Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	ID018		
Policy Title	Vonicog alfa for treating von Willebrand disease Proposal **for routine commission** (ref A3.1)		
Lead Commissioner	Will Horsley	**Clinical Lead**	Michael Laffan
Finance Lead		**Analytical Lead**	Click here to enter text.

Integrated Impact Assessment – Index		
Section A – Activity	**Section B - Service**	**Section C – Finance**
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop-down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Based on the UK National Haemophilia Database Bleeding Disorder Statistics for April 2017 to March 2018 it is estimated that 7,374 adults have von Willebrand disease in England. A total of 542 adults were treated with desmopressin or with plasma-derived VWF. Of the adults treated with plasma-derived VWF, around 10% (54) used them for prophylaxis. The eligible patient population for vonicog alfa in England is considered equivalent to the adults with all types of VWD who are currently treated with plasma concentrates but excluding those using the concentrates for prophylaxis. This is equivalent to 488 adults. *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	488 *Source:* UKHCDO database VWD plasma concentrates (with plasma-derived VWF/factor VIII complex or plasma-derived VWF with or without a recombinant factor VIII) are used to treat patients who do not respond to DDAVP, i.e. the more severe forms of VW. There were 542 adults on the UKHDO register treated with plasma concentrates in 2017/18 and 54 of these were considered to have had plasma treatments for prophylaxis purposes and are not eligible for vonicog alfa. Therefore 488 adults are eligible for treatment with vonicog alfa.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults** Vonicog alfa will be routinely commissioned for treatment of haemorrhage and surgical bleeding, and prevention of surgical bleeding in adults (aged 18 years or older), with a confirmed diagnosis of VWD when desmopressin and tranexamic acid treatment are ineffective or not

<table>
<tr><td></td><td>indicated (based on UK clinical practice); AND when VWF activity levels are <50 IU/dl (see British Society of Haematology guidelines on the diagnosis and management of von Willebrand disease 2014) OR diagnosis is type 2N VWD; AND there is no evidence of inhibitors to VWF.</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>Not applicable</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Unevenly</u>
If unevenly, estimate regional distribution by %:
<table><tr><td>North</td><td>23%</td></tr><tr><td>Midlands & East</td><td>17%</td></tr><tr><td>London</td><td>40%</td></tr><tr><td>South</td><td>20%</td></tr></table>Source: Policy Proposition section 6
Please specify
UK National Haemophilia Database 2018</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Constant</u>

No known factors other than demographic growth in patient population is identified. We have modelled rate of growth for the next ten years based on historical trends from the National Haemophilia Database.</td></tr>
</table>

<table>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>

Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

Are these numbers in line with ONS growth assumptions for the age specific population? If not, please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>+7</td></tr><tr><td>YR3 +/-</td><td>+10</td></tr><tr><td>YR4 +/-</td><td>+13</td></tr><tr><td>YR5 +/-</td><td>+16</td></tr><tr><td>YR10 +/-</td><td>+29</td></tr></table>Source: Service specification proposition section 3.1

<u>No</u>
We have used historical trends from the National Haemophilia Database.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u>
The purpose is to <u>routinely commission vonicog alfa</u> for treatment of haemorrhage and surgical bleeding, and prevention of surgical bleeding in adults (aged 18 years or older) with a confirmed diagnosis of VWD, when desmopressin and tranexamic acid treatment are ineffective or not indicated (based on UK clinical practice); AND when VWF activity levels are <50 IU/dl (see British Society of Haematology guidelines on the diagnosis and management of von Willebrand disease 2014) OR diagnosis is type 2N VWD; AND there is no evidence of inhibitors to VWF.</td></tr>
</table>

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	488 *Source:* UKHCDO These are people with all types of VWD who are registered with the National Haemophilia Database for the full twelve months 2017/2018 and who are currently treated with plasma derived concentrates.
What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	488 *Source:* UKHCDO
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Current treatment options for treating people with VWD who do not respond to desmopressin are VW plasma concentrates such as Voncento, Willate, Willfact and Alphanate. Treatment could be on-demand or prophylaxis depending on clinical severity and bleeding manifestations. Some are only treated occasionally and in hospital. Treatment aims to correct the deficiency in the clotting process and reduce the prolonged bleeding time. People with VWD may also need treatment before and after surgery or a dental procedure. *Source:* Policy Proposition 3

