

## 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

**Brendan G. Carr**



## **Policy Manual Imaging:**

## Unveiling the Power of Verbal Artistry: An Mental Sojourn through **Policy Manual Imaging**

In a global inundated with displays and the cacophony of fast connection, the profound power and mental resonance of verbal artistry often fade in to obscurity, eclipsed by the constant assault of sound and distractions. Yet, nestled within the lyrical pages of **Policy Manual Imaging**, a fascinating work of literary beauty that pulses with organic feelings, lies an unforgettable journey waiting to be embarked upon. Written by way of a virtuoso wordsmith, that enchanting opus manuals visitors on a psychological odyssey, lightly exposing the latent potential and profound influence stuck within the complicated internet of language. Within the heart-wrenching expanse of the evocative evaluation, we will embark upon an introspective exploration of the book is key subjects, dissect its fascinating writing design, and immerse ourselves in the indelible effect it leaves upon the depths of readers souls.

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