



David Dolan
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

August 11, 2021

Submitted electronically via www.cms.gov.
Re: CAG-00460N

Dear Mr. Dolan:

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. We write in response to the call for stakeholder input from the Centers for Medicare and Medicaid Services regarding the *National Coverage Determination (NCD) Tracking Sheet for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)*.¹

NDSS, along with LuMind IDSC and The National Task Group on Intellectual Disabilities and Dementia Practices is encouraged by new developments in medications that help those persons with Alzheimer's disease in the United States. Consistent with the actions noted in the National Plan to Address Alzheimer's Disease, we commend the federal government's efforts to encourage innovation in developing medications that may effectively treat or delay the progression of Alzheimer's disease. As these developments continue, we will work to ensure the voices of individuals with Down syndrome (DS) are part of the discussion in all corners of the healthcare space.

As such new medications are authorized for use by the FDA, we urge CMS to ensure that all application efforts consider neuroatypical adults, such as those with Down syndrome, and work to ensure that the impact, utility and safety of these treatments are given due consideration. To advance these priorities, we are pleased to offer the following recommendations:

1. Both Medicare program plans and commercial plans should always include individuals with Down syndrome in all coverage of new therapies or benefits. Exclusion or denial of coverage for an underlying health condition is prohibited under most types of coverage, including employer-sponsored coverage and Medicare.
2. In its administration of Medicare and Medicaid, CMS should ensure that coverage policies do not limit the professional latitude of physicians to make an individualized assessment and diagnosis as well as develop a treatment plan. Physicians with patients with Down syndrome

¹ <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=305>

should be authorized to use what biomarker and other diagnostic tools are in place for the general population as a basis for determining eligibility for any medication authorized for use to mitigate the effects of Alzheimer's disease and permitted to use their judgment when determining whether a patient has sufficient amyloid plaque accumulation to substantiate a diagnosis of Alzheimer's disease. Likewise, a physician should have the professional autonomy to make a shared decision with the individual with Down syndrome and his/her family whether the benefits of the treatment outweigh the risks for the individual with Down syndrome. This is particularly critical for the adults with Down syndrome, who tend to be more susceptible to drug-related adverse events, such as brain bleeds (microhemorrhages).

3. Cost for this treatment should be reasonable. Many adults with Down syndrome cannot afford a copayment, or their secondary coverage, such as Medicaid, will not pay. Ability to pay should not be an impediment to treatment.

Additionally, we urge CMS to ensure there is adequate coverage of imaging services (PET, MRI) for individuals with Down syndrome. The current Medicare imaging rules contain certain restrictions on payment for imaging. However, individuals with Down syndrome suspected of having co-occurring Alzheimer's disease need diagnostic imaging to gauge whether they are likely to experience side effects from a new Alzheimer's procedure or drug treatment and to determine whether the treatment is effective.

NDSS asks that, in proceeding with this NCD, CMS remains committed to equity and is cognizant of the special circumstances that adults with atypical life situations, such as Down syndrome, face in receiving high-quality healthcare. Recognizing that therapy and safety profiles for individuals with Down syndrome may be different than those for neurotypical patients, NDSS will continue to promote the safety of the Down syndrome community by advocating for the inclusion of individuals with Down syndrome in all stages of the development and rollout of treatment, including discovery and development, preclinical research, clinical research, review, safety monitoring and public rollout.

We thank the Centers for Medicare & Medicaid Services for the opportunity to comment on this analysis. The National Down Syndrome Society is eager to work with CMS to promote positive outcomes for the Down syndrome community throughout the NCA process. For further information regarding these comments, please contact us at info@ndss.org.

Sincerely,

A handwritten signature in black ink that reads "Kandi Pickard". The signature is fluid and cursive, with a large loop at the end of the last name.

Kandi Pickard
President and CEO, National Down Syndrome Society

Further Background and Explication:

Down syndrome is a condition resulting from a person's birth with an extra copy of chromosome 21. Approximately 1 in 1,563 Americans has Down syndrome, and it is the most common genetic cause of intellectual disability. In addition to utilizing services associated with intellectual disability, individuals with Down syndrome frequently have a variety of co-occurring medical conditions that contribute to medical complexity and require individualized, coordinated treatment, and supports.

Advances in medicine and care have contributed to a dramatic increase in the life expectancy of people with Down syndrome in the United States. Life expectancy has risen from 25 years in 1983 to 60 years today. While this progress is fantastic news, it has also spotlighted an issue: individuals with Down syndrome develop diseases associated with aging much younger than their counterparts in the general population—this is the case with Alzheimer's disease. Of the approximately 210,000 individuals with Down syndrome in the United States, about 40% are over 30 years of age, and most older adults with Down syndrome are eventually diagnosed with Alzheimer's disease and are likely to experience early-onset dementia. Alzheimer's disease is the leading cause of death for adults with Down syndrome.²

We are pleased to offer specific answers to the questions posed by CMS, reflective of the aforementioned recommendations:

1. Which health outcomes are important, and what degree of improvement in them is meaningful for patients receiving treatment?

