FEP Medical Policy Manual

FEP 2.01.84 Chromoendoscopy as an Adjunct to Colonoscopy

Effective Date: April 15, 2018

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.

FDA REGULATORY STATUS
In August 2014, the Fujifilm EPX-4440HD Digital Video Processor with Fujinon Intelligent Color Enhancement (FICE®) and Light Source was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA documents stated that FICE® could be used to supplement white-light endoscopy but is not intended to replace histopathologic sampling as a means of diagnosis.

In April 2013, the i-SCAN™ (Pentax [Tokyo, Japan]), used for virtual chromoendoscopy, was cleared for marketing by FDA through the 510(k) process. This digital image enhancement technology is part of the Pentax EPK-i5010 Video Processor. The i-SCAN™ has several modes that digitally enhance images in real time during endoscopy. The FDA documents stated that i-SCAN™ is intended as an adjunct following white-light endoscopy but not intended to replace histopathologic analysis.

No dye or stain product has been specifically approved by FDA for use in chromoendoscopy.

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.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).
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RATIONALE

Summary of Evidence

Chromoendoscopy
For individuals who have an average risk of CRC who receive chromoendoscopy, the evidence includes an RCT focused on this population. Relevant outcomes are overall survival, disease-specific survival, test accuracy and 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 accuracy and 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 accuracy and validity, and change in disease status. The 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 accuracy and 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 on the impact of virtual chromoendoscopy on CRC incidence or 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 accuracy and 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 on the impact of virtual chromoendoscopy on CRC incidence or 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 accuracy and 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 endoscopy method used. There is a lack of studies on the impact of virtual chromoendoscopy CRC incidence or 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

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 patients with inflammatory bowel disease (IBD). The statement, developed by an international multidisciplinary group representing a variety of stakeholders, incorporated systematic reviews of the literature. Relevant recommendations included the following (see Table 1).

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>
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<tbody>
<tr>
<td>&quot;When performing surveillance with white-light colonoscopy, high definition is recommended rather than standard definition.&quot;</td>
<td>80%</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>&quot;When performing surveillance with standard-definition colonoscopy, chromoendoscopy is recommended rather than white-light colonoscopy.&quot;</td>
<td>85%</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>&quot;When performing surveillance with high-definition colonoscopy, chromoendoscopy is suggested rather than white-light colonoscopy.&quot;</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 detection of dysplasia and not disease progression or survival. Moreover, the authors noted the lack of longitudinal data on clinical outcomes in patients with dysplastic lesions detected using chromoendoscopy.

American Society for Gastrointestinal Endoscopy

In 2015, ASGE issued guidelines on endoscopy in the diagnosis and treatment of inflammatory bowel disease, which made the following recommendations about chromoendoscopy26: “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.”

In 2015, ASGE 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 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’
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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 2012 Multi-Society Task Force 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. The guidelines noted that these technologies currently do not have an impact on surveillance interval.28

U.S. Preventive Services Task Force Recommendations

The 2016 U.S. Preventive Services Task Force 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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The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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POLICY HISTORY

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