Medical Policy
Confocal Laser Endomicroscopy

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Policy Number: 618
BCBSA Reference Number: 2.01.87

Related Policies
• Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus, #218
• Chromoendoscopy as an Adjunct to Colonoscopy, #904
• Virtual Colonoscopy and CT Colonography, #179

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Use of confocal laser endomicroscopy is INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>43206</td>
<td>Esophagoscopy flexible, transoral; with optical endomicroscopy</td>
</tr>
<tr>
<td>43252</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy</td>
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<tr>
<td>88375</td>
<td>Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session</td>
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### ICD-9 Diagnosis Codes

Investigational for all diagnoses.

### ICD-9 Procedure Codes

There is no specific ICD-9 procedure code for this service.

### Description

Confocal laser endomicroscopy (CLE), also known as confocal fluorescent endomicroscopy and optical endomicroscopy, allows in vivo microscopic imaging of cells during endoscopy. CLE is proposed for a variety of purposes, especially as a real-time alternative to histology during colonoscopy and for targeting areas to undergo biopsy in patients with inflammatory bowel disease and Barrett’s esophagus.

### Background

Confocal laser endomicroscopy (CLE), also known as confocal fluorescent endomicroscopy and optical endomicroscopy, allows in vivo microscopic imaging of the mucosal epithelium during endoscopy. According to the American Society for Gastrointestinal Endoscopy (ASGE), (1) with CLE, light from a low-power laser illuminates tissue and, subsequently, the same lens detects light reflected from the tissue through a pinhole. The term confocal refers to having both illumination and collection systems in the same focal plane. Light reflected and scattered at other geometric angles that is not reflected through the pinhole is excluded from detection which dramatically increases the special resolution of CLE images.

To date, 2 types of CLE systems have been cleared by the U.S. Food and Drug Administration (FDA). One is an endoscope-based system in which a confocal probe is incorporated onto the tip of a conventional endoscope. The other is a probe-based system; the probe is placed through the biopsy channel of a conventional endoscope. The depth of view is up to 250 um with the endoscopic system and about 120 um with the probe-based system. A limited area can be examined; no more than 700 um in the endoscopic-based system and less with the probe-based system. As pointed out in review articles, the limited viewing area emphasizes the need for careful conventional endoscopy to target the areas for evaluation. Both CLE systems are optimized using a contrast agent. The most widely used agent is intravenous fluorescein, which is FDA-approved for ophthalmologic imaging of blood vessels when used with a laser scanning ophthalmoscope.

Unlike techniques such as chromoendoscopy (see policy 2.01.84), which are primarily intended to improve the sensitivity of colonoscopy, CLE is unique in that it is designed to immediately characterize the cellular structure of lesions. CLE can thus potentially be used to make a diagnosis of polyp histology, particularly in association with screening or surveillance colonoscopy, which could allow for small hyperplastic lesions to be left in place rather than removed and sent for histological evaluation. This would reduce risks associated with biopsy and reduce the number of biopsies and histological evaluations. Another key potential application of CLE technology is targeting areas for biopsy in patients with Barrett’s esophagus undergoing surveillance endoscopy. This is an alternative to conducting random biopsies during surveillance and has the potential to reduce the number of biopsies and/or improve the
detection of dysplasia. Other potential uses of CLE under investigation include better diagnosis and
differentiation of conditions such as gastric metaplasia, lung cancer and bladder cancer.

As noted previously, limitations of CLE systems include a limited viewing area and depth of view. Another
issue is standardization of systems for classifying lesions viewed with CLE devices. Although there is not
currently an internationally accepted classification system for colorectal lesions, 2 systems have been
developed that have been used in a number of studies conducted in different countries. These are the
Mainz criteria for endoscopy-based CLE devices and the Miami classification system for probe-based
CLE devices. (2) Lesion classification systems are less developed for non-gastrointestinal lesions viewed
by CLE devices, e.g., those in the lung or bladder. Another potential issue is the learning curve for
obtaining high-quality images and classifying lesions. Several recent studies, however, have found that
the ability to acquire high-quality images and interpret them accurately can be learned relatively quickly;
these studies were limited to colorectal applications of CLE. (3, 4)

Summary
Confocal laser endomicroscopy (CLE) is a device that allows in vivo microscopic imaging of cells during
endoscopy. For patients undergoing screening or surveillance colonoscopy, multiple studies have
evaluated the diagnostic accuracy of CLE. While the reported sensitivity and specificity in these studies is
high, it may not be sufficiently high to replace biopsy/polypectomy and histopathologic analysis.
Therefore, this evidence is not sufficient to conclude that CLE improves outcomes when used as an
adjunct to colonoscopy.

Several studies have evaluated CLE for identifying areas of dysplasia and targeting biopsies in patients
undergoing surveillance for Barrett’s esophagus. Evidence from RCTs supports that CLE is more
sensitive than white-light endoscopy for identifying areas of dysplasia. However, this evidence is
insufficient to determine the impact of this technology on health outcomes in this population, particularly
outside of the research setting. National guidelines continue to recommend 4-quadrant random biopsies
for patients with Barrett’s esophagus undergoing surveillance. There are less data on the use of CLE in
non-gastrointestinal conditions such as lung or bladder cancer. Thus, use of CLE with endoscopy is
considered investigational for all indications.

Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>4/2014</td>
<td>New references added from BCBSA National medical policy. Coding information clarified</td>
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<tr>
<td>1/2014</td>
<td>Coding information clarified</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References