Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	NHS England URN 1717		
Policy Title	Emicizumab as prophylaxis in people with congenital haemophilia A with factor VIII inhibitors (all ages) Proposal **for routine commissioning** (ref A3.1)		
Lead Commissioner	Will Horsley	**Clinical Lead**	Peter Collins
Finance Lead	Click here to enter text.	**Analytical Lead**	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.	The UK National Haemophilia Database Bleeding Disorder Statistics for 2015-2016 reports that between April 2015 and March 2016 there were 5,930 people in the UK with mild, moderate or severe forms of haemophilia A (not including low-level carriers; factor VIII level ≥40 IU/dL). Of these, 230 people (3.9%) have current inhibitors, the majority of whom have severe haemophilia A (164 people; 71%), followed by moderate (42 people; 18%) and mild (24 people; 10%). For this time period there were 29 people with haemophilia A who had newly reported inhibitors (excluding low-level carriers). Of these 19 people (66%) had severe haemophilia A, 4 people (14%) had moderate and 6 people (21%) had mild. For England only, the number of with mild, moderate or severe forms of haemophilia A (not including low-level carriers; factor VIII level ≥40 IU/dL) is estimated to be 4,990. Based on the UK National Haemophilia Database from 2012/13 – 2016/17, the average number of people in England with congenital haemophilia A with inhibitors is 177. During the same period an average of 26 new people with congenital haemophilia A with inhibitors were registered each year. Therefore the total number of people with congenital haemophilia A with inhibitors is estimated at 203. This is the target population. The number of people eligible for treatment under this policy document is therefore 203 *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.	About **117** people with congenital haemophilia A with inhibitors were treated with by-passing agents and **59** people who had low levels of

<table>
<tr><td></td><td>inhibitors (<5BU/ml) treated with prophylactic and on-demand high dose factor VIII and are eligible for treatment under this policy. This gives a total of 176 people with congenital hemophilia A with inhibitors who currently eligible for treatment under this policy.
Source: UK National Haemophilia Database 2016</td></tr>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>All ages</u>
Please specify
Haemophilia A generally affects males on the maternal side.(Srivastava et al. 2013) Haemophilia may be suspected in childhood; however, some patients may not present with bleeding symptoms until they undergo trauma or surgery.(Srivastava et al. 2013)</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>Not applicable
Source: required
Please specify
Click here to enter text.</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: UK National Haemophilia Database 2016</td></tr>
<tr><td colspan="2"></td></tr>
</table>

<table>
<tr><th colspan="2">A2 Future Patient Population & Demography</th></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 identified.
Source: Clinical Evidence Review, Policy Working Group
Source: Policy Proposition section 6</td></tr>
<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>
Please specify
Click here to enter text.
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>Year2 +/-</td><td>0</td></tr><tr><td>Year3 +/-</td><td>0</td></tr><tr><td>Year4 +/-</td><td>0</td></tr><tr><td>Year5 +/-</td><td>0</td></tr><tr><td>Year10 +/-</td><td>0</td></tr></table>Source: Service specification proposition section 3.1

<u>Yes</u>
Click here to enter text.</td></tr>
<tr><th colspan="2">A3 Activity</th></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new</u></td></tr>
</table>

	<u>treatment</u> The purpose of the new policy is to commission emicizumab to prevent bleeding episodes where the person has a factor VIII inhibitor confirmed on more than one occasion by a Nijmegen-modified Bethesda assay, that compromises the effect of prophylaxis or treatment of bleeds at standard doses of factor VIII and is for whom ITI has not eradicated the inhibitor; OR is an existing patient with uncontrolled bleeding episodes; OR currently receives bypass agents either prophylactically or on-demand; OR is undergoing ITI and needs prophylaxis to prevent breakthrough bleeds during ITI treatment.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	**176** *Source:* UK National Haemophilia Database 2016 Please specify Of these 117 people with congenital haemophilia A with inhibitors were treated with by passing agents in England in 2015/16 and 59 with low inhibitor titres were treated with high dose factor VIII in 2016. These are the people who could go on to receive emicizumab.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	**203** *Source:* UK National Haemophilia Database 2016. *Policy Proposition section 6* Please specify The eligible patient population for emicizumab (according to the anticipated licence) in the UK is considered to be equivalent to the patients with current inhibitors.
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	Not applicable *Source:* *required*

applicable' and move to A4.	Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Eradication of the inhibitors (through immune tolerance induction [ITI]) is the main treatment option for patients who are newly diagnosed with inhibitors to FVIII. If ITI eradicates the inhibitor, these patients can return to treatment with FVIII as prophylaxis or on demand. This is NOT the target population. The target population includes the following: • Patients with haemophilia A with inhibitors who had ITI, but their inhibitors have not been eradicated • Patients with haemophilia A with inhibitors for whom ITI is not indicated (usually due to the length of time they have had inhibitors – the longer you have inhibitors, the less likely you would be able to eradicate the inhibitor) who have uncontrolled bleeds. • Patients with haemophilia A with inhibitors who are receiving ITI but need prophylaxis to prevent breakthrough bleeds The current treatments for these patients includes: • bypassing agents either prophylactically or on-demand (including recombinant factor VIIa and activated prothrombin complex concentration • high dose factor VIII (without the intention of using it for ITI). The policy applies to patients of all ages in-line with the expected product

	license. UKHCDO register estimates that: 117 patients currently receive by-passing agents and 59 currently receive non-ITI factor VIII. *Source:* Policy Proposition section 3. UK National Haemophilia Database 2016
A4.2. What are the current treatment access and stopping criteria?	Click here to enter text.
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 criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Click here to enter text. 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*	**No** If yes, Click here to enter text. *Source: required*

• *Patient pathway* • *Actual or estimated eligibility and uptake*	
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Not applicable a) enter % b) enter % c) enter % d) enter % e) enter % *Source: required*
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 criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Click here to enter text. a) 100% b) 0% c) 100% d) 100% e) 100% *Source* Policy proposition 3*:*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long** For time limited treatments, specify frequency and/or duration. Click here to enter text.

