

## Integrated Impact Assessment Report for Clinical Commissioning Policies

|                                |   |                        |                           |
|--------------------------------|---|------------------------|---------------------------|
| <b>Policy Reference Number</b> | 1703  |                        |                           |
| <b>Policy Title</b>            | Susoctocog alfa for treating bleeding episodes in people with acquired haemophilia A<br>Proposal Choose an item. (ref A3.1) |                        |                           |
| <b>Lead Commissioner</b>       | Will Horsley  | <b>Clinical Lead</b>   | Dan Hart                  |
| <b>Finance Lead</b>            | Click here to enter text.   | <b>Analytical Lead</b> | Click here to enter text. |

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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.

AHA has an incidence of about 1.5 per million/year and presents most commonly in older people with a median age of 75–80 years. It is a rare complication of pregnancy, reported in 1 in 350,000 births in the UK ([UK Haemophilia Centres Doctors' Organisation \[UKHCDO\] Guideline on diagnosis and management of acquired coagulation inhibitors](#), 2013).

The UK National haemophilia database has [Bleeding disorder statistics for April 2015 to March 2016](#). In total, 475 people (236 male and 239 female) with historical AHA were on the register between those dates, 102 of whom were treated (21.4%).

In England the number of people with AHA on the register by end of year 2016/2017 is 434. Of these around (15%) 65 people are treated with by-passing agents each year and will be eligible for treatment under this policy document.

*Source:* Policy Proposition section 6: UK National Haemophilia Database 2016

A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.

65 people are currently eligible for treatment with by-passing agents. Upon implementation of the policy these people will be eligible for susoctocog as an additional treatment option.

*Source:* UK National Haemophilia Database 2016.

A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.

**All ages**

Please specify

Acquired haemophilia A presents most commonly in older people, with a

|   |  |       |     |                 |     |        |     |       |     |
|---|--|-------|-----|-----------------|-----|--------|-----|-------|-----|
|   | median age of 75–80 years.   |       |     |                 |     |        |     |       |     |
| A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria  | Not applicable   |       |     |                 |     |        |     |       |     |
| A1.5 How is the population currently distributed geographically?  | <p><b><u>Unevenly</u></b><br/>If unevenly, estimate regional distribution by %:</p> <table border="1"> <tr> <td>North</td> <td>23%</td> </tr> <tr> <td>Midlands &amp; East</td> <td>17%</td> </tr> <tr> <td>London</td> <td>40%</td> </tr> <tr> <td>South</td> <td>20%</td> </tr> </table> <p>Source: UK National Haemophilia Database 2016<br/>Please specify<br/><a href="#">Click here to enter text.</a></p> | North | 23% | Midlands & East | 17% | London | 40% | South | 20% |
| North   | 23%  |       |     |                 |     |        |     |       |     |
| Midlands & East   | 17%  |       |     |                 |     |        |     |       |     |
| London  | 40%  |       |     |                 |     |        |     |       |     |
| South   | 20%  |       |     |                 |     |        |     |       |     |
| <b>A2 Future Patient Population &amp; Demography</b>  |  |       |     |                 |     |        |     |       |     |
| 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? | <p><b><u>Constant</u></b></p> <p><i>No known factors other than demographic growth in patient population identified.</i></p> <p>66 year 2<br/>67 year 5<br/>69 year 10</p>   |       |     |                 |     |        |     |       |     |
| A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?                                 | <p><b><u>No</u></b></p> <p>Source: Policy Proposition section 6</p>  |       |     |                 |     |        |     |       |     |

