

## FEP 2.01.87 Confocal Laser Endomicroscopy

**Effective Date:** April 15, 2018

**Related Policies:**

2.01.80 Endoscopic Radiofrequency Ablation or Cryoablation for Barrett Esophagus  
2.01.84 Chromoendoscopy as an Adjunct to Colonoscopy  
6.01.32 Virtual Colonoscopy/Computed Tomography Colonography

### Confocal Laser Endomicroscopy

#### 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 biopsy/polypectomy and histopathologic analysis during colonoscopy and for targeting areas to undergo biopsy in patients with inflammatory bowel disease or Barrett esophagus.

#### FDA REGULATORY STATUS

Two CLE devices have been cleared for marketing by FDA through the 510(k) process.

Celvizio® (Mauna Kea Technologies, Paris, France) is a confocal microscopy with a fiber optic probe (ie, a probe-based CLE system). The device consists of a laser scanning unit, proprietary software, a flat-panel display, and miniaturized fiber optic probes. The F-600 system, cleared by FDA in 2006, can be used with any standard endoscope with a working channel of at least 2.8 mm. According to FDA, the device is intended for confocal laser imaging the internal microstructure of tissues in the anatomic tract (gastrointestinal or respiratory) that are accessed by an endoscope. The 100 series version of the system was cleared by FDA in 2015 for imaging the internal microstructure of tissues and for visualization of body cavities organs and canals during endoscopic and laparoscopic surgery. FDA product code: GCJ.

Confocal Video Colonoscope (Pentax Medical, Montvale, NJ) is an endoscopy-based CLE system. The EC-3570CILK system, cleared by FDA in 2004, is used with a Pentax Video Processor and with a Pentax Confocal Laser System. According to FDA, the device is intended to provide optical and microscopic visualization of and therapeutic access to the lower gastrointestinal tract. FDA product code: GCJ/KOG (endoscope and accessories).

#### POLICY STATEMENT

Use of confocal laser endomicroscopy is considered **investigational**.

#### BENEFIT APPLICATION

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

# Policy Manual Imaging

**Patricia C. Messick, Aspen Health Law  
and Compliance Center**

## **Policy Manual Imaging:**

Medical Subject Headings National Library of Medicine (U.S.),1997      **Procedure and Policy Manual 1976-77** New York State College of Veterinary Medicine. Teaching Hospital,1976      **ZENworks 6.5 Suite Administrator's Handbook** Brad Dayley,Ron Tanner,2004-12-09 Novell ZENworks 6 5 is a comprehensive set of integrated tools that automate IT management and business processes across the lifecycle of desktops laptops servers and handhelds across diverse server and client platforms The Novell ZENworks 6 5 Suite Administrator s Handbook is a solid reference guide to all the new features of ZENworks 6 5 It includes descriptions of all the ZENworks 6 5 components as well as the new features from the merged products Packed with detailed information on how to install efficiently use and troubleshoot ZENworks 6 5 in an enterprise environment Novell ZENworks 6 5 Suite Administrator s Handbook is sure to be the only guide you need to maximize your ZENworks 6 5 experience      *Nuclear Medicine Technology: Procedures and Quick Reference* Pete Shackett,2019-08-14 Completely updated with the latest advances in imaging technology this quick reference manual is the only procedures guide specifically geared to nuclear medicine technologists A concise easy to read bulleted outline format provides clear step by step instructions for 61 scan procedures including listings of possible artifacts and problems that may arise during each scan Detailed anatomic illustrations clarify anatomy and body systems and Patient History sections enhance students patient communication and education capabilities      *Master Medicare Guide* Wolters Kluwer Law & Business,2015-02-25 The 2015 Master Medicare Guide is packed with timely and useful information to help you stay on top of one of the most complex programs administered by the federal government The 2015 Edition includes Over 500 explanation summaries for all aspects of the Medicare program coverage eligibility reimbursement fraud and abuse and administration Highlights of the Protecting Access to Medicare Act of 2014 P L 113 93 and the Improving Medicare Post Acute Care Transformation Act of 2014 P L 113 185 the most recent physician fee schedule reimbursement fix A focus on the continuing implementation of the Affordable Care Act as it relates to Medicare including accountable care organizations and a tighter link between the quality of health care and Medicare reimbursement All discussions include cross references to relevant laws regulations CMS manual sections administrative and judicial decisions and more      **Handbook of Functional Neuroimaging of Cognition** Roberto Cabeza,Alan Kingstone,2001 With its strong theoretical focus this book serves as an essential resource on the functional neuroimaging of cognitive processes and on the latest discoveries obtained through positron emission tomography PET and functional magnetic resonance imaging fMRI techniques It is organized into three sections The first covers the history and methods of PET and fMRI as well as cognitive networks showing how the brain regions involved in the different cognitive processes interact The second part the book s core covers PET and fMRI findings in specific domains attention visual recognition language semantic memory episodic memory and working memory The third part covers the effects of aging on brain activity during cognitive performance and also examines research with neuropsychologically impaired patients

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pain management acute visual changes orthopedic emergencies dizziness palpitations acute stroke syndromes abuse and neglect and electrolyte and endocrine emergencies      **Radiology Department Compliance Manual** Patricia C.

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