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)[1]: Vonicog alfa for the treatment and prevention of bleeding in adults with von Willebrand disease (1709)

2. Brief summary of the proposal in a few sentences

About the condition:
People with von Willebrand disease (VWD) have a low amount of a missing protein called von Willebrand factor (VWF) in their blood, or this protein doesn't work very well. This means that people with VWD have difficulty forming a blood clot (which is needed to stop bleeding when it occurs), and as a result, they bleed more after events such as injury, childbirth, or during surgery.

About the treatment:
Vonicog alfa works in the body in the same way as von Willebrand factor made by the body itself, by replacing the protein needed to stop bleeding that is missing or not working. It is artificially made rather than taking it from human blood. Vonicog alfa may be preferred over products taken from human blood because it is less likely to have the problems associated with alternative treatment and, as factor VIII does not need to be given with every dose of vonicog alfa, it avoids the risk of factor VIII building up in the body (a risk factor for clots).

[1] 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.**

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.	The policy is for treatment of patients from 18 years of age (adult), which is linked to the licensing of the product. Children and young people under the age of 18 years will continue to access treatments within the current pathway which would involve the use of plasma-derived products.	Medicines often initially only have a licence for patients who are 18 years and above because this is the group of patients on whom the medicine has initially been researched. NHS England's Policy: Commissioning Medicines for Children in Specialised Services (https://www.england.nhs.uk/wp-content/uploads/2017/03/commissioning-medicines-children-specialised-services.pdf) outlines that patients aged less than 18 years who meet the conditions set out in a NICE Technology Appraisal, Highly Specialised Technology Appraisal or NHS England policy relating to adults will be able to receive the medicine, mitigating some of the access restrictions on the basis of age. We understand that the manufacturer intends to seek a license in patients aged under 18 years old across several different types of use and we expect to develop clinical policies for these indications in due course.

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
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	There are no considered positive or adverse impacts on people in this protected characteristic group from this policy.	
Gender Reassignment and/or people who identify as Transgender	There are no considered positive or adverse impacts on people in this protected characteristic group from this policy.	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	There are no considered positive or adverse impacts on people in this protected characteristic group from this policy.	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	People with VWD may experience increased bleeding during childbirth, so access to this treatment helps to prevent excessive bleeding and the complications this causes during childbirth. One of the more common uses of VWF in surgical prophylaxis is during birth (vaginal or abdominal); this will account for a disproportionate volume of use and therefore will impact on pregnancy.	The policy recommends use to prevent bleeding, which will have a positive impact on people with this protected characteristic. One of the more common uses of VWF in surgical prophylaxis is during birth (vaginal or abdominal) and this will account for a disproportionate volume of use and therefore will impact on pregnancy.

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
Race and ethnicity[2]	There are no considered direct positive or adverse impacts on people in this protected characteristic group from this policy. There may be an indirect bias in favour of patients from minority racial groups as some BAME groups have a higher prevalence of severe VWD.	No action recommended; this is an inherent feature of the condition.
Religion and belief: people with different religions/faiths or beliefs, or none.	There is a positive impact on people from faiths where the use of donated blood products are not acceptable, e.g. Jehovah's Witnesses. There may be an indirect bias in favour of patients from some religious groups due to a higher prevalence of severe VWD affecting some minority ethnic groups which are in turn associated with specific religions.	No action recommended; the policy supports access to recombinant products for all patients, and the higher prevalence seen in some minority ethnic groups and therefore religions is an inherent feature of the condition.
Sex: men; women	There is a gender bias in the diagnosis of VWD due to the presentation of	No action recommended; this is an inherent feature of the condition.

[2] 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
	menorrhagia which results in a higher rate of diagnosis in female patients. In addition, one of the more frequent planned uses of VWF in surgical prophylaxis is during birth (vaginal or abdominal); this will account for a disproportionate volume of use and therefore will impact on pregnancy.	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	There are no considered positive or adverse impacts on people in this protected characteristic group from this policy.	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.**

Groups who face health inequalities[3]	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	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A

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

Groups who face health inequalities[3]	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
Carers of patients: unpaid, family members.	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	Treatment is accessed via Haemophilia Comprehensive Care Centres (HCCC) to ensure specialist teams oversee it's use. These services are provided by a limited number of providers across the country to maintain competency. Homeless people may be less likely to be in regular contact with healthcare services and may not be linked in with a HCCC for management of their condition.	Access can be supported locally through shared care arrangements between the HCCC and the local trust, which increases the opportunities for homeless people to access this care locally.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Treatment is accessed via HCCCs to ensure specialist teams oversee its use. These services are provided by a limited number of providers across the country to maintain competency. People involved in the criminal justice system with this condition should be under the care of an HCCC, but this may not be easily accessible if it is not in the same area as the prison where they are remanded to.	Where people involved in the criminal justice system are not in an area where they can easily access their HCCC, shared care arrangements with the local trust help to ensure access to this treatment is available.

