Press Release
27 June 2023 08:32:00 CEST

BrainCool AB (publ): New fast track reimbursement pathway proposal for FDA Breakthrough devices in the US

The Biden administration, with the support of the Centers for Medicare & Medicaid Services (CMS), has introduced a new pathway called Transitional Coverage for Emerging Technologies (TCET) aimed at ensuring Medicare coverage for breakthrough devices.

The TCET pathway will be accessible for FDA-designated breakthrough devices falling under a specific Medicare benefit category.

The Cooral® System, which also has a Breakthrough device designation, is approved by the US FDA since October 16, 2022. The product prevents and reliefs the serios side effect of cancer treatment, oral mucositis.

The program aims to accelerate Medicare coverage for new medical technology innovations by providing an estimated **three to five years** of transitional coverage. This transitional coverage would eventually transition into long-term coverage by Medicare.

The new TCET proposal "supports both improved patient care and innovation by providing a clear, transparent, and consistent coverage process while maintaining robust safeguards for the Medicare population," CMS said in a statement.

The proposal in short:
· The program is only applicable for products that benefit the Medicare patient population group. Patients 65 + years of age, veterans and disabled.
· CMS intends to finalize reimbursement decisions quickly, within six months of FDA market authorization.
· The program would last for three to five years as evidence is generated to address evidence gaps identified in the evidence preview and lead to a predictable, long-term Medicare coverage determination,"
· Device manufacturers will need to develop an evidence development plan (EDP) to address any evidence gaps bridging the Breakthrough device reimbursement (3 – 5 years) to the long term Medicare coverage decision. EDPs might include traditional clinical studies, fit-for-purpose studies, and secondary use of real-world data.

CMS will be taking public comment on the notice for 60 days after publication. The notice is scheduled for publication on June 27, 2023. (https://public-inspection.federalregister.gov/2023-13544.pdf)

CEO Martin Waleij comment
- "Considering that the Cooral® System aligns perfectly with the Medicare patient group, which encompasses over 50% of cancer patients in the US, this presents an excellent opportunity for BrainCool. We are already actively collaborating with Medicare for evidence development of Cooral,

and we have recently submitted a request for a new CPT code for the treatment to the American Medical Association."

About Oral Mucositis (OM)
Oral Mucositis is a highly significant and sometimes dose-limiting condition that has been reported as the most debilitating complication of cancer therapy. OM can occur in combination with a variety of debilitating symptoms that can compromise patients' ability to maintain oral hygiene. For example, unpleasant oral pain, which can lead to an increased need for painkillers and sometimes opioids administered intravenously. OM is further associated with malnutrition, weight loss, use of feeding tubes or total parenteral nutrition, and reduced quality of life, and it may represent a portal for systemic infections that can lead to sepsis and death. Taken together, these symptoms together with their related sequelae can lead to hospitalization and can increase costs for healthcare systems.

Contacts
For more information
Martin Waleij - CEO
+46 - 733 -93 70 76
E-mail: martin.waleij@braincool.se

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. The company focuses on two business segments, Brain Cooling and Oncology. 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): New fast track reimbursement pathway proposal for FDA Breakthrough devices in the US