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 CLINICAL COMMISSIONING POLICY: Emicizumab for Moderate Haemophilia A without Inhibitors

2. Brief summary of the proposal in a few sentences

Haemophilia A is an inherited genetic condition characterised by a deficiency or dysfunction of coagulation factor VIII (FVIII) which causes increased bleeding. It usually affects natal males, especially in the more severe phenotypes, as it is an X-linked chromosomal disorder. Insufficient functional FVIII level in patients with HA prevents normal clot formation and therefore these patients experience abnormal bleeding which can be external or internal and can be caused by trauma or develop spontaneously. Bleeding can be life threatening, and bleeding into joints causes acute pain and over time irreversible arthropathy which impacts mobility. There is currently no cure and lifelong treatment with prophylaxis against bleeding is recommended for all patients with a severe bleeding phenotype. Historically, this consisted of replacement of factor VIII with intravenous injections every 2 to 3 days. Younger patients often require surgery to implant a central venous access device (CVADs). The aim of prophylaxis is to prevent joint bleeds (and therefore prevent joint damage) and other serious bleeds which can otherwise lead to disability and death (Rayment et al., 2020). In up to a third of patients with haemophilia A treated with long-term replacement factor, allo-antibodies, known as 'inhibitors', against the replacement factor develop and render the treatment essentially ineffective at standard doses. Development of inhibitors is associated with increased frequency and extended duration of bleeding episodes leading to increased morbidity and decreased quality of life.

The proposed population of this policy is patients with moderate haemophilia A without FVIII inhibitors, with a severe bleeding phenotype for whom prophylaxis is indicated (see below).

Licensed indication: Haemophilia A without FVIII inhibitors and Moderate disease (FVIII ≥ 1% and ≤ 5%) with severe bleeding phenotype

Use will be in line with BSH Guidelines on the use of prophylactic factor replacement for children and adults with Haemophilia A (and B) https://onlinelibrary.wiley.com/doi/10.1111/bjh.16704 which suggest prophylaxis primarily for patients with a native factor FVIII level < 3%.

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
Age: older people; middle years; early years; children and young people.	Treatment is licensed for any age and policy will have same scope. Because the condition affects children, it can result in an inability to work or attend school. Therefore, the policy is expected to have a positive impact on adults and children.	The policy criteria will involve paediatric and adult specialists qualified to make inclusive decisions for patients of all ages.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Treatment will have a positive impact on disability as it is a prophylactic preventative treatment and one of the primary consequences of poorly controlled bleeding in haemophilia A is cumulative musculoskeletal disability, especially in hip and knee joints. So better control through use of emicizumab will reduce future disability.	No specific action required.
Gender Reassignment and/or people who identify as Transgender	No impact	This policy aims to make emicizumab available for all patients who meet the implementation criteria, regardless of gender identity/reassignment
Marriage & Civil Partnership: people married or in a civil partnership.	No impact	This policy aims to make emicizumab available for all patients who meet the implementation criteria, regardless of marital status
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Few to nil patients affected by Moderate Haemophilia A with severe bleeding phenotype are female, i.e. almost all	Pregnant patients, or those seeking to become pregnant, or breast-feeding patients, may need to

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
	patients are natal males as it is an X-linked chromosome disorder. Emicizumab safety in pregnancy etc. is **not** established.	switch away from emicizumab and use FVIII instead during the period of risk.
Race and ethnicity[1]	No considered impact. There are some familial clusters of Haemophilia A as it is primarily an inherited condition, but there are no significant racial or ethnic differences in the UK patient population.	This policy aims to make emicizumab available for all patients who meet the implementation criteria, regardless of ethnicity.
Religion and belief: people with different religions/faiths or beliefs, or none.	No impact.	This policy aims to make emicizumab available for all patients who meet the implementation criteria, regardless of religion/belief. Emicizumab is not made from blood products and therefore may be more acceptable to some religious groups.
Sex: men; women	Almost all patients with Moderate Haemophilia A with severe bleeding phenotype are male.	There is little which can be done to change this impact as it is an inherent component of the condition being an X-linked chromosomal disorder.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	No impact.	This policy aims to make emicizumab available for all patients with who meet the implementation criteria, regardless of sexual orientation

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

[1] 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.

