

August 9, 2024

To whom it may concern:

On behalf of the American Foregut Society, we are writing this letter to request an update to your medical policy to identify the Cellvizio procedure – Confocal Laser Endomicroscopy (CLE) – as a covered service.

The American Foregut Society is comprised of gastroenterologists and surgeons collaborating to personalize treatment and improve patient outcomes in foregut disease. Our mission is driven by the belief that cross-specialty collaboration will translate into improved care, safety, and value for patients with Foregut disease.

Esophageal adenocarcinoma (EAC) has increased more than 500% in recent decades, is often undetected in its early stages, and still carries an 80% 5-year mortality. Barrett's esophagus is the precursor to EAC, similar to polyps being the precursor to colon cancer. Endoscopic evaluation of Barrett's esophagus is, likewise, necessary if we are to ever decrease the incidence of EAC and reduce the mortality of EAC.

Evaluation of Barrett's esophagus to identify pre-cancerous changes and early cancer requires careful, detailed evaluation of the full extent of the Barrett's mucosa. By the time obvious visible changes occur, advanced cancer is typically found. Though endoscopically-obtained random biopsies have been the mainstay of evaluating pre-cancerous and cancerous changes in Barrett's esophagus, these protocols have not proven sufficient to change the course of the disease. This is not unexpected given that random biopsies only sample 2-5% of the Barrett's esophagus.

Cellvizio uses Confocal Laser Endomicroscopy and is the only technology to provide real-time microscopic imaging of the cellular and vascular organization of tissues. This provides the ability to target biopsies and increase the yield of endoscopic surveillance. When used adjunctively with standard esophageal biopsies, Cellvizio has significantly improved overall absolute and relative detection rates of pre-cancerous (dysplastic) and early cancerous changes in patients with Barrett's esophagus. Cellvizio has been evaluated in numerous clinical studies and has *been found to double the rate of detection of Barrett's compared to random biopsies*. A recent meta-analysis examined the benefit of adding Cellvizio to standard 4-quadrant random biopsies in patients with Barrett's esophagus<sup>1</sup>. Nine research studies enrolled 688 patients with Barrett's esophagus and 1,299 lesions were examined. For detection of neoplasia, Cellvizio had a pooled per-patient sensitivity of 96%, specificity of 93%, and negative predictive value of 98%. These findings meet the criteria set by the American Society of Gastrointestinal Endoscopy Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) committee to conclude that a new endoscopic technology is beneficial for patients with Barrett's esophagus.<sup>2</sup> For individual lesions examined, Cellvizio had a per-lesion pooled sensitivity of 82%, specificity of 90%, and negative predictive value of 90%. Cellvizio increased the absolute detection for neoplasia from 4% with random biopsies to 9%, or relative detection rate of neoplasia increase by 243%.

Cellvizio has also been evaluated by the Society of American Gastrointestinal and Endoscopic Surgeons Technology and Value Committee, which concluded that Cellvizio had an excellent safety profile and can increase detection of Barrett's with dysplasia.<sup>3</sup>

Members of the American Foregut Society have found Cellvizio probe-based Confocal Laser Endomicroscopy beneficial in providing earlier and more accurate detection of Barrett's esophagus and dysplasia. They have expressed to the AFS Board their belief that Cellvizio should be a covered benefit.

Thank you for your attention to this important matter.

Respectfully,



Reginald CW Bell MD  
Chair of the Board  
American Foregut Society

1. DeMeester SRW, K.; Ayub, K.; Buckley, F.P.; Leggett, P.; Severson, P.; Chahine, A.; Samarsena, J.B. High-definition Probe-based Confocal Laser Endomicroscopy Review and Meta-analysis for Neoplasia Detection in Barrett's Esophagus. *Techniques and Innovations in Gastrointestinal Endoscopy* 2022;24(4):340-350.
2. Sharma P, Savides TJ, Canto MI, et al. The American Society for Gastrointestinal Endoscopy PIVI (Preservation and Incorporation of Valuable Endoscopic Innovations) on imaging in Barrett's Esophagus. *Gastrointest Endosc* 2012;76(2):252-4. (In eng). DOI: S0016- 5107(12)02247-X [pii]
3. Al-Mansour MR, Caycedo-Marulanda A, Davis BR, et al. SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy. *Surg Endosc* 2021;35(5):2091-2103. DOI: 10.1007/s00464-020-07607-3.