|  |   |         |    |         |    |         |    |         |    |          |    |
|--|---|---------|----|---------|----|---------|----|---------|----|----------|----|
| <p>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?</p> <p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p> | <table border="1" data-bbox="1093 183 1601 454"> <tr> <td>YR2 +/-</td> <td>+1</td> </tr> <tr> <td>YR3 +/-</td> <td>+1</td> </tr> <tr> <td>YR4 +/-</td> <td>+2</td> </tr> <tr> <td>YR5 +/-</td> <td>+2</td> </tr> <tr> <td>YR10 +/-</td> <td>+4</td> </tr> </table> <p>Source: Service specification proposition section 3.1</p> <p><b>Yes</b><br/>Click here to enter text.</p>   | YR2 +/- | +1 | YR3 +/- | +1 | YR4 +/- | +2 | YR5 +/- | +2 | YR10 +/- | +4 |
| YR2 +/-  | +1  |         |    |         |    |         |    |         |    |          |    |
| YR3 +/-  | +1  |         |    |         |    |         |    |         |    |          |    |
| YR4 +/-  | +2  |         |    |         |    |         |    |         |    |          |    |
| YR5 +/-  | +2  |         |    |         |    |         |    |         |    |          |    |
| YR10 +/-   | +4  |         |    |         |    |         |    |         |    |          |    |
| <p><b>A3 Activity</b></p>  |   |         |    |         |    |         |    |         |    |          |    |
| <p>A3.1 What is the purpose of new policy?</p>   | <p><b><u>Confirm routine commissioning position of an additional new treatment</u></b></p> <p>The purpose of the new policy is to commission susoctocog within its recommended licensed dose as an alternative first-line clotting agent to treat bleeding in people with a confirmed diagnosis of AHA:</p> <ul style="list-style-type: none"> <li>• who have an active bleed; and</li> <li>• who are at a treatment centre which specialises in the treatment of acquired haemophilia A; and</li> <li>• for whom, in the opinion of a clinician experienced in assessing and treating AHA (as defined in the governance arrangements and proposed patient pathway), susoctocog alfa is considered clinically appropriate.</li> </ul> |         |    |         |    |         |    |         |    |          |    |
| <p>A3.2 What is the annual activity associated with the existing</p>   | <p>65</p>   |         |    |         |    |         |    |         |    |          |    |

|   |  |
|---|--|
| pathway for the eligible population?  | Source: UK National Haemophilia Database 2016<br>Click here to enter text.       |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?   | 65<br>Source: UK National Haemophilia Database 2016<br>Click here to enter text. |
| 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.

People with acquired haemophilia A just have bleeds treated. In most cases by-passing agents (BPA) are used for 2-3 days and then tailed off. The majority of people only have one bleed before the inhibitor is eradicated by immunosuppression. In a few cases patients may have 2-4 bleeds but more than that would be exceptional.

Current uptake % and number of people treated are:

|   |     |    |
|---|-----|----|
| Activated prothrombin complex concentration (FEIBA)   | 74% | 48 |
| Recombinant factor VIIa (NovoSeven)   | 10% | 7  |
| Recombinant factor VIIa (NovoSeven) and Activated prothrombin complex concentration (FEIBA) | 16% | 10 |

|   |   |
|---|---|
|   | Source: UK National Haemophilia Database 2016   |
| A4.2. What are the current treatment access and stopping criteria?  | <p>Treatment access:<br/>Acute/short-term/on-demand: Any significant bleeding episode</p> <p><u>Stopping criteria:</u><br/>Acute/short-term/on-demand: Bleeding under control or healed</p> <p>Patients with acquired haemophilia A just have bleeds treated. In most cases BPA are used for 2-3 days and then tailed off. The majority of patients only have one bleed before the inhibitor is eradicated by immunosuppression. In a few cases patients may have 2-4 bleeds but more than that would be exceptional.</p> <p>Source: Policy Proposition section 1</p> |
| <p>A4.3 What percentage of the total eligible population is expected to:</p> <p>a) Be clinically assessed for treatment</p> <p>b) Be considered to meet an exclusion criteria following assessment</p> <p>c) Choose to initiate treatment</p> <p>d) Comply with treatment</p> <p>e) Complete treatment?</p> | <p>If not known, please specify <a href="#">Click here to enter text.</a></p> <p>a) 100%</p> <p>b) 0%</p> <p>c) 100%</p> <p>d) 100%</p> <p>e) 100%</p> <p>Source: Policy Working Group</p>  |
| <p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b><br/>(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>   |   |
| <p><b>A5.1 Next best comparator:</b><br/>Is there another 'next best' alternative treatment which is a relevant</p>   | <b><u>No</u></b>  |