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[2]	**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**
Looked after children and young people	Potentially positive impact as emicizumab is usually administered once-fortnightly by subcutaneous injection which is distinctly easier and more acceptable than 3 or 4 times weekly intravenous factor VIII.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
Carers of patients: unpaid, family members.	As above, where administration falls to third parties, emicizumab is much easier to administer than the alternative both in terms of frequency and also injection technique.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	All Haemophilia A prophylaxis treatments require refrigerated storage which may be difficult to achieve if the patient is homeless, so the use of emicizumab does not negate the potential disadvantage to this group.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Potentially easier to manage due to substantially reduced dose frequency of emicizumab vs. alternative FVIII intravenous injections.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
People with addictions and/or substance misuse issues	Potentially easier to manage the condition as fewer dose injections	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local

[2] Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities[2]	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
	required with each conferring ~2 weeks protection.	Authority, charities) maximise the positive impacts for this group.
People or families on a low income	Potentially positive impact as emicizumab is usually administered once-fortnightly by subcutaneous injection which can be self-administered, compared to the potential cost and time taken to travel to healthcare settings to receive 3 or 4 times weekly intravenous factor VIII.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	People from this group often experience difficulties accessing services and accessing follow up. Training for self-administration may be difficult.	Provision of training and support regarding administration to patients and carers is essential. This includes offering verbal and written mediums of treatment information and training tools and providing translated and Easy Read materials.
People living in deprived areas	Potentially positive impact as emicizumab is usually administered once-fortnightly by subcutaneous injection which can be self-administered, compared to the potential cost and time taken to travel to healthcare settings to receive 3 or 4 times weekly intravenous factor VIII.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
People living in remote, rural and island locations	Potentially positive impact as emicizumab is usually administered once-fortnightly by subcutaneous injection which is likely to be easier and more acceptable than 3 or 4 times weekly intravenous factor VIII.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.

Groups who face health inequalities[2]	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
Refugees, asylum seekers or those experiencing modern slavery	Potentially positive impact as emicizumab is usually administered once-fortnightly by subcutaneous injection which is easier and more acceptable than 3 or 4 times weekly intravenous factor VIII.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to maximise the positive impacts for this group.
Other groups experiencing health inequalities (please describe)		

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

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	The policy went out for a 14 day period of stakeholder testing in July 2024. Key stakeholders were identified by the Policy Working Group including the below: • Clinical staff, • Professional groups • Patients & patient groups	July 2024

		• Industry groups	
2			
3			

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

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An external review of available clinical evidence was undertaken to inform this policy.	No evidence was returned for cost-effectiveness
Consultation and involvement findings	None known	
Research	The UK clinical community has participated in most major P3 clinical studies of emicizumab.	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Emicizumab has been routinely commissioned by NHSE since 2018 and 2019 and it is now established as the standard of care for severe haemophilia A. The UK has extensive experience of the clinical use of emicizumab. The UK, and the CRG, benefits from an active patient group exemplified by the Haemophilia Society.	

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?			
Uncertain whether the proposal will support?	X	X	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 : Reducing an inequality in access to the standard of care for patients with severe bleeding phenotypes, but with different disease classification based on laboratory-measured native FVIII levels	
The proposal may support?		X : Reducing an inequality in access to the standard of care for patients with severe bleeding phenotypes, but with different disease classification based on laboratory-measured native FVIII levels
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		

2		
3		

10. Summary assessment of this EHIA findings

This policy will make an effective and substantially more convenient, treatment, which is already established as the standard of care for Haemophilia A with severe bleeding phenotype, available to a slightly wider group of patients with Haemophilia A (+~5% of current eligible patient population) with similar bleeding profiles to the current eligible patient population. In the absence of emicizumab the only prophylaxis treatment available is intravenous FVIII injected 3 or 4 times per week. Emicizumab is a subcutaneous injection administered once per fortnight in most patients (range once-weekly to 4-weekly). There are no established inequalities across the patient group other than almost all patients with severe or moderate haemophilia A are natal males as the condition is an X-linked chromosomal disorder.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	CFO
Date EHIA agreed:	8 March 2024
Date EHIA published if appropriate:	