

MAUNA KEA TECHNOLOGIES ANNOUNCES REIMBURSEMENT COVERAGE IN FRANCE FOR THE USE OF CONFOCAL LASER ENDOMICROSCOPY FOR BARRETT'S ESOPHAGUS

Announcement of the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM) published in the Official Journal of French Republic

Paris and Boston, June 17th, 2019 – 6.00 PM CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe-based and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, announced the reimbursement coverage of confocal laser endomicroscopy, specifically for Barrett's esophagus, through the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM) published in the Official Journal of the French Republic.

In a decision dated April 18th 2019 and published in the Official Journal on June 14th 2019, the French National Association of Health Insurance Funds (UNCAM) created the following procedure, in subparagraph "07.01.09.01 - Endoscopy of the salivary glands and digestive tract" of Book II of the Social Security Code: "Esophageal endoscopy with confocal laser endomicroscopy-guided biopsy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy"¹. The tariffs reimbursed are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for anesthesia (Activity 4). This UNCAM's decision will take effect 30 days after its publication.

"We are pleased with the decision of the "Union Nationale des Caisses d'Assurance Maladie", or UNCAM, to create a new code dedicated to esophageal procedures with Confocal Laser Endomicroscopy," said **Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies**. "This decision confirms the relevance of our technology for patients at risk of esophageal cancer and we look forward to expanding our unique probe-based Confocal Laser Endomicroscopy system, Cellvizio, to the more than 300 hospitals throughout France that specialize in following patients with Barrett's esophagus."

Mr. Gershon continued: "There are more than 45,000 esophagogastroduodenoscopy procedures in France each year that potentially can be performed with Cellvizio going forward. Importantly, now clinicians performing these procedures will all be eligible for reimbursement at an attractive rate. Thanks to the creation of this new procedural code, the French market - a market in which we already enjoy a strong reputation - is finally available to Mauna Kea for broad-commercialization of our Cellvizio technology."

¹ Decision of April 18th 2019 of the National Association of Health Insurance Funds (UNCAM) on the list of procedures and services covered by health insurance, published in the Official Journal of the French Republic. Accessed at <https://www.legifrance.gouv.fr> on June 14, 2019

**Background:**

About 4,300 new cases of esophageal cancer² are diagnosed in France each year, 75% of which occur in men, more frequently beyond the age of 50. Although the epidemiology of Barrett's esophagus is not precisely known, several studies report a prevalence of around 5.6% in the general population^{3,4}. Barrett's esophagus is a well-recognized precursor of esophageal adenocarcinoma (subtype of esophageal cancer). Cellvizio is used to help target biopsies and may also reduce the number of biopsies needed to achieve a diagnosis.

A dossier on probe-based Confocal Laser Endomicroscopy (pCLE) was submitted to the French National Authority for Health (HAS) in 2010 by the French Society of Digestive Endoscopy (SFED). Then, the HAS conducted an assessment of real-time optical endomicroscopy performed during mapping of Barrett's esophagus and issued an opinion in favor of including this new procedure into the List of reimbursed procedures and services on September 17th 2014⁵.

SFED has strongly supported CLE-guided biopsy esophageal mapping procedure throughout the reimbursement process and contributed to the expert panel discussions.

The UNCAM agreed to enlist probe-based confocal laser endomicroscopy on the CCAM list (i.e. French coding system of medical procedures, which concerns any medical procedure performed in an ambulatory setting or within hospital). And in 2019, a reimbursement tariff was fixed for the exam¹.

² French National Authority for Health (HAS) and National Cancer Institute (INCa). LDD n°30 - Patient guide: the management of esophageal cancer. January 2012. Accessed at <https://www.has-sante.fr> or <https://www.e-cancer.fr>

³ Rex DK, Cummings OW, Shaw M, et al. Screening for Barrett's esophagus in colonoscopy patients with and without heartburn. *Gastroenterology*. 2003;125(6):1670-1677.

⁴ Ward EM, Wolfsen HC, Achem SR, et al. Barrett's esophagus is common in older men and women undergoing screening colonoscopy regardless of reflux symptoms. *Am. J. Gastroenterol.* 2006;101(1):12-17.

⁵ Decision n°2014.0182/DC/SEAP, https://www.has-sante.fr/portail/jcms/c_1731777



About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company's flagship product, Cellvizio[®], has received clearance/approval in a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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