	Source: **Company submission. Roche**
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: 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 5 MIDLANDS & EAST 8 LONDON 4 SOUTH 5 This represents the Haemophilia Comprehensive Care Centres in

<table>
<tr><td></td><td>England, to which treatment is restricted.</td></tr>
<tr><td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td><td><u>No</u>

Source: Policy Working Group</td></tr>
<tr><td colspan="2">A8 Coding</td></tr>
<tr><td>A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity</td><td>Select all that apply:
<table><tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr><tr><td>Patient level contract monitoring</td><td>☐</td></tr><tr><td>Patient level drugs dataset</td><td>☐</td></tr><tr><td>Patient level devices dataset</td><td>☐</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☐</td></tr><tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☐</td></tr><tr><td>Clinical Database**</td><td>☒</td></tr><tr><td>Other**</td><td>☐</td></tr></table>**If National Return, Clinical database or other selected, please specify:
The UK National Haemophilia Database</td></tr>
</table>

<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>Not already specified in current NHS England Drugs List document</u>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:
Click here to enter text.
If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:
Upon approval of the policy, the above combination will be added to the current MDS
The drug is already listed as a tariff exemption.</td>
</tr>
<tr>
<td>A8.4 Identification Rules for Devices:
How are device costs captured?</td>
<td><u>Not applicable</u>
I</td>
</tr>
<tr>
<td>A8.5 Identification Rules for Activity:
How are activity costs captured?</td>
<td><u>Not captured by an existing specialised service line</u>
If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</td>
</tr>
</table>

<table>
<tr><td></td><td>There is no specific rule for emicizumab or Haemophilia A with Inhibitors. Closest match is NCBPS03Z
If activity costs are already captured please specify whether this service needs a separate code. <u>No</u>
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.
N/A
If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. <u>No</u></td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u>
Please specify
Click here to enter text.</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: Click here to enter text.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u>
If yes, please specify mitigation:</td></tr>
</table>

	Click here to enter text.
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** If yes, please specify contract monitoring requirement: Acute Contract Monitoring and Drugs Minimum Data Sets
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No** If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text. If no, will one be developed? Click here to enter text.
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No** If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.
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 nominated Haemophilia Comprehensive Care Centres only, confirmed by UKHCDO National network, plus local networks. *Source:* Commissioning Policy: Immune Tolerance Induction (ITI) for haemophilia A (all ages). Reference: NHS England: 16042/P
B1.2 Will the proposition change the way the commissioned service is organised?	**No**

<table>
<tr><td></td><td>Please specify:
Click here to enter text.
Source: required</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No change to delivery of care</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☐</td></tr><tr><td>Tertiary care</td><td>☐</td></tr><tr><td>Other</td><td>☒</td></tr></table>Please specify:
People will be referred from within comprehensive care centres or haemophilia centres as they will already be receiving treatment.</td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u>
Please specify:
Click here to enter text.</td></tr>
</table>

	Source: Equalities Impact Assessment
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**No impact** Please specify: Click here to enter text. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Click here to enter text.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	**No** Please specify: Click here to enter text.

B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No** Please specify: Click here to enter text.
B3.7 Are there changes in the support services that need to be in place?	**No** Please specify: Click here to enter text.
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No** Please specify: Click here to enter text.
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** see A7.2 *Please complete table:* Click here to enter text.
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 ☒ Please specify: Click here to enter text.
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** Please specify: Click here to enter text.
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	☐
	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	☐

<table>
<tr><td></td><td>
<table>
<tr><td rowspan="7">Activity</td><td>Paid entirely by National Tariffs</td><td>☐</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☒</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table>
</td></tr>
<tr><td>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.</td><td>Emicizumab has not yet been granted marketing authorisation in the UK and as such a list price is not yet set.</td></tr>
<tr><td>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.</td><td>Not applicable</td></tr>
<tr><td>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 %)</td><td>Haemophilia specialist services top up (NCBPS03Z) of 30.6%.</td></tr>
<tr><td>C1.5 Activity Costs covered by Local Tariff</td><td>Not applicable</td></tr>
</table>

<table>
<tr><td>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.</td><td></td></tr>
<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>
Please specify: Emicizumab 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></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table>
If yes, please specify:
To be confirmed following market authorisation and NHS price is confirmed</td></tr>
<tr><td colspan="2"></td></tr>
</table>

C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	**Cost pressure** Please specify: Not able to confirm until NHS price is confirmed, cost pressure is a possibility.
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** Please specify:
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Please specify: Potential for cost pressure to NHS, see section 3.1 It is expected uptake would reach 50% - 100% within 6 to 12 months following a positive policy recommendation.

C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Click here to enter text.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify:
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 have been identified
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?	No applicable

<table>
<tr><th colspan="2">C7 Value for Money</th></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>The clinical evidence review for this technology found no studies relating to cost effectiveness</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☐</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☒</td></tr>
</table>Please specify:
Awaiting confirmation of NHS price</td></tr>
<tr><th colspan="2">C8 Cost Profile</th></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated</td><td><u>No</u></td></tr>
</table>

with this policy?	If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.