FEP 2.01.84 Chromoendoscopy as an Adjunct to Colonoscopy

Effective Date: April 1, 2019

Related Policies:
2.01.87 Confocal Laser Endomicroscopy
6.01.32 Virtual Colonoscopy/Computed Tomography
Colonography

Chromoendoscopy as an Adjunct to Colonoscopy

Description
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.

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.

OBJECTIVE

The objectives of this evidence review are to determine the diagnostic accuracy of chromoendoscopy and virtual chromoendoscopy and to evaluate whether they improve health outcomes compared with standard white-light colonoscopy.

POLICY STATEMENT

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.
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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 IBD 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society for Gastrointestinal Endoscopy and American Gastroenterological Association
The American Society for Gastrointestinal Endoscopy (ASGE) and the American Gastroenterological Association (2015) published the SCENIC consensus statement on surveillance and management of dysplasia in patients with inflammatory bowel disease (IBD). [23]

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 Patients With IBD

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOA</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 “When performing surveillance with white-light colonoscopy, high definition is recommended rather than standard definition.”</td>
<td>80%</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>2 “When performing surveillance with standard-definition colonoscopy, chromoendoscopy is recommended rather than white-light colonoscopy.”</td>
<td>85%</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>3 “When performing surveillance with high-definition colonoscopy, chromoendoscopy is suggested rather than white-light colonoscopy.”</td>
<td>84%</td>
<td>Conditional</td>
<td>Low</td>
</tr>
</tbody>
</table>

IBD: inflammatory bowel disease; 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 patients with IBD undergoing surveillance.

Commentaries in 2 gastroenterology journals questioned whether the SCENIC guidelines would be accepted as the standard of care in IBD surveillance.[24][25]

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 patients with dysplastic lesions detected using chromoendoscopy.

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.”[26]

ASGE (2015) also published a systematic review and meta-analysis assessing narrow-band imaging (NBI), 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.[27]
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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 (<=5mm) adenomatous polyps.”

The report addressed the “trepidation” of patients, 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

The Multi-Society Task Force (2012) guidelines on colonoscopy surveillance after screening and polypectomy (consensus update) stated that chromoendoscopy and NBI might enable endoscopists to accurately determine if lesions are neoplastic and if there is a need to remove them and send specimens to pathology.[28]

The guidelines noted that these technologies currently do not have an impact on surveillance interval.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2016) recommendations on screening for colorectal cancer do not mention chromoendoscopy.[29]

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<td>September 2012</td>
<td>New Policy</td>
<td>Policy updated with literature search, No change to policy statements,</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>References added, some renumbered or removed.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
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</tr>
<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>References 10, 15, 18, and 20 added.</td>
</tr>
<tr>
<td>June 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Reference 11 and 13 added. Policy</td>
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<td></td>
<td></td>
<td>statements unchanged.</td>
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<tr>
<td>March 2018</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 7, 2015;</td>
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<td></td>
<td>references 11 and 21-23 added. Policy statements unchanged.</td>
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<tr>
<td>March 2019</td>
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<td>Policy updated with literature review through September 14, 2017; reference</td>
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<td></td>
<td></td>
<td>27 added. Policy statement changed to correct error: Chromoendoscopy and</td>
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<tr>
<td></td>
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<td>virtual chromoendoscopy considered investigational since Sept. 2012 but</td>
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<td>policy incorrectly listed chromoendoscopy as medically necessary; also not</td>
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<td>medically necessary language corrected to investigational due to 510k FDA</td>
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