

## 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.

Celfvizio® (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

**Terry C. Jones**



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## **Table of Contents Policy Manual Imaging**

1. Understanding the eBook Policy Manual Imaging
  - The Rise of Digital Reading Policy Manual Imaging
  - Advantages of eBooks Over Traditional Books
2. Identifying Policy Manual Imaging
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Policy Manual Imaging
  - User-Friendly Interface
4. Exploring eBook Recommendations from Policy Manual Imaging
  - Personalized Recommendations
  - Policy Manual Imaging User Reviews and Ratings
  - Policy Manual Imaging and Bestseller Lists
5. Accessing Policy Manual Imaging Free and Paid eBooks
  - Policy Manual Imaging Public Domain eBooks

- Policy Manual Imaging eBook Subscription Services
- Policy Manual Imaging Budget-Friendly Options
- 6. Navigating Policy Manual Imaging eBook Formats
  - ePub, PDF, MOBI, and More
  - Policy Manual Imaging Compatibility with Devices
  - Policy Manual Imaging Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Policy Manual Imaging
  - Highlighting and Note-Taking Policy Manual Imaging
  - Interactive Elements Policy Manual Imaging
- 8. Staying Engaged with Policy Manual Imaging
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Policy Manual Imaging
- 9. Balancing eBooks and Physical Books Policy Manual Imaging
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Policy Manual Imaging
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Policy Manual Imaging
  - Setting Reading Goals Policy Manual Imaging
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Policy Manual Imaging
  - Fact-Checking eBook Content of Policy Manual Imaging
  - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks

## 14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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