Groups who face health inequalities[3]	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
People with addictions and/or substance misuse issues	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A
People or families on a low income	Treatment is accessed via HCCCs to ensure specialist teams oversee its use. These services are provided by a limited number of providers across the country to maintain competency, which may not be in the same area as people on low incomes are living.	Some people on low incomes will be eligible for help with the transport costs to get them to the specialist centre for their care (https://www.nhs.uk/using-the-nhs/help-with-health-costs/healthcare-travel-costs-scheme-htcs/). Shared care arrangements with local trusts also help to ensure access if available to patients who are less able to travel to an HCCC for treatment.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A
People living in deprived areas	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A
People living in remote, rural and island locations	Treatment is accessed via HCCCs to ensure specialist teams oversee its use. These services are provided by a limited number of providers across the country to maintain competency, which is unlikely to be in the remote, rural or island locations.	People living with VWD are likely to already be under the care of an HCCC and have agreed care plans in place for accessing treatment when needed. Shared care arrangements with local trusts also help to mitigate against some of the access issues for this treatment.

Groups who face health inequalities[3]	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	There are no considered positive or adverse impacts on people in this group who face health inequalities from this policy.	N/A
Other groups experiencing health inequalities (please describe)	None identified.	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

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 was undertaken for a two-week period	Points of clarification were made by the responses received, with minor amendments within the policy made to ensure the prior treatments within the pathway were clear and to use a more balanced description of the disadvantages of plasma-based products.	April 2019
2	Public consultation for 30 days	The public consultation was available on the NHS England engagement website and was alerted to all registered	August/Sept 2019

		stakeholders, including relevant patient representative organisations. Feedback from the consultation focused mainly on the comparator used within the evidence and the budget impact assessment (most responses from competitor pharmaceutical companies). The Haemophilia Society highlighted that commissioning of this product would reduce inequalities between people with bleeding disorders by enabling access to a recombinant product, many of which are available for other bleeding disorders, which are felt to have a better safety profile.	
3	Involvement of Clinical Reference Group (CRG) members in the development of the policy, including having PPV and professional bodies represented on the policy working group.	The Haemophilia Society was represented, at a senior level, on the Policy Working Group (PWG). The HSUK was an active participant in the PWG and has also raised issues via their membership of the associated Clinical Reference Group.	Jan-May 2019

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	The documents that have informed this impact assessment include a review of the clinical evidence available for vonicog alfa, the European public assessment report (EPAR), Summary of product characteristics (SPC), as well as the publications listed in the reference section of the policy.	The evidence was non-comparative, non-randomised, of a small sample size, related to single acute bleeding episodes, and did not include patients aged under 18 years.
Consultation and involvement findings	Responses to consultation and stakeholder testing, alongside review and assurance from stakeholders and PPV	None identified. Few responses were received.

Evidence Type	Key sources of available evidence	Key gaps in evidence
	members via the CRG and Programme of Care.	
Research	N/A	The manufacturer is actively supporting ongoing research in other patient groups, most importantly in children, and in other types of use, most usefully in prophylaxis. The manufacturer actively supports post-marketing observation in various markets.
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The policy criteria and pathway are based primarily on UK guidelines with substitution of plasma VWF products for vonicog alfa.	/

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	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?		
The proposal may support?	X	X

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	The product is a recombinant (synthetic) blood product where the only other treatment options are plasma-derived.	Consideration is required of the need to commission a recombinant product in preference to plasma products.
2		
3		

10. Summary assessment of this EHIA findings

The commissioning of vonicog alfa is unlikely to directly impact on equality of opportunity or health inequalities as there are effective direct substitute products already available and routinely commissioned. The product offers a recombinant (synthetic) treatment option in a situation where the only treatment options currently available are plasma-derived. Access to a recombinant product is routinely available for other factors, which is felt to provide more sustainable sources of product and remove theoretical risk associated with plasma- based products.