|   |   |
|---|---|
| <p>comparator?</p> <p><i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>  |   |
| <p>A5.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul> | <p>Not applicable</p>   |
| <p><b>A6 New Patient Pathway</b></p>  |   |
| <p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>  | <p>If not known, please specify <a href="#">Click here to enter text.</a></p> <ul style="list-style-type: none"> <li>a) 67%</li> <li>b) 20% of patients are expected to have an anti-pFVIII level &gt;5 BU which will rule out use of susoctocog alfa</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 100%</li> </ul> <p>Source: Policy Proposition 3</p> |
| <p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p>  | <p><b><u>Time limited</u></b></p> <p>Treatment is only given during a bleeding episode.</p>   |



Source: Policy Proposition 3 and 8

## A7 Treatment Setting

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

Select all that apply:

|                                    |                                     |
|------------------------------------|-------------------------------------|
| Emergency/Urgent care attendance   | <input type="checkbox"/>            |
| Acute Trust: inpatient             | <input checked="" type="checkbox"/> |
| Acute Trust: day patient           | <input type="checkbox"/>            |
| Acute Trust: outpatient            | <input type="checkbox"/>            |
| Mental Health provider: inpatient  | <input type="checkbox"/>            |
| Mental Health provider: outpatient | <input type="checkbox"/>            |
| Community setting                  | <input type="checkbox"/>            |
| Homecare                           | <input type="checkbox"/>            |
| Other                              | <input type="checkbox"/>            |

Please specify:

Nominated Haemophilia Comprehensive Care Centres only, confirmed by UKHCDO. National network, plus local networks

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

|                 |   |
|-----------------|---|
| NORTH           | 4 |
| MIDLANDS & EAST | 6 |
| LONDON          | 3 |
| SOUTH           | 5 |

A7.3 Does the proposition require a change of delivery setting or capacity requirements?

No

**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 *             | <input type="checkbox"/>            |
| Patient level contract monitoring           | <input type="checkbox"/>            |
| Patient level drugs dataset                 | <input type="checkbox"/>            |
| Patient level devices dataset               | <input type="checkbox"/>            |
| Devices supply chain reconciliation dataset | <input type="checkbox"/>            |
| Secondary Usage Service (SUS+)              | <input type="checkbox"/>            |
| Mental Health Services DataSet (MHSDS)      | <input type="checkbox"/>            |
| National Return**                           | <input type="checkbox"/>            |
| Clinical Database**                         | <input type="checkbox"/>            |
| Other**                                     | <input checked="" type="checkbox"/> |

\*\*If National Return, Clinical database or other selected, please specify:  
The UK National Haemophilia Database

A8.2 Specify how the activity related to the new patient pathway will be identified.

*Select all that apply:*

|           |                          |
|-----------|--------------------------|
| OPCS v4.8 | <input type="checkbox"/> |
|-----------|--------------------------|

