



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

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Equality Screening, Disability Duties and Human Rights Assessment Template

Part 1 – Policy scoping

Part 2 – Screening questions

Part 3 – Screening decision

Part 4 – Monitoring

Part 5 – Disability Duties

Part 6 – Human Rights

Part 7 – Approval and Authorisation

Guidance on completion of the template can be found on the Equality Commission website at [S75 screening template 2010 \(web access checked 230920\) .docx](#)

Part 1. Policy scoping

1.1 Information about the policy

Name of the policy:

NICE Technology Appraisal TA1126 - Natalizumab (originator and biosimilar) for treating highly active relapsing–remitting multiple sclerosis after disease-modifying therapy

Is this an existing, revised or a new policy?

New

What is it trying to achieve? (intended aims/outcomes)

This guidance provides evidence-based recommendations on natalizumab originator (Tysabri) and biosimilar (Tyruko) for treating highly active relapsing–remitting multiple sclerosis after disease-modifying therapy in adults.

Natalizumab (subcutaneous originator and intravenous biosimilar)

Natalizumab (subcutaneous originator or intravenous biosimilar) can be used as an option to treat highly active relapsing–remitting multiple sclerosis (RRMS) in adults, only if:

- it has not responded to a full and adequate course of at least 1 disease-modifying therapy
- the characteristics of the person and the activity of their MS mean that cladribine is not suitable.

Natalizumab (subcutaneous originator or intravenous biosimilar) can only be used if the companies have an agreed price within the Medicines Procurement and Supply Chain.

Natalizumab (intravenous originator)

Natalizumab (intravenous originator) **should not be used** to treat highly active RRMS that has not responded to a full and adequate course of at least 1 disease-modifying therapy in adults.

Are there any Section 75 categories which might be expected to benefit from the intended policy?
If so, explain how.

This guidance should benefit clinical suitable adult patients with highly active relapsing–remitting multiple sclerosis (RRMS).

Who initiated or wrote the policy?

National Institute for Health and Care Excellence (NICE)

Who owns and who implements the policy?

NICE owns the policy. The Department determines whether the policy should be endorsed for Northern Ireland, and, if endorsed, the SPPG / HSC Trusts implement it.

1.2 Implementation factors

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision?

No (Northern Ireland currently does not have access to MPSC contract prices. However, NICE has confirmed with RPhPS that Northern Ireland’s revised price for natalizumab biosimilar is within the cost-effective range).

1.3 Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon? (please delete as appropriate)

staff

service users

other public sector organisations

voluntary/community/trade unions

other, please specify __ Families/Carers _____

1.4 Other policies with a bearing on this policy

- what are they? NICE Technology Appraisal TA127 - Natalizumab for treating rapidly evolving severe relapsing–remitting multiple sclerosis (endorsed by DoH in January 2008) - <https://www.nice.org.uk/guidance/ta127>
- who owns them? NICE/DoH

1.5 Available evidence

What evidence/information (both qualitative and quantitative¹) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

In developing this guidance, NICE have assessed its equality impact in scoping, consulting and before issuing the final guideline. This process is designed to mitigate the impact on equality. In addition, DoH locally consult on equality and human rights issues.

Religious belief evidence / information:

Religion will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their religious belief.

Political Opinion evidence / information:

Political opinion will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their political opinion.

Racial Group evidence / information:

Ethnicity will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their ethnicity.

Age evidence / information:

The NICE guidance is aimed at clinically suitable adult patients.

¹ * **Qualitative data** – refers to the experiences of individuals related in their own terms, and based on their own experiences and attitudes. Qualitative data is often used to complement quantitative data to determine why policies are successful or unsuccessful and the reasons for this.

Quantitative data - refers to numbers (that is, quantities), typically derived from either a population in general or samples of that population. This information is often analysed either using descriptive statistics (which summarise patterns), or inferential statistics (which are used to infer from a sample about the wider population).

Marital Status evidence / information:

Marital status will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their marital status.

Sexual Orientation evidence / information:

Sexual orientation will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their sexual orientation.

Men & Women generally evidence / information:

During the NICE evaluation it was noted that the onset of MS may coincide with family planning and recalled that most high-efficacy disease-modifying therapies cannot be used in pregnancy or when pregnancy is planned. However, the NICE 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. Gender will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of their gender.

Disability evidence / information:

Disability will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients irrespective of disability.

Dependants evidence / information:

Dependant status will have no bearing on the guidance, the NICE guidance is aimed at clinically suitable patients, regardless of whether they have dependants.

1.6 Needs, experiences and priorities

Taking into account the information referred to above, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision?

Specify details of the needs, experiences and priorities for each of the Section 75 categories below:

Religious belief

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that different religions will have any different needs, experiences, priorities or issues in relation to the guidance.

Political Opinion

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that different political opinions will have any different needs, experiences, priorities or issues in relation to the guidance.

Racial Group

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that different racial groups will have any different needs, experiences, priorities or issues in relation to the guidance.

Age

The NICE guidance relates to and should benefit all clinically suitable adult patients, in particular people with MS who are older and who often have a higher risk of infections or have comorbidities that complicate management decisions.

Marital status

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that those of different marital status will have any different needs, experiences, priorities or issues in relation to the guidance.

Sexual orientation

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that different sexual orientation will have any different needs, experiences, priorities or issues in relation to the guidance.

Men and Women Generally

The NICE guidance relates to and should benefit all clinically suitable patients. However, during the NICE evaluation it was highlighted that a higher proportion of people with highly active RRMS are female than male.

Disability

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that people with disabilities will have any different needs, experiences, priorities or issues in relation to the guidance.

Dependants

The NICE guidance relates to and should benefit all clinically suitable patients. There is no evidence that those of different dependant status will have any different needs, experiences, priorities or issues in relation to the guidance.

