NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Donanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation 1

1.	Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

The issues identified in scoping were:

- Early onset (<65) dementia might be examined separately due to greater costs of disease on families, increased chance of having amyloid pathology confirmed, potentially more tolerant of monitoring, less likely to die of other conditions and more likely to see longer term benefits, also they have fewer comorbidities.
- People with Down's syndrome are universally amyloid positive by mid-life. Since studies in this group, have not been undertaken, safety and efficacy is not known.
- People with mild dementia or mild cognitive impairment due to Alzheimer's disease are not routinely tested for amyloid pathology in the NHS. A large majority are diagnosed and treated in psychiatry-led services where the delivery of infusions and monitoring would be challenging. This means that there is a high risk that existing geographical and demographic inequalities in access to a diagnosis of Alzheimer's disease will become inequalities in access to a disease-modifying treatment.
- Beyond significant regional variation in dementia diagnosis rates, there are further structural and cultural inequalities in diagnosis, symptom presentation and care amongst people from different ethnic groups and cultural populations.

See section 2 for how the committee addressed these.

2. Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the committee addressed these?

The issues raised were similar to those raised during scoping but from a wider group of submitting organisations. The issues are summarised as follows:

- There is current inequality in terms of who has an Alzheimer's disease diagnosis and accessing care. This will be exacerbated by introducing the complex diagnostic pathway for donanemab. People without a caregiver who can help them get a timely diagnosis will be among those disadvantaged.
- People with Down's syndrome (who have a 90% lifetime risk of developing Alzheimer's disease), people with young-onset dementia and people from diverse family backgrounds were not fully represented in TRAILBLAZER-ALZ 2 trial. These groups are at risk of being excluded from accessing donanemab.
- Donanemab would need significant increases in NHS capacity for service delivery. Inequalities may increase as existing services that are already under strain would be needed to deliver the treatment. The effect of this is likely to be seen more profoundly for people in deprived socioeconomic circumstances.

In relation to the issues identified in sections 1 and 2: The committee noted the concerns raised with getting a diagnosis, accessing care in a new and complex pathway, and substantial demand on NHS services. It understood these concerns but noted that they were outside of its remit. The committee understood that some people with Alzheimer's disease have Down's syndrome and may be considered disabled under the Equality Act 2010. It also noted that age, sex, family background and disability are protected characteristics under the Equality Act 2010. The committee agreed that any recommendation should not restrict access to treatment for some people over others on the basis of protected characteristics.

3.	Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?
No other issues identified.	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No.	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No.	

6.	Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
No.	

7.	Have the committee's considerations of equality issues been described in the draft guidance, and, if so, where?
Yes, see section 3.24	

Approved by Associate Director (name): Ross Dent

Date: 21/10/2024

Consultation 2

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?
No new issues were raised in response to consultation.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
The recommendations have not changed after consultation	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
The recommendations have not changed after consultation	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
The recommendations have not changed after consultation	

5.	Have the committee’s considerations of equality issues been described in the draft guidance, and, if so, where?
Yes, see section 3.29	

Approved by Associate Director (name): Ross Dent

Date: 25/02/2025

Final draft guidance

1.	Have any additional potential equality issues been raised during the second consultation, and, if so, how has the committee addressed these?
No new issues were raised in response to the second consultation.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
The recommendations have not changed after the second consultation.	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
The recommendations have not changed after the second consultation.	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
The recommendations have not changed after the second consultation.	

5.	Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?
Yes, see section 3.27.	

Approved by Associate Director (name): Ross Dent

Date: 10/06/2025