for Barrett's Esophagus (BE) and Colon Cancer Screening (CRC). MPC approved to adopt MTAC's recommendation of coverage for chromoendoscopy for Inflammatory Bowel Disease (IBD). Criteria align with Kaiser Permanente payment policy (not separately reimbursed). Requires 60-day notice, effective date August 15, 2021.
10/03/2023	MPC approved to eliminate the chromoendoscopy clinical criteria for use in CRC screening of patients with IBD and instead point to KPWA payment policy. Requires 60-day notice, effective date March 1, 2024.

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