Medica Coverage Policy

Policy Name: Confocal Laser Endomicroscopy for Barrett’s Esophagus
Effective Date: 12/1/2016

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Confocal laser endomicroscopy for Barrett’s esophagus is investigative and therefore NOT COVERED.

Note: See also related position statement, Endoscopic Radiofrequency Ablation for Barrett’s Esophagus.

Description
Confocal laser endomicroscopy (CLE), also known as confocal fluorescent endomicroscopy and optical endomicroscopy, is an emerging endoscopic technology that purports to provide high-resolution histological assessment of mucosal tissue in real-time at a cellular and sub-cellular level. Examination is performed in vivo with use of a contrast agent (e.g., intravenous fluorescein) and real-time image display. Unlike other techniques (e.g., chromoendoscopy) which are primarily intended to improve visual sensitivity, CLE is designed to characterize the cellular structure of lesions. Thus, CLE is proposed to be used to make a diagnosis based on mucosal histology, particularly in association with screening or surveillance.

One potential application of CLE technology is targeting areas for biopsy in patients with Barrett's esophagus undergoing surveillance endoscopy. As an alternative to conducting random biopsies during surveillance, CLE is purported to have the potential of reducing the number of biopsies and/or improving the detection and severity of dysplasia. Other proposed indications under study include, but are not limited to, use in colonoscopy and surveillance of gastric metaplasia, lung cancer, and bladder cancer.

There are two types of CLE systems currently available: (1) an endoscope-based system using a confocal probe incorporated onto the tip of a conventional endoscope, and (2) a probe-based system using a probe that is placed through the biopsy channel of a conventional endoscope. Current limitations in using CLE devices include: (1) limited depth of view, (2) lack of a standardized system for classifying lesions viewed with CLE devices, and (3) the learning curve needed to perform and interpret CLE findings.

FDA Approval
Multiple endoscopes and endoscopic accessories have received 510(k) marketing clearance by the FDA. Two CLE device systems currently available are:
1. Cellvizio System (Mauna Kea Technologies; Paris, France): The F-600 system was originally cleared by the FDA in 2006 for use with a standard endoscope. This system uses fiber optic probe-based technology consisting of a laser scanning unit, miniaturized fiber optic probes, proprietary software, and a panel display.

2. Confocal Video Colonoscope (Pentax Medical Company: Montvale, NJ): The ISC-1000 Pentax Confocal Laser System was originally cleared by the FDA in 2004. The Pentax CLE system is comprised of a video-controlled endoscopic system, software-controlled accessories, and a confocal laser module consisting of a laser light source, a system computer, and a display monitor.

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Code
0397T - Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure)

Original Effective Date: 12/1/2016

Re-Review Date(s):