



February 10, 2022

Ms. Chiquita Brooks La-Sure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS Proposed Decision Memorandum on Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

Dear Administrator La-Sure:

On behalf of the Global Down Syndrome Foundation and our partner organizations striving to improve the lives of Americans with intellectual disabilities and developmental disorders, I am writing to share our public comments on CMS' proposed National Coverage Determination (NCD) decision memorandum to cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease through coverage with evidence development (CED) for beneficiaries enrolled in qualifying clinical trials.

Many individuals have interpreted the proposed decision memorandum's clinical trial coverage exclusion for individuals with "neurological conditions" apart from Alzheimer's disease as excluding people with Down syndrome from participating in these trials and by extension from Medicare coverage. As the leading public non-profit dedicated to significantly improving the lives of people with Down syndrome as relates to research, medical care and advocacy, we rigorously oppose any and all efforts to discriminate and exclude individuals with Down syndrome from fully and completely participating in all facets of life including access to clinical trials, research, and medical care. Further, we believe excluding persons with Down syndrome from these proposed clinical trials would establish an unjust and discriminatory precedent at a time when we are making advancements in establishing equitable medical care, research, education, and employment policies.

According to the National Institutes of Health (NIH) and our own internationally recognized researchers at the Crnic Institute for Down Syndrome, an estimated 70% of individuals with Down syndrome will develop dementia due to Alzheimer's disease as they grow older. By the age of 40, most persons with Down syndrome have beta-amyloid plaques along with other protein deposits called tau tangles which are linked to Alzheimer's disease although not all individuals with these brain plaques experience dementia.

Given the high prevalence of Alzheimer's disease among individuals with Down syndrome, Congress and the NIH have recognized the importance of studying this connection, and have made important investments in research to study this co-occurrence including new basic and translational research and clinical trials involving persons with Down syndrome. If CMS were to exclude persons with Down syndrome from these clinical trials, this would say to individuals with Down syndrome that CMS does

not value their participation in important science, and will set back efforts to advance important research to improve health outcomes for persons with Down syndrome as well as typical individuals.

Given the significant health challenges facing this vulnerable population, we urge CMS to reconsider this exclusion criteria and promote efforts to ensure that persons with intellectual disabilities and developmental disorders, including Down syndrome, are able to fully participate in all current and future clinical trials and remain eligible for full Medicare coverage. We appreciate the complexity of this issue, and thank you for your kind consideration of these comments.

Respectfully,

Michelle Sie Whitten

Michelle Sie Whitten

President and CEO, Global Down Syndrome Foundation