A4.2. What is the current treatment access and stopping criteria?	*Source:* Treatment access and stopping criteria are defined by BCSH Guidelines: The diagnosis and management of von Willebrand disease: a United Kingdom Haemophilia Centre Doctors Organization guideline approved by the British Committee for Standards in Haematology - Laffan - 2014 - British Journal of Haematology - Wiley Online Library
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify a) 100% b) 0% c) 100% d) 100% e) 100% *Source:* Policy Working Group
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**Yes** Plasma derived concentrates such as voncento and willfact.
A5.2 What percentage of the total eligible population is estimated to:	If not known, please specify f) 100%

a) Be clinically assessed for treatment b) Be considered to meet an exclusion criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	g) 0% h) 100% i) 100% j) 100% *Source:* Policy Working Group
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify a) 100% b) 0% c) 100% d) 100% e) 100% *Source:* Policy Working Group
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**<u>Time limited</u>** Treatment of bleeding episodes (on-demand treatment, surgery, or prophylaxis) *Source:* Market authorisation
A7 Treatment Setting	

A7.1 How is this treatment delivered to the patient?

Select all that apply:

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☒
Acute Trust: day patient	☒
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☐
Other	☐

Please specify:

Specialist haemophilia centres commissioned by NHS England provide services for people with VWD. Services contribute to the UKHCDO register for VWD patients, as well as other haematological disorders.

A7.2 What is the current number of contracted providers for the eligible population by region?

NORTH	7
MIDLANDS & EAST	5
LONDON	4
SOUTH	5

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** The introduction of vonicog alfa is not expected to require a change of delivery setting or capacity requirements. However, the introduction of vonicog alfa would require consideration as to whether non-specialist bleeding disorder treatment centres would have access to vonicog alfa for urgent or life-threatening bleeds (would also require access to timely Factor VIII and VWF assays), or whether treatment would be restricted to specialist centres only. *Source:* Policy Working Group
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☐ Patient level contract monitoring ☐ Patient level drugs dataset ☐ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☐ Mental Health Services Dataset (MHSDS) ☐ National Return** ☐ Clinical Database** ☒ Other** ☐ **If National Return, Clinical database or other selected, please specify: The UK National Haemophilia Database

<table>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Select all that apply:<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☒</td></tr><tr><td>Treatment function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table></td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Already specified in current NHS England Drugs List document</u></td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u></td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts</td><td><u>None</u></td></tr>
</table>

<table>
<tr><td>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td></td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</td><td>Select all that apply:
<table><tr><td>Drugs or Device MDS</td><td>☒</td></tr><tr><td>BlueTeq</td><td>☐</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table>Please specify:
BlueTeq requests may not be needed due to the urgent need for treatment and the potential adverse impact from any delay.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u></td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
Standard processes for high cost drugs</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u>

No current dashboards are in place for VWF products. The UKHCDO already collects data on the treatment of VWF patients, and consideration could be given to engaging with the UKHCDO to collect data in a manner supportive of the needs of NHS England.</td></tr>
<tr><td>A9.6 NICE reporting</td><td><u>No</u></td></tr>
</table>

Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Access is through Specialist Haemophilia Centres including inpatient care where the cause of admission is related to a bleeding disorder. *Source: Policy Working Group*
B1.2 Will the proposition change the way the commissioned service is organised?	**Yes** The introduction of vonicog alfa would require consideration as to whether non-specialist bleeding disorder treatment centres would have access to vonicog alfa for urgent or life-threatening bleeds (would also require access to timely Factor VIII and VWF assays), or whether treatment would be restricted to specialist centres only.
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care**:
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☐

<table>
<tr><td></td><td>
<table>
<tr><td>Secondary care</td><td>☐</td></tr>
<tr><td>Tertiary care</td><td>☐</td></tr>
<tr><td>Other</td><td>☒</td></tr>
<tr><td></td><td></td></tr>
</table>

The introduction of vonicog alfa is not expected to impact on referral rates.
</td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>

Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>No impact</u>
Source: Equalities Impact Assessment</td></tr>
<tr><td colspan="2">B3 Implementation</td></tr>
<tr><td>B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?</td><td><u>No action required</u>:</td></tr>
<tr><td>B3.2 Time to implementation:
Is a lead-in time required prior to implementation?</td><td><u>No - go to B3.4</u></td></tr>
</table>

