



MAUNA KEA TECHNOLOGIES RECEIVES ADDITIONAL CPT® REIMBURSEMENT CODE IN THE U.S SUPPORTING KEY APPLICATION OF ENDOMICROSCOPY WITH CELLVIZIO IN THE BILIARY TRACT

New code reflects rapidly expanding recognition of positive clinical results involving use of endomicroscopy to enhance diagnostic accuracy during ERCP procedures.

PARIS, March 17th 2015—Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, today announced that the American Medical Association (AMA) Editorial Panel has awarded a new CPT Code related to the use of endomicroscopy during endoscopic retrograde cholangiopancreatography (ERCP) procedures to enable physicians to diagnose health problems in the biliary tract including diagnosis of biliary strictures and the presence of biliary cancer. More than 500,000 ECRPs are completed annually in the United States.

“The creation of a new CPT code for biliary tract endomicroscopy is excellent news for patients with biliary strictures, representing a significant level of recognition for its applications in this area,” said David L. Carr-Locke, MD, Director, GI Services, Continuum Cancer Centers of New York, Co-Director, Comprehensive Digestive Diseases Center of New York at Mount Sinai Beth Israel and former President of the American Society for Gastrointestinal Endoscopy (ASGE). *“This achievement recognizes years of carefully designed clinical trials that have demonstrated the value of endomicroscopy in enhancing the diagnostic accuracy of ERCP. It will also continue to foster the acceptance of a technology that has proven benefit in many other fields of medicine.”*

In January 2015, Mauna Kea announced publication of final results from a multi-center international prospective clinical trial (the FOCUS trial) assessing the use of probe-based confocal laser endomicroscopy (pCLE) in the diagnosis of biliary cancer during ERCP. Among the 112 patients enrolled in this study, pCLE correctly diagnosed 88% of patients (accuracy: 88%, Sensitivity: 89%, specificity: 88%, positive predictive value: 93%, negative predictive value: 82%) when combined with ERCP. Results were published in the peer-reviewed journal *Gastrointestinal Endoscopy*.

“The advantage that Cellvizio can deliver in terms of more rapid and accurate diagnosis of biliary strictures has been well established in both the clinical literature and in medical practice. We are very encouraged by both the designation of a new CPT code covering this procedure and the continuing adoption of this technology by gastroenterologists in the U.S. and around the world,” said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. *“These important developments provide strong support for our continuing efforts to help physicians provide improved care to more patients.”*

The designation of CPT coding for medical procedures supports more accurate physician communication to payers for specific coding and payment guidelines about the procedure. Physician use of optical endomicroscopy with ERCP enables more appropriate treatment decisions and improved access to care for patients. This new Category III CPT Code 039X7T for ERCP with optical endomicroscopy using Cellvizio, was announced in the Summary of Panel Actions of the AMA Editorial Panel, will be released July 1st, 2015 and go into effect on January 1st, 2016. The Category III code is applicable for all Third Party payers, including Medicare.



About Current Procedural Terminology (CPT®)

CPT codes are a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable nationwide communication among physicians and other healthcare providers, patients, and third parties. CPT® is registered trademark of the American Medical Association. For more information on CPT codes, see: <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq/code-becomes-cpt.page>

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. The company's flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers with high-resolution cellular imaging of internal tissues. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with practically all endoscopes. Cellvizio has 510(k) clearance from the United States Food and Drug Administration and CE Marking in the European Union for use in the gastrointestinal tract and the urinary and respiratory systems, for endoscopic exploration of the biliary and pancreatic ducts, and for fine-needle aspiration procedures. Cellvizio also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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