

For Immediate Release

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CYBERNET SYSTEMS CO., LTD.

The computer-aided detection system “EndoBRAIN-EYE®” will be entitled to add-on reimbursement

The endoscopic computer-aided detection system “EndoBRAIN-EYE” will be regarded as a technology entitled to add-on reimbursements during the evaluation of its clinical effectiveness. It is expected that the AI program will be expanded to additional medical sites to provide more accurate medical treatment.

CYBERNET SYSTEMS CO., LTD. (head office: Tokyo, President & CEO: Reiko Yasue, hereinafter “CYBERNET”) is pleased to announce that the Central Social Insurance Medical Council (CSIMC, the advisory committee under the Ministry of Health, Labour and Welfare (MHLW) proposed the amended reimbursement prices of drugs and medical devices to encourage the evaluation of “EndoBRAIN-EYE” as classification “C2: new function, new technology” for insurance medical material¹. This is the first case of software as a service for colonoscopy to be reimbursable by health care insurance system.

The amended medical fees will encourage the adoption of AI by medical centers to promote the early detection of colorectal neoplasms.

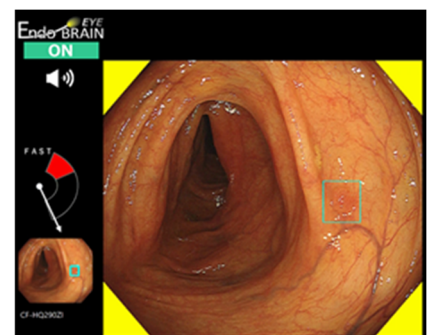
The AI-equipped medical device is called the Software as Medical Device (SaMD). Since EndoBRAIN® was first approved under the Pharmaceutical Device Law and released in 2018 in Japan, more than 20 products have been released. However, most of the products are classified as class “A1: inclusion” under the health insurance system, which means they are not eligible for reimbursement. This is one of the reasons why investment in SaMD among medical organizations has not spread widely.

CYBERNET started working on a “challenge application”² in February 2022 to update the classification of EndoBRAIN-EYE from A1 (not eligible for reimbursement). As the result of deliberation by the MHLW about its medical effectiveness³, it has been recognized that the use of this product by experts improves the adenoma detection rate and has the potential to reduce the risk of colorectal cancer for patients. Consequently, the MHLW announced that EndoBRAIN-EYE was proposed to be classified as C2 (add-on reimbursement) by the CSIMC, in February 2024⁴. Therefore, the hospitals and clinics which perform colonoscopy using EndoBRAIN-EYE and perform polypectomy will be able to receive an additional 600 JPY on top of the standard polypectomy fee from June 2024.

This new classification is expected to promote further spread of AI for colonoscopy for early detection of adenomas and cancers.

What is EndoBRAIN-EYE ?

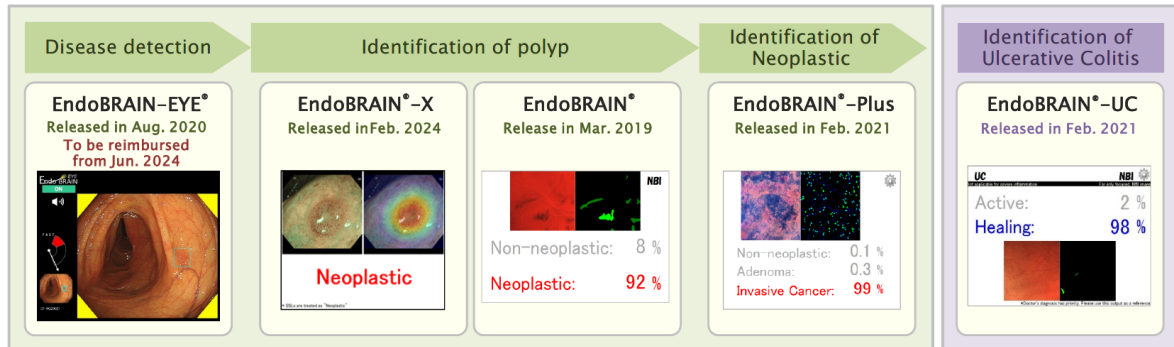
EndoBRAIN-EYE is a computer-aided detection (CADE) which support the detection of polyps in colonoscopy. The training images are provided by 5 institutions in Japan: the Showa University Northern Yokohama Hospital, the National Cancer Center Hospital, the Shizuoka Cancer Center, the Tokyo Medical and Dental University Hospital, the Cancer Institute Hospital of JFCR. Kensaku Mori laboratory of the Nagoya University Graduate School of Informatics developed the basic machine learning model, and CYBERNET integrated the model into the system, Artificial Intelligence⁵ assists doctors in the detection of lesions by analyzing colonoscopy images and noticing when it detects lesions, such as polyps. This software can be used widely since it can be combined with general colonoscopy system made by OLYMPUS.



