



BrainCool AB (publ) – CMS repeals MCIT breakthrough device final rule, leaves open other coverage pathways

Today, November 12, 2021, the Centers for Medicare and Medicare Services (CMS) is rescinding the Medicare Coverage of Innovative Technology and Definition of “Reasonable and Necessary” (MCIT/R&N) final rule because of concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients. However CMS said it plans to work with FDA, medical device manufacturers and other stakeholders to "develop an expeditious process" to cover new technologies that benefit Medicare patients. Please see the press release from CMS below ^[1]. Previously, BrainCool commented the proposal published on September 14, 2021

CMS created the MCIT pathway in the last days of the Trump Administration. It was among a host of regulations the Biden Administration immediately put on hold for further consideration. This, although the MCIT pathway have had strong support from both sides of the aisle, republicans and democrats.

In a recent, November 5, letter, a bipartisan group of ten (10) lawmakers in the US Senate have urged CMS Administrator Chiquita Brooks-LaSure to propose a new rule, although a final decision had not at that point been communicated.

The major concern of the MCIT pathway have been the availability of clinical evidence on Breakthrough Devices when used in the Medicare population (age from 65 years).

CEO Martin Waleij comments:

Given the fact that in the recent clinical trial data of the Cooral System published in Bone Marrow Transplantation - Nature, the patients population have an average age of around 60 years old, we have a positive outlook of the path for reimbursement for the device in the US. We remain focused on building out our reimbursement strategy for both commercial and government payers.

Given the strong political and industry support for reimbursement of Breakthrough devices we have a positive outlook, given that the patient population of the Cooral® System in clinical trials match Medicare requirements.

[1] [CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices | CMS](#)

This disclosure contains information that BrainCool is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 2021-11-12 19:15 CET.

For more information

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

About BrainCool AB (publ)

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 Spotlight Stock Market.