Part 2. Screening questions

2.1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? minor/major/none

Details of the likely policy impacts on Religious belief: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Political Opinion: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Racial Group: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Age: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Marital Status: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Sexual Orientation: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Men and Women: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Disability: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Dependents: No impact on equality of opportunity

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

2.2 Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories? Yes/ No

Detail opportunities of how this policy could promote equality of opportunity for people within each of the Section 75 Categories below:

Religious Belief - If Yes, provide details:
If No, provide reasons: No evidence to support this

Political Opinion - If Yes, provide details:
If No, provide reasons: No evidence to support this

Racial Group - If Yes, provide details:
If No, provide reasons: No evidence to support this

Age - If Yes, provide details:
If No, provide reasons: No evidence to support this

Marital Status - If Yes, provide details:
If No, provide reasons: No evidence to support this

Sexual Orientation - If Yes, provide details:
If No, provide reasons: No evidence to support this

Men and Women generally - If Yes, provide details: this
If No, provide reasons: No evidence to support

Disability - If Yes, provide details:
If No, provide reasons: No evidence to support this

Dependants - If Yes, provide details:
If No, provide reasons: No evidence to support this

2.3 To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group?

Please provide details of the likely policy impact and determine the level of impact for each of the categories below i.e. either minor, major or none.

Details of the likely policy impacts on Religious belief: The policy will not impact on good relations

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Political Opinion: The policy will not impact on good relations

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

Details of the likely policy impacts on Racial Group: The policy will not impact on good relations

What is the level of impact? ~~Minor~~ / ~~Major~~ / None (circle as appropriate)

2.4 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?

Detail opportunities of how this policy could better promote good relations for people within each of the Section 75 Categories below:

Religious Belief - If Yes, provide details:
If No, provide reasons: No evidence to support this

Political Opinion - If Yes, provide details:
If No, provide reasons: No evidence to support this

Racial Group - If Yes, provide details:
If No, provide reasons: No evidence to support this

2.5 Additional considerations

Multiple identity

Generally speaking, people can fall into more than one Section 75 category.

Taking this into consideration, are there any potential impacts of the policy/decision on people with multiple identities?

(For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people).

No impact. This guidance will benefit all relevant service users, including those with multiple identities.

Provide details of data on the impact of the policy on people with multiple identities. Specify relevant Section 75 categories concerned.

N/A

2.6 Was the original policy / decision changed in any way to address any adverse impacts identified either through the screening process or from consultation feedback. If so please provide details.

N/A

Part 3. Screening decision

3.1 Would you summarise the impact of the policy as; No Impact/ Minor Impact/ Major Impact?

No Impact

3.2 Do you consider that this policy/ decision needs to be subjected to a full equality impact assessment (EQIA)?

No

3.3 Please explain your reason.

This guidance will impact on all sections of the community equally.

3.4 Mitigation

When the public authority concludes that the likely impact is 'minor' and an equality impact assessment is not to be conducted, the public authority may consider mitigation to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

No

If so, give the reasons to support your decision, together with the proposed changes/amendments or alternative policy.

N/A

3.5 Timetabling and prioritising

Factors to be considered in timetabling and prioritising policies for equality impact assessment.

If the policy has been ‘**screened in**’ for equality impact assessment, then please answer the following questions to determine its priority for timetabling the equality impact assessment.

On a scale of 1-3, with 1 being the lowest priority and 3 being the highest, assess the policy in terms of its priority for equality impact assessment.

Effect on equality of opportunity and good relations – **Rating** ____ (1-3)

Social need – **Rating** ____ (1-3)

Effect on people’s daily lives – **Rating** ____ (1-3)

Relevance to a public authority’s functions – **Rating** ____ (1-3)

Note: The Total Rating Score should be used to prioritise the policy in rank order with other policies screened in for equality impact assessment. This list of priorities will assist the public authority in timetabling. Details of the Public Authority’s Equality Impact Assessment Timetable should be included in the quarterly Screening Report.

Is the policy affected by timetables established by other relevant public authorities?

N/A

If yes, please provide details.

Part 4. Monitoring

Monitoring is an important part of policy development and implementation. Through monitoring it is possible to assess the impacts of the policy / decision both beneficial and adverse.

4.1 Please detail how you will monitor the effect of the policy / decision?

To provide further assurance regarding implementation, the Regulation Quality Improvement Authority (RQIA) will extend its support of regional audits to cover some clinically based NICE guidance and will look at a sample of the technology appraisals each year.

4.2 What data will you collect in the future in order to monitor the effect of the policy / decision?

N/A

Please note: - For the purposes of the annual progress report to the Equality Commission you may later be asked about the monitoring you have done in relation to this policy and whether that has identified any Equality issues.

Part 5. Disability Duties

5.1 Does the policy/decision in any way promote positive attitudes towards disabled people and/or encourage their participation in public life?

N/A

5.2 Is there an opportunity to better promote positive attitudes towards disabled people or encourage their participation in public life by making changes to the policy/decision or introducing additional measures? N/A

N/A

Part 6. Human Rights

6.1 Does the policy / decision affects anyone's Human Rights?

Not applicable to NICE guidance.

6.2 If you have identified a likely negative impact who is affected and how?

At this stage we would recommend that you consult with your line manager to determine whether to seek legal advice and to refer to Human Rights Guidance to consider:

- whether there is a law which allows you to interfere with or restrict rights*
- whether this interference or restriction is necessary and proportionate*
- what action would be required to reduce the level of interference or restriction in order to comply with the Human Rights Act (1998).*

N/A

6.3 Outline any actions which could be taken to promote or raise awareness of human rights or to ensure compliance with the legislation in relation to the policy/decision.

N/A