Act of Pharmaceutical and Medical Device⁶ class II managed medical device (approved number: 30200BZX00208000)⁷

“EndoBRAIN” Series

The EndoBRAIN series is an AI-based group of software tools to support diagnosis by doctors, with the packages supporting the total workflow from lesion detection, identification, and selection of treatment method.



Recently, the number of deaths due to colorectal cancer has been increasing and is now ranked as the second common cancer in Japan.*⁸ We plan to continue developing and improving products in order to further contribute to improve accuracy of medical treatment and to reduce the burden on patients using the latest AI and endoscopy technology.

The detail of EndoBRAIN series is shown in the web site below.

<https://www.cybernet.co.jp/medical-imaging/products/endobrain/>

Activities of CYBERNET on Medical region

CYBERNET has developed and released software such as Virtual Bronchus navigation software “DirectPath”, general purpose DICOM⁹ editor “INTAGE Station” series, and visceral fat area measurement software “LungVision”, amongst others, to the market for many years. We have been researching accurate image diagnosis software using AI in collaboration with Showa University and Nagoya University, an endeavor which is financially supported by Japan Agency for Medical research and development (AMED) amongst other partners.

Notes

- *1: Classification of insurance medical material is determined by the Central Social Insurance Medical Council. Medical material is classified as “A1(inclusion)”, “A2(specific inclusion)”, “A3(existing technology, changed)”, “B1(existing function)”, “B2(existing function, changed)”, “B3(Time-limited improvement addition)”, “C1(new function)”, “C2(new function, new technology)” or “R(reproduction)”
- *2: “Challenge application” is a scheme established in 2018 that enables the re-evaluation of classification based on the usage history. This is because the need for lengthy periods of development and testing precludes final validation before insurance coverage in case of innovative technology or the products implanted in the body for a long time. The challenge application enables the retrospective evaluation.
- *3: The medical effectiveness of EndoBRAIN-EYE is introduced by:
 - The representative paper that validated the medical effectiveness of the product is below.
Ishiyama M, Kudo S, et al. Gastrointest Endosc 2022;95:155-63
 - The second section of planning and regulation, Medical Affairs Division, Health Insurance Bureau , MHLW, “(draft) regarding the evaluation of medical technologies for the Revision of Medical reimbursement in the fiscal year 2024; agenda for the second meeting of Subcommittee on Medical Technology Evaluation in Expert Panel on Medical Fee Investigation 2023”, published in 15th January 2024, p12
<https://www.mhlw.go.jp/content/12404000/001209024.pdf>
- *4: Proposal of modified medical treatment point table published by Central Social Insurance Medical Council.
https://www.mhlw.go.jp/stf/shingi2/0000212500_00139.html
The description related to EndoBRAIN-EYE is on page 285 “Chapter 10, Surgery, Subsection 9, K721 removal of colon polyp and mucous membrane by endoscopy”
- *5: The Artificial Intelligence used in EndoBRAIN-EYE is a machine learning technique called deep learning. Once training is complete in development, it stops learning.
- *6: Named as “Act on ensuring the quality, effectiveness, and safety of drugs, medical devices, etc.” It ensure the quality, effectiveness, and safety of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medicine products, strengthen safety measures for medical devices, and approve and regulate pharmaceuticals, medical devices, regenerative medicine products, etc. It also covers software for diagnostic and therapeutic purposes.

- *7: Due to the wide variety of medical devices, they are classified into general medical devices (Class I), controlled medical devices (Class II), and highly controlled medical devices (Class III and Class IV) depending on the risk they pose to patients.
- *8: Cited from the rank of the death from cancer in 2021.
National cancer center, "Latest Cancer Statistics" Cancer information service statistics,
https://ganjoho.jp/reg_stat/statistics/stat/summary.html, viewed on 13th Dec. 2023
- *9: DICOM (Digital Imaging and Communications in Medicine) is a standard that defines the format of medical image file acquired with CT, MRI, CR, etc., and the communication protocols between medical imaging devices that handle them.

About CYBERNET

As a leading CAE company, CYBERNET SYSTEMS CO., LTD. has been providing software, educational services, technical support, and consulting to R&D and design-related departments of manufacturing companies, universities, and government research institutes for more than 30 years. In the IT field, we also provide IT security solutions such as endpoint security and cloud security to protect information assets from cyber attacks. In recent years, we have been proposing solutions in the areas of IoT, digital twin, big data analysis, and AI, combined with CAE and AR/VR technologies, which are our specialties.

Our corporate vision is "Creating a sustainable society and inspiring the world through technology and ideas". Our goal is to solve the problems of our customers, who face increasingly diverse and complex technological issues every day, with technology and ideas that exceed their expectations, and to lead them to the next level of innovation.

More details on <https://www.cybernet.co.jp/english/>

※ CAE (Computer Aided Engineering) : An engineering technology that enables testing and experimentation in manufacturing research and development processes—which in the past would have required physical prototypes—using computer-based simulations and analyses. It offers the advantage of significantly shortening development periods and reducing materials costs by dramatically reducing the need for prototypes and numbers of actual experimental tests.

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