

## NHS England and NHS Improvement: 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)<sup>1</sup>:** Clinical commissioning policy: Rituximab and eculizumab for the prevention and management of delayed haemolytic transfusion reactions and hyperhaemolysis in patients with haemoglobinopathies.
- 2. Brief summary of the proposal in a few sentences**

This is a clinical commissioning policy proposition which proposes the use of rituximab adult and post pubescent patients for the prevention and management and eculizumab for patients of all ages for management of delayed haemolytic transfusion reactions (DHTR) and hyperhaemolysis (HH) in patients with haemoglobinopathies.

DHTR and HH are rare, life threatening complications of blood transfusion associated with red cell alloantibody formation and activation of complement. They are more typically seen in patients with haemoglobinopathies – sickle cell disease and thalassaemia, who may have undergone multiple blood transfusions over their lifetime. Current treatments consist of supportive care with products to stimulate new red cell production (erythropoietin) and treatments such as steroids and intravenous immunoglobulin (IVIg) to reduce the immune system breaking down red blood cells.

Rituximab has been used both to prevent the occurrence of DHTR in high risk patients and to manage severe ongoing DHTR/HH and eculizumab has been used to manage severe ongoing DHTR/ HH in patients at high risk of death and organ damage.

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<sup>1</sup> Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.



**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.

<b>Protected characteristic groups</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>
<p><b>Age:</b> older people; middle years; early years; children and young people.</p>	<p>The policy proposition outlines the inclusion criteria as being adult and post-pubescent children for rituximab, due to licence restrictions on rituximab, which is not currently licensed in children. Eculizumab is licensed for all ages.</p>	<p>Safety and efficacy have not been proven in the paediatric population by licensing or via the evidence review, therefore the policy proposition excludes this group at this time. The NHS England guideline “Commissioning medicines for Children in Specialised Services” mitigates the impact on children by providing guidance on when NHS England will support access to treatments that are not licensed/ commissioned for children.</p>
<p><b>Disability:</b> physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>Patients with haemoglobinopathies who have an impairment which has ‘substantial’ and ‘long-term’ negative effect on your ability to do normal daily activities would be classified as having a disability under the terms of the Equality Act 2010.</p> <p>This policy proposition would therefore, have a beneficial impact on this group with a protected characteristic.</p>	<p>Provision of potentially life-saving treatment for patient group with a protected characteristic.</p>

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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>	N/A	N/A
<b>Marriage &amp; Civil Partnership:</b> people married or in a civil partnership.	N/A	N/A
<b>Pregnancy and Maternity:</b> women before and after childbirth and who are breastfeeding.	Pregnancy has not been made an exclusion criterion, however the policy proposition does not go as far as to recommend the use in pregnant women, stating ‘There is no well-controlled data for either drug when used in pregnancy. In both instances, this would be a risk benefit judgement balancing the clear and present danger to the mother with the unknown but theoretical risk of complement inhibition or B-cell depletion in the baby.’	The policy proposition has not expressly prevented the use of these medicines in pregnancy and has left the decision to clinicians’ discretion. This provides a potential for improved access for pregnant women.
<b>Race and ethnicity<sup>2</sup></b>	This policy proposition is specifically for patients with haemoglobinopathies, including sickle cell disease (SCD) and thalassemia.	Provision of potentially life-saving treatment for patient group with a protected characteristic.

<sup>2</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.

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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
	The majority of SCD patients are of Afro-Caribbean background, while people from Mediterranean, India, Pakistan, Bangladesh, the Middle East, China and southeast Asia are more likely to have thalassaemia. Making this treatment available will primarily benefit patients of a BAME background.	
<b>Religion and belief:</b> people with different religions/faiths or beliefs, or none.	N/A	N/A
<b>Sex:</b> men; women	N/A	N/A
<b>Sexual orientation:</b> Lesbian; Gay; Bisexual; Heterosexual.	N/A	N/A

**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.

<b>Groups who face health inequalities<sup>3</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>Looked after children and young people</b>	N/A	N/A
<b>Carers of patients:</b> unpaid, family members.	N/A	N/A
<b>Homeless people.</b> People on the street; staying temporarily with friends /family; in hostels or B&Bs.	N/A	N/A
<b>People involved in the criminal justice system:</b> offenders in prison/on probation, ex-offenders.	N/A	N/A
<b>People with addictions and/or substance misuse issues</b>	N/A	N/A
<b>People or families on a low income</b>	N/A	N/A
<b>People with poor literacy or health Literacy:</b> (e.g. poor understanding of health services poor language skills).	N/A	N/A
<b>People living in deprived areas</b>	N/A	N/A