|  |  |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
|--|--|-------|-------------------------------------|-------------------------|--------------------------|----------------------|--------------------------|-----|--------------------------|--------|--------------------------|---|--------------------------|
|  | <table border="1"> <tr> <td data-bbox="1079 97 1753 156">ICD10</td> <td data-bbox="1753 97 1839 156"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 156 1753 215">Treatment function code</td> <td data-bbox="1753 156 1839 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 215 1753 274">Main Speciality code</td> <td data-bbox="1753 215 1839 274"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 274 1753 333">HRG</td> <td data-bbox="1753 274 1839 333"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 333 1753 392">SNOMED</td> <td data-bbox="1753 333 1839 392"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 392 1753 483">Clinical coding / terming methodology used by clinical profession</td> <td data-bbox="1753 392 1839 483"><input type="checkbox"/></td> </tr> </table> | ICD10 | <input checked="" type="checkbox"/> | Treatment function code | <input type="checkbox"/> | Main Speciality code | <input type="checkbox"/> | HRG | <input type="checkbox"/> | SNOMED | <input type="checkbox"/> | Clinical coding / terming methodology used by clinical profession | <input type="checkbox"/> |
| ICD10  | <input checked="" type="checkbox"/>  |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| Treatment function code  | <input type="checkbox"/>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| Main Speciality code   | <input type="checkbox"/>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| HRG  | <input type="checkbox"/>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| SNOMED   | <input type="checkbox"/>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| Clinical coding / terming methodology used by clinical profession                          | <input type="checkbox"/>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| <p><b>A8.3 Identification Rules for Drugs:</b><br/>How are drug costs captured?</p>        | <p>Drug is listed as a tariff-exempt treatment and data will be reported via the Drugs Minimum Dataset.</p>  |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| <p><b>A8.4 Identification Rules for Devices:</b><br/>How are device costs captured?</p>    | <p><b><u>Not applicable</u></b></p>  |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |
| <p><b>A8.5 Identification Rules for Activity:</b><br/>How are activity costs captured?</p> | <p><b><u>Not captured by an existing specialised service line</u></b></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).<br/>There is no specific rule for susoctocog or Haemophilia A with Inhibitors.<br/>Closest match is NCBPS03Z</p> <p>If activity costs are already captured please specify whether this service needs a separate code. <b><u>No</u></b></p> <p>If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. <b><u>N/A</u></b></p> <p>If the activity is not captured please specify whether the proposed</p>   |       |                                     |                         |                          |                      |                          |     |                          |        |                          |   |                          |

|  |   |                     |                                     |         |                          |                      |                          |
|--|---|---------------------|-------------------------------------|---------|--------------------------|----------------------|--------------------------|
|  | identification rules have been documented and agreed with the Identification Rules team. <b><u>No</u></b>   |                     |                                     |         |                          |                      |                          |
| <b>A9 Monitoring</b>   |   |                     |                                     |         |                          |                      |                          |
| <b>A9.1 Contracts</b><br>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.   | <b><u>None</u></b>  |                     |                                     |         |                          |                      |                          |
| <b>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</b><br>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. | <i>Select all that apply:</i> <table border="1"> <tr> <td>Drugs or Device MDS</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Blueteq</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other prior approval</td> <td><input type="checkbox"/></td> </tr> </table> | Drugs or Device MDS | <input checked="" type="checkbox"/> | Blueteq | <input type="checkbox"/> | Other prior approval | <input type="checkbox"/> |
| Drugs or Device MDS  | <input checked="" type="checkbox"/>   |                     |                                     |         |                          |                      |                          |
| Blueteq  | <input type="checkbox"/>  |                     |                                     |         |                          |                      |                          |
| Other prior approval   | <input type="checkbox"/>  |                     |                                     |         |                          |                      |                          |
| <b>A9.3 Business intelligence</b><br>Is there potential for duplicate reporting?   | <b><u>No</u></b>  |                     |                                     |         |                          |                      |                          |
| <b>A9.4 Contract monitoring</b><br>Is this part of routine contract monitoring?  | <b><u>Yes</u></b><br>Acute Contract Monitoring and Drugs Minimum Data Sets  |                     |                                     |         |                          |                      |                          |
| <b>A9.5 Dashboard reporting</b><br>Specify whether a dashboard exists for the proposed intervention?   | <b><u>No</u></b><br>Not required  |                     |                                     |         |                          |                      |                          |
| <b>A9.6 NICE reporting</b><br>Are there any directly applicable NICE or equivalent quality   | <b><u>No</u></b>  |                     |                                     |         |                          |                      |                          |

|  |  |
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| 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.) | <p>Specialist haemophilia centres commissioned by NHS England provide services for patients with haemophilia. Access is through nominated Haemophilia Comprehensive Care Centres only, confirmed by the United Kingdom Haemophilia Centre Doctors' Organisation (UKHCDO) National network, plus local networks. Services contribute to the UKHCDO register for AHA patients, as well as other haematological disorders</p> <p><i>Source: NHS England</i></p> |
|---|--|

|   |           |
|---|-----------|
| B1.2 Will the proposition change the way the commissioned service is organised? | <b>No</b> |
|---|-----------|

|   |   |
|---|---|
| B1.3 Will the proposition require a new approach to the organisation of care? | <b><u>No change to delivery of care</u></b> |
|---|---|

