

National Down Syndrome Society Comments to the Centers for Medicare & Medicaid Services (CMS)

Re: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease  
(CAG-00431R)

July 15, 2022

The National Down Syndrome Society (NDSS) is the leading human rights organization for all individuals with Down syndrome. NDSS envisions a world in which all people with Down syndrome have the opportunity to enhance their quality of life, realize their life aspirations, and become valued members of welcoming communities. In collaboration with our colleagues at Down Syndrome Affiliates in Action (DSAIA), GiGi's Playhouse Down Syndrome Achievement Centers, Global Down Syndrome Foundation (GLOBAL), LuMind IDSC Foundation (LuMind IDSC), National Down Syndrome Congress (NDSC), and the National Task Group on Intellectual Disabilities and Dementia Practices (NTG), and on behalf of the community we serve, NDSS writes today to respond to CMS' request for input regarding whether the current policy (220.6.20) of covering one positron emission tomography (PET) beta amyloid (also referred to as amyloid-beta ( $A\beta$ ) scan per patient lifetime should be revisited.

We recommend that CMS revisit this policy because the current coverage regime does not provide sufficient access to PET imaging for the Down syndrome community, which has a demonstrable need for more than one scan per lifetime. The need for individualized care, as well as the need for data collection and analysis make it difficult, if not impossible, for us to comment on exactly how many scans CMS should cover, but we can say definitively the current coverage regime of one-per-lifetime is insufficient. We believe that the professional discretion of health care providers on how to treat their patients should not be limited arbitrarily – including the appropriate use of PET scans to assess brain health, and we stand ready to assist CMS in bringing together the right stakeholders to work towards a reasonable, evidence-based coverage recommendation.

Ongoing work at the CMS related to Alzheimer's disease has an outsized impact on the Down syndrome community because of the genetic intersection of the two conditions: the amyloid precursor protein

(APP) gene is present on chromosome 21 and is strongly associated with the formation of amyloid peptides and plaques, a hallmark of Alzheimer's disease. Because people with Down syndrome have three copies of chromosome 21 and thus three copies of the APP gene, they are at a higher risk for developing Alzheimer's disease than people in the general population who only have two copies. In the real world, the somber reality is that individuals with Down syndrome face an estimated lifetime risk higher than 90% for developing Alzheimer's disease, with the onset of symptoms coming earlier and progressing faster than their counterparts in the general public. Because people with Down syndrome are so likely to develop Alzheimer's disease, it is critical that they receive access to high-quality medical care, including PET scans, an important method for evaluation of a patient, detection and diagnosis, efficacy of treatment for Alzheimer's disease, and testing for adverse events.

CMS determined in 2013 that there was "insufficient evidence to conclude that the use of positron emission tomography (PET) beta amyloid (also referred to as amyloid-beta (A $\beta$ ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for Medicare beneficiaries with dementia or neurodegenerative disease." This one-size-fits-all approach is non-inclusive and does not reflect what both the research community and the broader disability community have learned about the relationship between Alzheimer's disease and Down syndrome in the intervening years. People with Down syndrome benefit from and need access to PET scans for multiple reasons:

#### Patient Evaluation and Diagnostic Use

Because people with Down syndrome develop Alzheimer's disease on a different timeline than patients who do not have Down syndrome – both in terms of onset and rate of progression – good patient care requires consistent monitoring as well as a patient-specific understanding and analysis of disease progression, with a baseline observed and recorded at the right time. A single PET scan is not sufficient to do so, as it could easily be utilized at the wrong moment, potentially identifying an inaccurate initial understanding of a patient's condition. Similarly, one scan – one snapshot – will never be enough to monitor the progression of the disease over time. The existing policy of covering only one scan per lifetime deprives this patient population of a useful diagnostic tool that can and should be used by health care providers to provide improved care.

### Measuring Efficacy of Treatment

Another use of PET scans is to monitor the effectiveness of treatments for Alzheimer's disease, whether meant to address the cause or the symptoms of disease. As both FDA and CMS have been and continue to explore new developments in anti-amyloid treatments, we are entering a period where monitoring effectiveness is especially important for researchers and health care providers to understand the safety and efficacy of these new treatments. Covering one scan per patient lifetime limits the data produced per case, chilling the field's understanding of how Alzheimer's disease functions in the Down syndrome population.

### Monitoring for Adverse Events and Reactions to Interventions

The National Down Syndrome Society has previously shared with CMS its concerns about the predisposition of members of our community to develop microhemorrhages – brain bleeds – and in 2021 we recommended that CMS take action to ensure these patients have access to diagnostic imaging tools, including PET scans, to ensure their health care providers are well-equipped to ensure their safety. Now, as CMS is considering revisiting its existing PET coverage policy, the agency has the opportunity to respond to that recommendation in a meaningful way that will have a direct impact on the quality of care our population is able to receive.

### Conclusion

NDSS, along with our co-signing organizations, strongly urges CMS to revisit its coverage for positron emission tomography (PET) beta amyloid (also referred to as amyloid-beta ( $A\beta$ )) imaging and increase the limit to more than one per patient lifetime. PET scans are an important tool for health care practitioners, enabling them to provide better care to their patients. They are similarly an important way for researchers to understand the safety and efficacy of new and developing interventions. For more information regarding these comments, please contact us at [info@ndss.org](mailto:info@ndss.org). We look forward to working with you on this important issue.

Sincerely,

A handwritten signature in black ink that reads "Kandi Pickard". The signature is written in a cursive, flowing style.

Kandi Pickard

President and CEO

National Down Syndrome Society

Co-signing Organizations

Down Syndrome Affiliates in Action (DSAIA)

GiGi's Playhouse Down Syndrome Achievement Centers

Global Down Syndrome Foundation (GLOBAL)

LuMind IDSC Foundation (LuMind IDSC)

National Down Syndrome Congress (NDSC)

National Task Group on Intellectual Disabilities and Dementia Practices (NTG)