<sup>3</sup> Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities <sup>3</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>People living in remote, rural and island locations</b>	DHTR and HH are emergencies, requiring rapid identification and management. Given this, patients living in remote areas and being cared for at a non-specialist hospital may face a delay in approval for this treatment.	To facilitate approval for treatment the policy proposition includes a pathway for patients outside of haemoglobinopathy coordinating centres to be discussed with the specialists there. This will mitigate potential delays to treatment which could disadvantage patients living in more remote areas.
<b>Refugees, asylum seekers or those experiencing modern slavery</b>	N/A	N/A
<b>Other groups experiencing health inequalities (please describe)</b>	N/A	N/A

## 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.

Yes X	No	Do Not Know
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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.

Name of engagement and consultative activities undertaken	Summary note of the engagement or consultative activity undertaken	Month/Year
1	Stakeholder testing undertaken for a period of 2 weeks	No responses received to stakeholder testing
		Nov 2019

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<b>2</b>	Patient public voice representative was part of the policy working group for this policy and the assurance process for the development of this policy proposition	Provided an opportunity for a member of the public to directly comment on the proposition as it progressed	Nov'19- May '20
<b>3</b>	Review with the Patient and Public Voice Assurance Group	Discussion with the PPVAG chair to confirm that 13Q is not triggered to require further public and patient involvement in the commissioning policy development.	May '20

**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>	<p>Boonyasampant M, Weitz IC, Kay B et al. Life threatening delayed hyperhaemolytic. transfusion reaction in a patient with sickle cell disease: effective treatment with eculizumab followed by rituximab. Transfusion 2015; 55: 2398-2403</p> <p>Cattoni A, Cazzaniga G, Perseghin P et al. An attempt to induce transient immunosuppression pre-erythrocytapheresis in a girl with sickle cell disease, a history of severe delayed haemolytic transfusion reactions and need for hip prosthesis. Hematol Rep 2013; 28: 5</p> <p>Chonat S, Quarmyne MO, Bennett CM, Dean CL, Joiner CH, Fasano RM, Stowell SR. Contribution of alternative complement pathway to delayed hemolytic transfusion reaction in sickle cell disease. Haematologica. 2018 Oct;103(10): e483-e485</p>	Impact of treatment on pregnant women and developing foetuses.

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<b>Evidence Type</b>	<b>Key sources of available evidence</b>	<b>Key gaps in evidence</b>
	Dumas G, Habibi A, Onimus T et al. Eculizumab salvage therapy for delayed haemolytic transfusion reaction in sickle cell disease patients. Blood 2016; 127:1062-1064	
<b>Consultation and involvement findings</b>	Involvement of the patient and public voice assurance members of the policy working group, CRG and PoC.	N/A
<b>Research</b>	N/A	N/A
<b>Participant or expert knowledge</b> For example, expertise with the team or expertise drawn on external to your team	Policy working group expert knowledge has informed the clinical commissioning policy proposition.	N/A

**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?			
The proposal may support?	X	X	
Uncertain whether the proposal will support?			X



**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
The proposal may support?	X	
Uncertain whether the proposal will support?		

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

Key issue or question to be answered		Type of research or other evidence that would address the issue and/or answer the question
1	Use in pregnancy	Monitoring of outcomes for mother and child should this be routinely commissioned when used in patients who are pregnant and further clinical research on use in pregnancy.
2	Use in pre-pubescent children	Depending on licence restrictions and demand for this treatment in pre-pubescent children, further clinical research on use for this age group
3	Use as a first line treatment	Monitoring of outcomes if routinely commissioned and further clinical research on use as a first line treatment to build evidence base for this.

**10. Summary assessment of this EHIA findings**

Patients with haemoglobinopathies are overwhelmingly from black and minority ethnic backgrounds, and some will be disabled as a result of their disease. This clinical commissioning policy will provide a potentially life-saving treatment for these patients who share one or more protected characteristic. The policy proposition also provides a route for patients to access this

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treatment, regardless of whether or not they are being cared for in a haemoglobinopathies coordinating center. This has the potential to reduce inequalities in health outcomes for patients living in remote areas.

**11. Contact details re this EHIA:**

Team/Unit name:	Blood & Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Finance
Date EHIA agreed:	03 June 2020
Date EHIA published if appropriate:	July 2020