B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	**No change**
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	*Select all that apply:* Publication and notification of new policy ☒

	Market intervention required ☐ Competitive selection process to secure increase or decrease provider configuration ☐ Price-based selection process to maximise cost effectiveness ☐ Any qualified provider ☐ National Commercial Agreements e.g. drugs, devices ☐ Procurement ☐ Other ☒
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	**No**
Section C - Finance Impact	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:* **Drugs**: Not separately charged – part of local or national tariffs ☐ **Drugs**: Excluded from tariff – pass through ☒

		Excluded from tariff - other	☐
	Devices	Not separately charged – part of local or national tariffs	☐
		Excluded from tariff (excluding ZCM) – pass through	☐
		Excluded from tariff (excluding ZCM) – other	☐
		Via Zero Cost Model	☐
	Activity	Paid entirely by National Tariffs	☐
		Paid entirely by Local Tariffs	☐
		Partially paid by National Tariffs	☐
		Partially paid by Local Tariffs	☐
		Part/fully paid under a Block arrangement	☐
		Part/fully paid under Pass-Through arrangements	☐
		Part/fully paid under Other arrangements	☐

C1.2 **Drug Costs** Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Vonicog alfa received a marketing authorisation for the treatment of adults with VWD, when desmopressin treatment alone is ineffective or not indicated for the treatment of haemorrhage and surgical bleeding, and prevention of surgical bleeding. <u>List price (including VAT): Vonicog alfa.</u> £1,196 (£1,435.20 including VAT) for a 1,300 IU powder and solvent for solution for injection. Treatment with vonicog alfa will also require use of factor VIII and this would be an additional cost. The cost of factor VIII is based on the price of Haemoctin, 1 vial (250 units) at a list price of £180 including VAT.

	For budget impact purposes, the list price has been used. This can be amended in the model in the supporting worksheet, - unit costs worksheet and will carry through the model. Willate and Voncento are the most prescribed treatments in the NHS for VWD and have been used as comparators to vonicog alfa. The annual treatment cost per patient for plasma derived concentrates and factor VIII products are also based on list prices. Plasma products are not charged with any VAT. See resource impact template, supporting info – unit costs sheet for more details.
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Outpatient activity can be identified under the treatment function code of 303 (Clinical Haematology). There is also a national tariff (2019/20) top up for specialist services for haemophilia and other related blood disorders (NCBPS03Z) of 55.6%. See NHS Commissioning Board Manual for Prescribed Specialised Services 2018/19.
C1.5 **Activity Costs covered by Local Tariff** List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Not applicable

<table>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Not applicable</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u>
Vonicog alfa is likely to be used to ensure only patients who meet the commissioning criteria as set out in the final policy are treated.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table>
<tr><td>YR1</td><td>£40,447</td></tr>
<tr><td>YR2</td><td>£61,527</td></tr>
<tr><td>YR3</td><td>£70,153</td></tr>
<tr><td>YR4</td><td>£70,638</td></tr>
<tr><td>YR5</td><td>£72,819</td></tr>
</table>
NO
If the policy is approved, uptake is likely to reach 40% by end of year 1 as treatments are acute short term/episodic, therefore the switch to vonicog alfa can happen quite quickly.</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u>:
Year 1 £7.9m</td></tr>
</table>

	Year 2 £19.8m Year 3 £26.1m Year 4 £30.0m Year 5 £33.0m Most products used to treat VWD are subject to confidential UK wide tenders and as such contract prices paid by the NHS are usually lower than list prices. As a result, the true annual cost per person and budget impact may be considerably different. Also, the treatment cost will depend on actual product quantities used per treatment episode so this may impact on the budget impact as well.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Not applicable
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **No impact on providers**

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure**
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	N/A
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**Unknown**
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG prioritisation reserve
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	No material financial risk
C6.2 How can these risks be mitigated?	Not applicable
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable
C6.4 What scenario has been approved and why?	Not applicable

C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**There is no published evidence of cost-effectiveness**
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☐ Available clinical practice data suggests the new treatment has the potential to improve value for money ☐ Other data has been identified ☐ No data has been identified ☐ The data supports a high level of certainty about the impact on value ☒ The data does not support a high level of certainty about the impact on value ☐
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No**
C8.2 If yes, confirm the source of funds to meet these costs.	N/A