## **FEP Medical Policy Manual**

#### 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.

Cellvizio® (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-3S70CILK 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

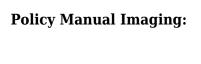
Use of confocal laser endomicroscopy is considered investigational.

#### BENEFIT APPLICATION

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

# **Policy Manual Imaging**

**Michael Seilmaier** 



Unveiling the Power of Verbal Beauty: An Psychological Sojourn through Policy Manual Imaging

In a world inundated with monitors and the cacophony of quick communication, the profound power and emotional resonance of verbal artistry usually disappear in to obscurity, eclipsed by the constant barrage of noise and distractions. Yet, nestled within the lyrical pages of **Policy Manual Imaging**, a captivating perform of fictional beauty that impulses with organic emotions, lies an memorable trip waiting to be embarked upon. Published by a virtuoso wordsmith, that interesting opus guides readers on an emotional odyssey, softly exposing the latent possible and profound affect stuck within the complex internet of language. Within the heart-wrenching expanse of this evocative evaluation, we shall embark upon an introspective exploration of the book is main styles, dissect its fascinating publishing style, and immerse ourselves in the indelible impression it leaves upon the depths of readers souls.

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