

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).

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Jiyuan Zhang



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Policy Manual Imaging: Bestsellers in 2023 The year 2023 has witnessed a noteworthy surge in literary brilliance, with numerous engrossing novels captivating the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the engaging narratives that have enthralled audiences this year. The Must-Read : Colleen Hoover's "It Ends with Us" This poignant tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover skillfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can succeed. Uncover the Best : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids captivating storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Policy Manual Imaging : Delia Owens "Where the Crawdads Sing" This mesmerizing coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens crafts a tale of resilience, survival, and the transformative power of nature, entrancing readers with its evocative prose and mesmerizing setting. These popular novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of compelling stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a masterful and suspenseful novel that will keep you wondering until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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