It is incumbent upon CMS to reduce systemic barriers that restrict coverage and reduce access to the breadth of professional care and supports they might need – including new treatments for conditions they are likely to experience, such as Alzheimer's disease. In this specific instance, physicians with patients with Down syndrome should be able to utilize appropriate biomarker and other diagnostic protocols as a basis for determining eligibility for any medication to mitigate the effects of Alzheimer's disease that is authorized for use. They should be permitted to exercise their professional judgment in determining whether a patient has amyloid plaque accumulation and is living with Alzheimer's disease. Physicians must have the latitude to make an individualized assessment and diagnosis and to develop a personalized treatment plan. **NDSS recommends that, in making coverage determinations related to care for individuals with Down syndrome with complex care needs, CMS defer to physicians' judgment to the maximum extent reasonable.**

2. What characteristics of patients with Alzheimer's disease are important to optimizing the likelihood of positive health outcomes from treatment?

Time is a critical consideration to promote good outcomes for individuals with Down syndrome who develop Alzheimer's disease, both because they tend to experience symptoms earlier than those who develop the disease but do not have Down syndrome and because the disease progresses more rapidly in those with Down syndrome. Early identification and ready access to information and treatment are critical. **NDSS recommends that CMS ensure expedited access to services and treatment for Alzheimer's disease for individuals with Down syndrome because of early-onset and rapidly progressing symptoms.**

² <https://www.mdpi.com/2077-0383/10/9/1907>

A second important characteristic is the propensity of individuals with Down syndrome to develop microhemorrhages. To gauge whether an individual with Down syndrome is likely to experience side effects from a new Alzheimer's procedure or drug treatment and to determine whether treatment is effective, they need access to diagnostic imaging services, such as PET scans and MRIs. Currently Medicare imaging rules contain certain restrictions on payment for these services. **NDSS recommends that CMS ensure that diagnostic imaging services are covered for individuals with Down syndrome, and furthermore that they are not cost-prohibitive, and we recommend that Medicare cover imaging for individuals with Down syndrome without requiring their physician to consult a clinical decision support mechanism.**

3. What issues of equity and inclusion must be accounted for in the diagnosis and treatment of Alzheimer's disease?

As a general matter of equity, individuals with Down syndrome must have access to treatments and supports related to Alzheimer's disease because of the significant coincidence of the two conditions, including as especially to any new therapies that are developed. Access to today's treatments likely means people can extend the portion of their lives with few – or no – symptoms of Alzheimer's disease; in the future, treatment might prevent, curtail, or even reverse the symptoms. While exclusion from or denial of coverage for an underlying health condition – in this case Down syndrome – are already prohibited under most types of coverage, including employer-sponsored coverage and Medicare, **NDSS recommends that CMS proactively work to ensure that people with Down syndrome, because of their high risk, are prioritized in the delivery of treatment or supports related to Alzheimer's disease.**

An associated equity issue relates to patient cost once coverage of treatments has been established. While coinsurance for medical care, in an absolute sense, is an unavoidable reality, Alzheimer's treatments must not be unattainable for people who rely on them for their very survival. Due to longstanding issues in the education and employment systems all across the United States, however, many adults with Down syndrome simply cannot afford expensive copayments, and in many cases their secondary coverage, such as Medicaid, will not pay. **NDSS recommends that CMS work to ensure coinsurance for existing and future Alzheimer's disease treatments is affordable so that inability to pay will not be tantamount to denial of coverage.**

4. What health care providers should be included as part of the patient's treatment team? Should medical specialists be included in the care team of patients receiving treatment? If so, which specialists should be included in the care?

The individual's physician should have the professional autonomy to make a shared decision with the person with Down syndrome, their family, and the rest of the team about whether the benefits of a given treatment outweigh the risks. This need for conference is particularly critical for members of the people with Down syndrome, who are often more susceptible to drug-related adverse events, such as microhemorrhages. Because there is a lack of Down syndrome specific training for specialists, disparities in access to quality care persist between adults with Down syndrome and age peers in the general public. Further, the development of protocols would help guide physicians who are not already familiar with effective methods to assess the benefits and risks of different treatments and therapies for people with Down syndrome. **To promote informed decision-making among individuals with Down syndrome, their families, and their team of caregivers, NDSS recommends that CMS provide technical assistance, best-practice protocols and guidance documents related to the impact of different courses of treatment on those with Down syndrome as new treatments are developed and approved.**

5. *In what setting(s) should treatment and care be given?*

Individuals with Down syndrome – and indeed all types of patients – should be able to receive treatment and care in safe, convenient, and equitable locations. For people with Down syndrome, who often require assistance traveling to healthcare appointments, accessibility of location is a key factor. In the specific context of adult-focused healthcare, such as treatment for Alzheimer’s disease, additional considerations are at play: some adults with Down syndrome live independently but might need travel accommodations; others live with aging parents who themselves might have trouble getting around; still others live in group environments. Other access issues, such as rurality and the availability and accessibility of both emergency and non-emergency medical transport, are not unique to the Down syndrome community but nonetheless apply. Furthermore, individuals with Down syndrome may require assistance or accommodation after arriving at the destination where treatment will be administered, so treatment settings must be ready to accommodate those needs. **NDSS recommends that CMS work to ensure that treatment and care are accessible to the Down syndrome community so that geographic and structural barriers to access do not result in denial of treatment.**