

## NHS England: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. **Name of the proposal (policy, proposition, programme, proposal or initiative):** Obinutuzumab elective therapy to prevent immune TTP relapse in patients who are refractory or intolerant to rituximab (adults) [2255]

2. **Brief summary of the proposal in a few sentences**

This policy is focused on the drug obinutuzumab as an elective therapy for patients with TTP who have ADAMTS13 relapse (immunological relapse). Immune TTP is a critical medical condition requiring immediate transfer for treatment; 50% require critical care admission and without treatment, the mortality in acute immune TTP is >90%. There are approximately 100-150 new cases of acute immune TTP per year across the UK. Of those cases, approximately 10% relapse, requiring further treatment. Roughly 10-30 patients a year requiring further treatment will be refractory or intolerant to rituximab, thus requiring alternative anti-CD20 therapy.

The clinical policy was developed through conducting an externally conducted evidence review and by a Policy Working Group (PWG) consisting of haematology experts, a public health specialist and specialised commissioner for NHS England. This policy recommends that obinutuzumab is made available as an option in adults if they have ADAMTS13 relapse and meet the criteria outlined in the policy.

3. **Main potential positive or adverse impact of the proposal for protected characteristic groups summarised**

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A** if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p><b>Age:</b> older people; middle years; early years; children and young people.</p>	<p>Acute immune mediated TTP can affect all ages, although it is exceedingly rare in children. The average age at diagnosis is 40 years (TTP Registry).</p>	<p>This policy aims to make obinutuzumab available for all adult patients with ADAMTS13 relapse if clinically eligible.</p> <p>Obinutuzumab is only licenced for use in adults. The safety data for obinutuzumab does not include pre-pubescent children. Therefore, this policy is adult focused, but would allow post-puberty access, for children and young people meeting the inclusion criteria, as per Commissioning Medicines for Children in Specialised Services Policy (commissioning-medicines-children-specialised-services.pdf (england.nhs.uk)).</p>
<p><b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>Human Immunodeficiency Virus (HIV) is a long-term condition and a risk factor for TTP, with an estimated 40-fold increased incidence of TTP in HIV-infected patients compared with that in the general population (Miller et al. 2005).</p> <p>The aim of the policy is to improve patient outcomes, so will have a potential positive impact on patients with TTP and HIV and/or other co-morbidities.</p> <p>However, there may be concerns about the sharing of relevant clinical information between different treatment centres.</p>	<p>This policy proposes that treatment is initiated and reviewed by a specialist TTP MDT. This will enable the appropriate selection of patients who will benefit from the intervention and mean the drug will be stopped in those gaining no benefit or where the side effect profile is too great. This should mean the greatest benefit is gained from improving physical and mental health and reducing the impact of a long-term condition.</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<b>Gender Reassignment and/or people who identify as Transgender</b>	There should be no direct negative or positive impact on this group as people who have undergone gender reassignment and/or people who identify as transgender have not been identified as a high-risk group.	Not applicable
<b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.	There should be no direct negative or positive impact on this group as marriage/civil partnership has not been identified as a high-risk group.	Not applicable
<b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.	Pregnancy/ immediate post-partum period is a risk factor for TTP (McMinn & George, 2001). Therefore, this policy will disproportionately impact pregnant women who develop TTP.  This impact is intended to be positive due to improved patient outcomes.	Specific considerations should be given to pregnant women/ women who are immediately post-partum as they may have other specific needs including issues around shared care and access to antenatal/ postnatal/ neonatal services.
<b>Race and ethnicity<sup>1</sup></b>	Being of black race is a risk factor for TTP (BMJ Best Practice). Therefore, this policy will disproportionately impact people of black race who develop TTP.	All patients who meet the inclusion criteria would be considered for obinutuzumab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