**B2 Geography & Access**

|  |  |    |                          |                |                          |               |                          |
|--|--|----|--------------------------|----------------|--------------------------|---------------|--------------------------|
| B2.1 Where do current referrals come from? | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td data-bbox="1086 1214 1509 1273">GP</td> <td data-bbox="1509 1214 1597 1273"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1273 1509 1332">Secondary care</td> <td data-bbox="1509 1273 1597 1332"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 1332 1509 1391">Tertiary care</td> <td data-bbox="1509 1332 1597 1391"><input type="checkbox"/></td> </tr> </table> | GP | <input type="checkbox"/> | Secondary care | <input type="checkbox"/> | Tertiary care | <input type="checkbox"/> |
| GP   | <input type="checkbox"/>   |    |                          |                |                          |               |                          |
| Secondary care                             | <input type="checkbox"/>   |    |                          |                |                          |               |                          |
| Tertiary care                              | <input type="checkbox"/>   |    |                          |                |                          |               |                          |

|  |  |
|--|--|
|  | <div style="border: 1px solid black; display: inline-block; padding: 2px;">Other</div> <input checked="" type="checkbox"/> <p>Please specify:<br/>People will be referred from within comprehensive care centres or haemophilia centres as they will be already receiving treatment.</p> |
| B2.2 What impact will the new policy have on the sources of referral?  | <b><u>No impact</u></b>  |
| B2.3 Is the new policy likely to improve equity of access?   | <b><u>No impact</u></b><br><i>Source: Equalities Impact Assessment</i>   |
| B2.4 Is the new policy likely to improve equality of access and/or outcomes?   | <b><u>No impact</u></b><br><i>Source: Equalities Impact Assessment</i>   |
| <b>B3 Implementation</b>   |  |
| B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?                                       | <b><u>No action required</u></b>   |
| <b>B3.2 Time to implementation:</b><br>Is a lead-in time required prior to implementation?   | <b><u>No - go to B3.4</u></b>  |
| <b>B3.3 Time to implementation:</b><br>If lead-in time is required prior to implementation, will an interim plan for implementation be required? | <b><u>No - go to B3.4</u></b>  |
| B3.4 Is a change in provider physical infrastructure required?   | <b><u>No</u></b>   |

