

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

Re: Proposed Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

(CAG-00431R)

August 16, 2023

The National Down Syndrome Society (NDSS) empowers individuals with Down syndrome and their families by driving policy change, providing resources, engaging with local communities, and shifting public perceptions. In collaboration with our colleagues at Down Syndrome Affiliates in Action (DSAIA), GiGi's Playhouse Down Syndrome Achievement Centers, LuMind IDSC Foundation (LuMind IDSC), 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' proposed decision memo for the coverage of positron emission tomography (PET) beta amyloid imaging.

NDSS and the undersigned organizations wrote to CMS on July 15th, 2022, urging the agency to revisit the PET imaging coverage policy because the 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. We appreciate CMS' consideration of ours and other's input and the development of the proposed decision memo which removes the coverage with evidence determine (CED) and allows for coverage for more than one scan in a patient's lifetime. As we shared in our original letter, the Down syndrome community is uniquely positioned in the Alzheimer's landscape and subsequently in the need for PET imaging because the amyloid precursor protein (APP) gene, which is strongly associated with the formation of amyloid peptides and plaques, sits on the 21st chromosome. 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. 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.

We are concerned that the proposed decision memo permits Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors (MACs) under §1862(a)(1)(A) of the Social Security Act (the Act). If CMS determines that coverage should be determined through the MACs, it could result in some regions being covered for one scan per lifetime while another region may not impose these coverage limitations. This would be discriminatory to individuals in regions with limited coverage who could benefit from the more robust coverage determinations that other MACs offer. Variability in coverage and beneficiary access will result in delayed access to potential treatment that could drastically improve outcomes and quality of life for individuals with and without disabilities. Furthermore, while a CED authorizes coverage for individuals in the fee-for-service and Medicare Advantage programs, if the MACs make the decision about coverage, such coverage requirement does not apply to Medicare Advantage plans. This means that individuals with Down syndrome may not have choices regarding their coverage if it is inconsistent, thereby limiting access to potential therapies. **We believe that Medicare coverage for PET imaging should be uniform for all beneficiaries, including individuals with Down syndrome, who are enrolled in Medicare and being assessed for potential treatment of amyloid plaques.**

NDSS, along with our co-signing organizations, strongly urge CMS to establish a **uniform** coverage policy of PET scans based on medical necessity and without a one per lifetime limit. We value our discussions and work with CMS on positive efforts to ensure appropriate access to health care services for individuals with Down syndrome and we look forward to continuing to work with you on this important issue. For more information regarding these comments, please contact us at policy@ndss.org.

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

LuMind IDSC Foundation (LuMind IDSC)

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