<sup>1</sup> Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p><b>Religion and belief:</b> people with different religions/faiths or beliefs, or none.</p>	<p>Included within the treatment pathway for TTP is plasma exchange (PEX). As PEX involves the transfusion of plasma, a primary component of blood, patients who are Jehovah's Witness may refuse the treatment (George et al. 2017).</p> <p>Although this policy is focused on obinutuzumab, as PEX is part of the treatment pathway for TTP, this issue is important to highlight and would have an adverse impact on people who follow the Jehovah's Witness faith.</p>	<p>Specific considerations need to be given to alternative treatment options to PEX for patients with TTP who follow the Jehovah's Witness faith. Alternatives to PEX should be identified in the treatment pathway.</p>
<p><b>Sex:</b> men; women</p>	<p>TTP affects both males and females but two-thirds of the patients with TTP are females (TTP Registry). Therefore, this policy will disproportionately impact women who develop TTP. This impact is intended to be positive due to improved patient outcomes.</p>	<p>All patients who meet the inclusion criteria would be considered for obinutuzumab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.</p>
<p><b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.</p>	<p>There should be no direct negative or positive impact on people based on their sexual orientation compared to all patients with TTP.</p>	<p>Not applicable.</p>

#### 4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A** if your proposal will not impact on patients who experience health inequalities.

Groups who face health inequalities <sup>2</sup>	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<b>Looked after children and young people</b>	TTP is rare in children, so impact on looked after children would be extremely small.	<p>As outlined, the safety data for obinutuzumab does not include pre-pubescent children, therefore this policy is adult focused, but would allow post-puberty access, for children and young people meeting the inclusion criteria, as per Commissioning Medicines for Children in Specialised Services Policy (<a href="https://www.nhs.uk/commissioning-medicines-children-specialised-services.pdf">commissioning-medicines-children-specialised-services.pdf</a> (england.nhs.uk)).</p> <p>It is proposed that by use of the specialist haematology MDT to determine suitability for obinutuzumab, individual health, physical, mental, emotional, educational and developmental needs of the child are taken into consideration if obinutuzumab was proposed as a treatment option.</p>
<b>Carers of patients:</b> unpaid, family members.	<p>Carers may be indirectly affected by this policy.</p> <p>If the use of obinutuzumab is successful, it has the potential to improve an</p>	The policy reflects the best available evidence for treatment to be made available for those patients that would have positive outcomes.

<sup>2</sup> Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities <sup>2</sup>	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>individual's health status and reduce risk of acute relapse. This may reduce their care needs allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with TTP by reducing the assistance required to complete work, family and personal tasks.</p> <p>The use of obinutuzumab electively may require ongoing carer support to facilitate attendance at follow-up appointments. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of acute relapse.</p>	<p>If this policy is adopted, a commissioning plan will set out the pathway of provision for obinutuzumab which will include access at appropriately staffed centres.</p>
<p><b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&amp;Bs.</p>	<p>There are no identified potential positive or adverse impacts of this policy on this group.</p> <p>Though the lack of a permanent base for which follow-up appointments could be co-ordinated may be challenging in this cohort of patients.</p> <p>Those who are homeless could be at risk of adverse outcomes due to lack of access to services and/or incomplete follow up.</p>	<p>Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including homeless people, to ensure that access to the service is enabled/supported.</p>

<b>Groups who face health inequalities<sup>2</sup></b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
<b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people involved in the criminal justice system, to ensure that access to the service is enabled/supported.
<b>People with addictions and/or substance misuse issues</b>	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people with addiction and/or substance misuse issues, to ensure that access to the service is enabled/supported.
<b>People or families on a low income</b>	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people or families on low incomes, to ensure that access to the service is enabled/supported.
<b>People with poor literacy or health Literacy:</b> (e.g. poor understanding of health services poor language skills).	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people with poor literacy or health literacy, to ensure access to the service is enabled/supported.
<b>People living in deprived areas</b>	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people living in deprived areas, to ensure that access to the service is enabled/supported.