| B3.5 Is a change in provider staffing required?  | <b><u>No</u></b>  |                             |                          |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
|--|---|-----------------------------|--------------------------|-----------------------------|--------------------------|-------|---|---|----------|-----------------|---|---|----------|--------|---|---|----------|-------|---|---|----------|-------|----|----|----------|
| B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?   | <b><u>No</u></b>  |                             |                          |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| B3.7 Are there changes in the support services that need to be in place?   | <b><u>No</u></b>  |                             |                          |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)   | <b><u>No</u></b>  |                             |                          |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| 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 | <p><b><u>No change</u></b></p> <p><i>Please complete table:</i></p> <table border="1" data-bbox="1088 874 2013 1321"> <thead> <tr> <th>Region</th> <th>Current no. of providers</th> <th>Future State expected range</th> <th>Provisional or confirmed</th> </tr> </thead> <tbody> <tr> <td>North</td> <td>4</td> <td>4</td> <td><u>C</u></td> </tr> <tr> <td>Midlands &amp; East</td> <td>6</td> <td>6</td> <td><u>C</u></td> </tr> <tr> <td>London</td> <td>2</td> <td>2</td> <td><u>C</u></td> </tr> <tr> <td>South</td> <td>5</td> <td>5</td> <td><u>C</u></td> </tr> <tr> <td>Total</td> <td>17</td> <td>17</td> <td><u>C</u></td> </tr> </tbody> </table> <p>Please specify:<br/> <a href="#">Click here to enter text.</a></p> | Region                      | Current no. of providers | Future State expected range | Provisional or confirmed | North | 4 | 4 | <u>C</u> | Midlands & East | 6 | 6 | <u>C</u> | London | 2 | 2 | <u>C</u> | South | 5 | 5 | <u>C</u> | Total | 17 | 17 | <u>C</u> |
| Region   | Current no. of providers  | Future State expected range | Provisional or confirmed |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| North  | 4   | 4                           | <u>C</u>                 |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| Midlands & East  | 6   | 6                           | <u>C</u>                 |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| London   | 2   | 2                           | <u>C</u>                 |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| South  | 5   | 5                           | <u>C</u>                 |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |
| Total  | 17  | 17                          | <u>C</u>                 |                             |                          |       |   |   |          |                 |   |   |          |        |   |   |          |       |   |   |          |       |    |    |          |

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  | <input checked="" type="checkbox"/> |
| Market intervention required  | <input type="checkbox"/>            |
| Competitive selection process to secure increase or decrease provider configuration | <input type="checkbox"/>            |
| Price-based selection process to maximise cost effectiveness                        | <input type="checkbox"/>            |
| Any qualified provider  | <input type="checkbox"/>            |
| National Commercial Agreements e.g. drugs, devices                                  | <input type="checkbox"/>            |
| Procurement   | <input type="checkbox"/>            |
| Other   | <input type="checkbox"/>            |

**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:

|              |  |                                     |
|--------------|--|-------------------------------------|
| <b>Drugs</b> | Not separately charged – part of local or national tariffs | <input type="checkbox"/>            |
|              | Excluded from tariff – pass through                        | <input checked="" type="checkbox"/> |



