

## 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

**K Morrison**



## **Policy Manual Imaging:**

The book delves into Policy Manual Imaging. Policy Manual Imaging is a vital topic that needs to be grasped by everyone, ranging from students and scholars to the general public. The book will furnish comprehensive and in-depth insights into Policy Manual Imaging, encompassing both the fundamentals and more intricate discussions.

1. The book is structured into several chapters, namely:

- Chapter 1: Introduction to Policy Manual Imaging
- Chapter 2: Essential Elements of Policy Manual Imaging
- Chapter 3: Policy Manual Imaging in Everyday Life
- Chapter 4: Policy Manual Imaging in Specific Contexts
- Chapter 5: Conclusion

2. In chapter 1, this book will provide an overview of Policy Manual Imaging. The first chapter will explore what Policy Manual Imaging is, why Policy Manual Imaging is vital, and how to effectively learn about Policy Manual Imaging.
3. In chapter 2, this book will delve into the foundational concepts of Policy Manual Imaging. This chapter will elucidate the essential principles that must be understood to grasp Policy Manual Imaging in its entirety.
4. In chapter 3, this book will examine the practical applications of Policy Manual Imaging in daily life. The third chapter will showcase real-world examples of how Policy Manual Imaging can be effectively utilized in everyday scenarios.
5. In chapter 4, the author will scrutinize the relevance of Policy Manual Imaging in specific contexts. This chapter will explore how Policy Manual Imaging is applied in specialized fields, such as education, business, and technology.
6. In chapter 5, the author will draw a conclusion about Policy Manual Imaging. This chapter will summarize the key points that have been discussed throughout the book.

This book is crafted in an easy-to-understand language and is complemented by engaging illustrations. This book is highly recommended for anyone seeking to gain a comprehensive understanding of Policy Manual Imaging.

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