<b>Groups who face health inequalities<sup>2</sup></b>	<b>Summary explanation of the main potential positive or adverse impact of your proposal</b>	<b>Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact</b>
<b>People living in remote, rural and island locations</b>	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including people living in remote/ rural/ island locations, to ensure that access to the service is enabled/supported.
<b>Refugees, asylum seekers or those experiencing modern slavery</b>	There are no identified potential positive or adverse impacts of this policy on this group.	Consideration by commissioners and commissioned providers needs to be given to groups that face inequalities, including refugees, asylum seekers or those experiencing modern slavery, to ensure that access to the service is enabled/supported.
<b>Other groups experiencing health inequalities (please describe)</b>	Not applicable.	Not applicable.

## 5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

<b>Yes X</b>	<b>No</b>	<b>Do Not Know</b>
--------------	-----------	--------------------

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

<b>Name of engagement and consultative activities undertaken</b>	<b>Summary note of the engagement or consultative activity undertaken</b>	<b>Month/Year</b>
<b>1</b> Stakeholder testing (planned)	Testing has taken place with an appropriate group of stakeholders, including patients and patient groups. While a small number of	May 2023



		suggestions were made regarding specific wording, they were all supportive of the proposition.	
<b>2</b>	Public consultation (planned)	The Policy was agreed not to require public consultation by the PPVAG.	<b>May 2023</b>
<b>3</b>			

**6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?**

<b>Evidence Type</b>	<b>Key sources of available evidence</b>	<b>Key gaps in evidence</b>
<b>Published evidence</b>	An external review of available clinical evidence was undertaken to inform this policy.	Clinical effectiveness in acute TTP. Cost effectiveness of treatment. Larger and longer-term studies on the effect of the intervention
<b>Consultation and involvement findings</b>	Stakeholder testing was undertaken during May 2023.	None
<b>Research</b>	No pending research is known	Clinical effectiveness in acute TTP. Cost effectiveness of treatment. Larger and longer-term studies on the effect of the intervention
<b>Participant or expert knowledge</b> For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which included sarcoidosis specialists, a range of medical clinicians, a public health specialist, a pharmacist and a patient and public voice representative.	

**7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty?** Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?	X	X	
The proposal may support?			X
Uncertain whether the proposal will support?			

**8. Is your assessment that your proposal will support reducing health inequalities faced by patients?** Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	X	X
The proposal may support?		
Uncertain if the proposal will support?		

**9. Outstanding key issues/questions that may require further consultation, research or additional evidence.** Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1	Cost effectiveness of intervention versus usual care	Research
2	Clinical effectiveness of the intervention versus usual care in acute TTP.	Research
3		

## 10. Summary assessment of this EHIA findings

This policy aims to make obinutuzumab available for all adult patients with ADAMTS13 relapse if clinically eligible. The policy focuses on adults with ADAMTS13 relapse and excludes pre-pubescent children as obinutuzumab does not have a licenced use in children, and there is no evidence to support its safe use in children. This policy will extend the use of obinutuzumab in cases of ADAMTS13 relapse to post-pubescent children and adolescents via the Commissioning Medicines for Children in Specialised Services Policy ([commissioning-medicines-children-specialised-services.pdf \(england.nhs.uk\)](https://www.nhs.uk/commissioning-medicines-children-specialised-services.pdf)). It is not thought to adversely impact on any other individuals from protected characteristic groups.

The policy could provide a treatment option for patients who are currently experiencing the consequences of ADAMTS13 relapse who are refractory or intolerant to rituximab and currently have limited or no treatment options to control the disease. This policy is informed by the evidence base and the clinical expertise of the policy working group.

A national commissioned policy will reduce variation in clinical practice promoting an equity of care nationally for those in which this intervention is indicated.

## 11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning, NHS England
Directorate name:	Chief Finance Officer
Date EHIA agreed:	
Date EHIA published if appropriate:	