|   |  |                                     |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|---|--|-------------------------------------|------------------------------|--------------------------|----------------|--|--------------------------|---|--------------------------|--|--------------------------|---------------------|--------------------------|-----------------|-----------------------------------|--------------------------|--------------------------------|--------------------------|------------------------------------|--------------------------|---------------------------------|--------------------------|---|--------------------------|---|--------------------------|--|-------------------------------------|
|   | <table border="1"> <tr> <td data-bbox="1079 97 1243 156"></td> <td data-bbox="1243 97 2056 156">Excluded from tariff - other</td> <td data-bbox="2056 97 2130 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 156 1243 392" rowspan="4"><b>Devices</b></td> <td data-bbox="1243 156 2056 215">Not separately charged – part of local or national tariffs</td> <td data-bbox="2056 156 2130 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 215 2056 274">Excluded from tariff (excluding ZCM) – pass through</td> <td data-bbox="2056 215 2130 274"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 274 2056 333">Excluded from tariff (excluding ZCM) – other</td> <td data-bbox="2056 274 2130 333"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 333 2056 392">Via Zero Cost Model</td> <td data-bbox="2056 333 2130 392"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 392 1243 807" rowspan="7"><b>Activity</b></td> <td data-bbox="1243 392 2056 451">Paid entirely by National Tariffs</td> <td data-bbox="2056 392 2130 451"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 451 2056 510">Paid entirely by Local Tariffs</td> <td data-bbox="2056 451 2130 510"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 510 2056 569">Partially paid by National Tariffs</td> <td data-bbox="2056 510 2130 569"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 569 2056 628">Partially paid by Local Tariffs</td> <td data-bbox="2056 569 2130 628"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 628 2056 687">Part/fully paid under a Block arrangement</td> <td data-bbox="2056 628 2130 687"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 687 2056 746">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="2056 687 2130 746"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 746 2056 807">Part/fully paid under Other arrangements</td> <td data-bbox="2056 746 2130 807"><input checked="" type="checkbox"/></td> </tr> </table> <p data-bbox="1079 858 2130 933">Specialist centre only (including outreach when delivered as part of a provider network)</p> |                                     | Excluded from tariff - other | <input type="checkbox"/> | <b>Devices</b> | Not separately charged – part of local or national tariffs | <input type="checkbox"/> | Excluded from tariff (excluding ZCM) – pass through | <input type="checkbox"/> | Excluded from tariff (excluding ZCM) – other | <input type="checkbox"/> | Via Zero Cost Model | <input type="checkbox"/> | <b>Activity</b> | Paid entirely by National Tariffs | <input type="checkbox"/> | Paid entirely by Local Tariffs | <input type="checkbox"/> | Partially paid by National Tariffs | <input type="checkbox"/> | Partially paid by Local Tariffs | <input type="checkbox"/> | Part/fully paid under a Block arrangement | <input type="checkbox"/> | Part/fully paid under Pass-Through arrangements | <input type="checkbox"/> | Part/fully paid under Other arrangements | <input checked="" type="checkbox"/> |
|   | Excluded from tariff - other   | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
| <b>Devices</b>  | Not separately charged – part of local or national tariffs   | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Excluded from tariff (excluding ZCM) – pass through  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Excluded from tariff (excluding ZCM) – other   | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Via Zero Cost Model  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
| <b>Activity</b>   | Paid entirely by National Tariffs  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Paid entirely by Local Tariffs   | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Partially paid by National Tariffs   | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Partially paid by Local Tariffs  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Part/fully paid under a Block arrangement  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Part/fully paid under Pass-Through arrangements  | <input type="checkbox"/>            |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
|   | Part/fully paid under Other arrangements   | <input checked="" type="checkbox"/> |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |
| <p data-bbox="91 991 344 1023"><b>C1.2 Drug Costs</b></p> <p data-bbox="91 1038 1048 1145">Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <p data-bbox="91 1161 1048 1225">NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p> | <p data-bbox="1079 991 1944 1023">The list price of susoctocog alfa is (nominal activity of 500iu):</p> <ul data-bbox="1137 1038 1800 1193" style="list-style-type: none"> <li>• 1 vial=£1,145: (£1,374 including VAT)</li> <li>• 5 vials=£5,725: (£6,870 including VAT)</li> <li>• 10 vials=£11,450: (£13,740 including VAT)</li> <li>• i.e. £2.29 per unit (£2.75 per unit incl. VAT)</li> </ul> <p data-bbox="1079 1209 1756 1241">See Policy proposition 8 for treatment dosages.</p> <p data-bbox="1079 1257 2130 1390">Please see the details of the treatment costs per bleed for susoctocog and the comparator drugs in the resource impact template (Supporting info,- Unit costs worksheet). No VAT is payable for activated prothrombin complex concentrate, as it is a plasma product. VAT is payable for all</p>  |                                     |                              |                          |                |  |                          |   |                          |  |                          |                     |                          |                 |                                   |                          |                                |                          |                                    |                          |                                 |                          |   |                          |   |                          |  |                                     |

|   |  |
|---|--|
|   | <p>products used in hospital. In acquired haemophilia A, treatments are used in hospital, so home delivery VAT exemption does not apply.</p> <p>Source: <a href="#">eMC Dictionary of medicines and devices browser</a>.</p> |
| <p><b>C1.3 Device Costs</b></p> <p>Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p> | Not applicable   |
| <p><b>C1.4 Activity Costs covered by National Tariffs</b></p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p>  | Not applicable   |
| <p><b>C1.5 Activity Costs covered by Local Tariff</b></p> <p>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 it has been derived, validated and tested.</p>   | Not applicable   |
| <p><b>C1.6 Other Activity Costs not covered by National or Local Tariff</b></p> <p>Include descriptions and estimates of all key costs.</p>   | Not applicable   |
| <p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p>   | <p><b>No</b></p> <p>Please specify: Susoctocog is likely only to be used to ensure only patients who meet the commissioning criteria as set out in the final policy are treated.</p>   |
|   |  |

