

BrainCool AB (publ) A new CPT Code for Cryotherapy in Patients Undergoing Chemotherapy paves the way for reimbursement for BrainCool's Cooral® System and it advances its launch in the U.S.

BrainCool AB (publ) informs that the American Medical Association (AMA) formally announced the approval of a new Current Procedural Terminology (CPT®) code for cryotherapy – using the company's Cooral® System - in patients undergoing chemotherapy (see also link below). The new code CPT 3 will be released on January 1, 2024, and become effective on July 1 2024.

The new code has several positive implications for BrainCool and its product Cooral® System. It opens for reimbursement for Cooral® System from Medicare – the U. S public health care system. Reimbursement in this case does not require a U. S-based clinical trial over a period of 5 years. This implies that BrainCool can bring forward the official launch of Cooral® System on the U. S market to mid 2024 instead of 2025/26.

Reimbursement will facilitate a more rapid penetration of the market and provide more clinical evidence of Cooral's benefits to other players than Medicare in the market such as the major private insurers. The benefits include alleviating pain to patients undergoing chemotherapy and reducing cost. The medical costs for treating oral mucositis are estimated at approximately 25,000 USD per patient.

BrainCool will in the long-term benefit in seeking to establish a reimbursement framework also for the private insurance sector. As previously announced, BrainCool will establish a robust U. S structure with a randomized, controlled trial with U. S patients only. The focus is on patients affected by lymphoma that are also treated with stem cell transplants. The clinical trial will encompass 80-100 patients with the first patient enrolled in the first quarter of 2024. The study is expected to be completed by the end of 2025.

Martin Waleij, CEO of BrainCool has commented following the approval of the code:

"We are very pleased to achieve another milestone in our plan to expand our cryotherapy technology - already used in patients recovering from cardiac and neurological trauma - to oncology patients. This milestone follows the publication of a pivotal study of the Cooral device in the prestigious Bone Marrow Transplantation journal, reporting on the efficacy of the therapy, FDA designation of the Cooral® System as a Breakthrough Device, and FDA approval of the device, enabling its marketing in the U. S. With reimbursement from Medicare the company plans to start marketing the Cooral® System in the U. S already in 2024. We also continue the preparations for the clinical trial in the US to pave the way for a broader reimbursement coverage."

The new CPT code is unique as there previously was no code at all for treating oral mucositis with cryotherapy. The application process for the code was very smooth and there were no objections on the path to approval.

<https://www.ama-assn.org/system/files/september-2023-cpt-summary-panel-actions.pdf>

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About Us

BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Nasdaq First North Growth Market, named "BRAIN".

Eminova Fondkommission AB is the company's Certified Adviser.

Attachments

[BrainCool AB \(publ\) A new CPT Code for Cryotherapy in Patients Undergoing Chemotherapy paves the way for reimbursement for BrainCool's Cooral® System and it advances its launch in the U.S.](#)