

## Statement from The Memory and Aging Program at Butler Hospital on CMS National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

PROVIDENCE – The Memory and Aging Program at Butler Hospital is disappointed by the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination limiting coverage for monoclonal antibodies directed against amyloid to patients enrolled in a randomized controlled trial. This decision restricts access to this medication to patients with the means to cover the cost of treatment.

Alzheimer's disease is a progressive neurological disorder leading to disability and death and is the disease most feared by older people. Aducanumab (Aduhelm), and medicines like it, lower the build-up of amyloid plaques in the brain and may slow down the disease process, allowing patients the opportunity to remain independent longer with better quality of life. With this decision, many patients with early Alzheimer's disease will not have access to treatment. Further, other amyloid lowering drugs that may receive full approval from the FDA in the future will also be required to participate in a Coverage with Evidence Development trial, despite showing clear clinical benefit on testing, an unprecedented position that CMS has not taken with medications for other diseases.

“Clearly there needs to be improved collaboration between the FDA and CMS so that we can bring new treatments and diagnostic tests to patients who need them. The Memory and Aging Program (MAP) remains dedicated to making advances in the fight against Alzheimer's disease and to offering patients and families the very best treatment options. We are working closely with the FDA and other Alzheimer's disease experts to ensure that physicians have the information and guidance they need to safely offer these new treatments. MAP is working closely with the Alzheimer's Association, The American College of Radiology, the American College of Neuroradiology and the Brown Center for Biostatistics to create the Alzheimer's National Registry for Treatment and Diagnostics to serve as a national registry for studying the safety and efficacy of new treatments for Alzheimer's disease, aligned with CMS guidelines. Our ultimate goal is to offer patients and families the hope of greater dignity, and continue the gold standard of care they come to expect from our program,” said **STEPHEN SALLOWAY, MD, MS**, Director of Neurology and the Memory and Aging Program, Butler Hospital. ❖