| <b>C2 Average Cost per Patient</b>   |  |          |
|--|--|----------|
| C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?  | YR1  | £110,523 |
|  | YR2  | £179,882 |
|  | YR3  | £179,882 |
|  | YR4  | £181,980 |
|  | YR5  | £181,980 |
| Are there any changes expected in year 6-10 which would impact the model?  | This is the cost per patient per bleed. The patient population essentially matures at about year 2.  |          |
| <b>C3 Overall Cost Impact of this Policy to NHS England</b>  |  |          |
| C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.   | <p><b><u>Cost pressure</u></b><br/>           Year 1: £4.86 million<br/>           Year 2: £9.43 million<br/>           Year 5: £9.72 million</p> <p>This is the total cost increase against current practice and prices</p> |          |
| 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   |          |

| <b>C4 Overall cost impact of this policy to the NHS as a whole</b>  |  |
|---|--|
| C4.1 Specify the budget impact of the proposal on other parts of the NHS.   | Budget impact for CCGs:<br><b><u>No impact on CCGs</u></b><br>Budget impact for providers:<br><b><u>No impact on providers</u></b><br>Please specify:<br><a href="#">Click here to enter text.</a> |
| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.   | <b><u>Cost pressure</u></b><br>Same as C3.1  |
| C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured   | Not applicable   |
| C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?  | <b><u>No</u></b><br>Please specify:<br><a href="#">Click here to enter text.</a>   |
| <b>C5 Funding</b>   |  |
| 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  |
| <b>C6 Financial Risks Associated with Implementing this Policy</b>  |  |

|  |  |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
|--|--|---|--------------------------|--|--------------------------|--|--------------------------|--------------------------------|--------------------------|-----------------------------|--------------------------|---|-------------------------------------|
| C6.1 What are the material financial risks to implementing this policy?  | See C3.1   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| 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   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| <b>C7 Value for Money</b>  |  |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?                                | The clinical evidence review for this technology found no studies relating to cost effectiveness.  |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?                   | <p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other data has been identified</td> <td><input type="checkbox"/></td> </tr> <tr> <td>No data has been identified</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The data supports a high level of certainty about the impact on</td> <td><input checked="" type="checkbox"/></td> </tr> </table> | Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment | <input type="checkbox"/> | Available pricing data suggests the treatment is lower cost compared to current/comparator treatment | <input type="checkbox"/> | Available clinical practice data suggests the new treatment has the potential to improve value for money | <input type="checkbox"/> | Other data has been identified | <input type="checkbox"/> | No data has been identified | <input type="checkbox"/> | The data supports a high level of certainty about the impact on | <input checked="" type="checkbox"/> |
| Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment  | <input type="checkbox"/>   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| Available pricing data suggests the treatment is lower cost compared to current/comparator treatment   | <input type="checkbox"/>   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| Available clinical practice data suggests the new treatment has the potential to improve value for money   | <input type="checkbox"/>   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| Other data has been identified   | <input type="checkbox"/>   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| No data has been identified  | <input type="checkbox"/>   |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |
| The data supports a high level of certainty about the impact on  | <input checked="" type="checkbox"/>  |   |                          |  |                          |  |                          |                                |                          |                             |                          |   |                                     |

|  |   |                          |
|--|---|--------------------------|
|  | value   |                          |
|  | The data does not support a high level of certainty about the impact on value             | <input type="checkbox"/> |
| Please specify:<br><a href="#">Click here to enter text.</a>                       |   |                          |
| <b>C8 Cost Profile</b>   |   |                          |
| C8.1 Are there non-recurrent capital or revenue costs associated with this policy? | <b>No</b><br>If yes, specify type and range:<br><a href="#">Click here to enter text.</a> |                          |
| C8.2 If yes, confirm the source of funds to meet these costs.                      | Not applicable  |                          |