NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

MTA/ Natalizumab (originator and biosimilar) for treating highly active relapsing–remitting multiple sclerosis after disease-modifying therapy

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

Consultation

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

At scoping consultation it was raised that:

- multiple sclerosis affects 2 to 3 times more women than men. Therefore, a negative recommendation has the potential to disproportionately negatively impact women.
- a negative recommendation would disproportionately negatively impact younger people as natalizumab offers fewer restrictions on family planning than other treatments for multiple sclerosis.
- natalizumab is contraindicated for patients with increased risk for opportunistic infections, including immunocompromised patients but it is likely to be safer than other treatments for multiple sclerosis in this population.
- because natalizumab has the potential for home administration, a negative recommendation would disproportionately affect people who live far from a treatment centre, particularly those for whom travelling is difficult, or have more limited access to transport.

These have been considered by the committee:

- The committee noted that the issue of sex-related disease prevalence could not be addressed in a technology appraisal.
- The committee noted that the onset of MS may coincide with family planning and that most high-efficacy disease-modifying therapies cannot be used when pregnant or planning a pregnancy. Pregnancy and maternity are protected characteristics under the Equality Act 2010. The committee recalled that natalizumab had proven safety data in pregnancy, so a positive recommendation for natalizumab in highly active RRMS would address this unmet need. The committee considered this in its decision making.
- NICE can only make a recommendation within the marketing authorisation of a technology. Use of natalizumab in the population for whom it is contraindicated would be considered off label. The committee noted that this is not an equality issue.
- The committee recalled that subcutaneous natalizumab is normally administered in secondary care. So it considered that this is not an equality issue for the is appraisal.

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 professional organisation also stated that currently, people with highly active RRMS have to wait for another, potentially disabling relapse to meet the criteria for rapidly evolving severe RRMS to access natalizumab. The committee noted that this is not an equality issue.

3.	Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No

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?
N/A	

7.	Have the committee's considerations of equality issues been described in the draft guidance, and, if so, where?
Yes, section 3.25	

Approved by Associate Director (name): ……Richard Diaz……

Date: 05/03/2025

Final draft guidance

(when draft guidance issued)

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?
Stakeholders at the second committee meeting highlighted that people with MS who are older have higher risk of infections or have comorbidities that complicate management decisions would benefit more from natalizumab's non-immunosuppressive mechanism of action. The committee considered this in its decision making.	

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?
Natalizumab is recommended only when characteristics of the person and the activity of their MS mean that cladribine is not suitable. Cladribine is considered by clinicians to be a lower efficacy treatment for highly active RRMS compared to biologics, so is unlikely to be used in the population who would otherwise have natalizumab. See section 3.3. of the final draft guidance for further details.	

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?
No	

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?
No	

5.	Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?
Yes, section 3.26 of the final draft guidance	

Approved by Associate Director (name): …Richard Diaz ……

Date: 19 Dec 2025