Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1609		
Policy Title	Anakinra/Tocilizumab for the treatment Adult Onset Still's Disease refractory to second-line therapy(adults) Proposal **for routine commission** (ref A3.1)		
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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.	There is no consensus on the incidence and prevalence of AOSD overall in the English population. Studies estimate an incidence of AOSD in France is between 1 – 2 cases per million population per year. Therefore, it can be estimated that in England, approximately 55-110 new cases of AOSD could be expected every year, assuming the French and English populations are similar. No evidence was available as regards the proportion of patients thought to be refractory to methotrexate and corticosteroids with AOSD in the evidence review. Gerfaud-Valentin et al (2014) estimated between a quarter and third of patients with AOSD are thought to be refractory to DMARDs and could require biologicals. *Source: Policy Proposition section 5*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	*Approximately 81 patients in first year then approx. 27 newly refractory patients per year thereafter.* *Source: Policy Proposition section 5* Biologics where available until funding arrangements changed in 2015. It is estimated that approximately 80-85 patients presently require treatment with biologics and 25-30 new patients per year with AOSD will require treatment with biologics.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults** This policy covers adults from 18+. Children are covered by Policy: Biologic Therapies for the treatment of Juvenile Idiopathic Arthritis (JIA)
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	18+ *Source: Policy Proposition*

<table>
<tr><td></td><td></td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>unknown</u></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>Increasing</u>
We expect the incidence to increase in line with population growth, and that prevalence may increase in the longer term due to improved patient survival as a result of the use of anakinra, we would expect some patients to cease treatment as either they go into remission or if the treatment is no longer effective.
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>

Source: Policy Proposition section 6</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?</td><td><table>
<tr><td>YR2 +/-</td><td>102</td></tr>
<tr><td>YR3 +/-</td><td>66</td></tr>
<tr><td>YR4 +/-</td><td>77</td></tr>
<tr><td>YR5 +/-</td><td>88</td></tr>
<tr><td>YR10 +/-</td><td>146</td></tr>
</table>Source: Finance modelling</td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Confirm routine commissioning position of an additional new treatment</u>** To provide access to Anakinra or Tocilizumab for the treatment of Adult Onset Still's Disease refractory to disease modifying anti-rheumatic drugs and corticosteroids [adults] as second line treatments.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	A small number of patients are presently on Anakinra for AOSD based on the funding arrangements in place prior to April 2015. Since 2015 treatment has not been available for new patients. Patients on treatment prior to 2015 have not been included in activity modelling. Some will no longer require treatment as either in remission or treatment ineffective. *Source:*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	27 newly diagnosed patient/ annum refractory to second line treatments *Source: Section 5* Activity is expected to be higher in first year as the patients diagnosed with refractory AOSD between 2015 and 2018 start treatment. Overall annual activity will fluctuate due to mortality, treatment no longer being effective or patients going into remission as per financial modelling
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	N/A *Source: Policy Proposition* Click here to enter text.

applicable' and move to A4.	
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	As there is not an effective treatment for patients that are refractory to second line treatment, patients are regularly seen at OP, A&E and have inpatient admissions to deal with the symptoms and side effects of drugs.. A proportion will go on to develop diabetes and osteoporosis from high dose steroids and DMARDs. Macrophage activation syndrome (MAS) is a known serious complication of AOSD. The frequency of fully developed MAS is 12 to 15% in AOSD patients where symptoms are uncontrolled *Source: Policy Working Group.*
A4.2. What are the current treatment access and stopping criteria?	After an initial AOSD diagnosis using a diagnosis criterion such as Yamaguchi criteria the treatment pathway would be **First line treatments:** NSAIDS and corticosteroids: prednisolone 0.8-1 mg/kg/day for 4-6 weeks. **Second line treatments**: When diagnosis is confirmed, patients treated using a selection of the following conventional steroid-sparing effect DMARDs prescribed in line with NICE Clinical Knowledge Summary (CKS) for DMARDs : • MTX: 7.5 -25 Mg/week (oral or s/c) or • Cyclosporine: up to 5mg/kg/day depending on tolerance/side effects • mycophenolate 2-3g/day or • Leflunomide 10-20 mg od, or • Azathioprine 2-2.25mg/kg (in patients with normal thiopurine methyltransferase (TPMT) levels; 1-1.25mg.kg in patients with heterozygote level TPMT levels.)

	• Corticosteroids can be used in combination with any of these regimes. Patients on current pathway who do not respond to the above treatment options would be placed on higher dose corticosteroids and DMARDS to try and control symptoms. *Source: Policy Proposition*
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?	All patients diagnosed with AOSD will be started on NSAIDS and corticosteroids then move to 2nd line DMARDs a) 100% of patients diagnosed with AOSD b) 0% however 25-33% will be refractory to 2nd line DMARDs c) 100% d) Unknown e) Unknown- Variable as some patients will go into remission, treatment will be ineffective or remain on treatment for life *Source: Policy Proposition*
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*	**No**

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?	Total estimated eligible 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?	It is to be expected between 25-33% of patients diagnosed with AOSD will require treatments with biologics as refractory to second line tratments a) 25-33% who are refractory to 2nd line treatment b) 0% c) 100% d) unknown e) Unknown- Variable as some patients will go into remission, treatment will be ineffective or remain on treatment for life *Source: Policy Proposition*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Lifelong/time limited** Duration of treatment varies. It can be life-long however some patients go into remission or the treatment ceases as no longer effective. It is projected approx. 25% of patient population will cease requiring treatment as ineffective and another 25% may go into remission for periods.

	Source: Policy working group
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☐</td></tr><tr><td>Acute Trust: day patient</td><td>☒</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table> Anakinra is delivered as a subcutaneous injection daily home care. Tocilizumab as infusions every 4-6 weeks as day case
A7.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>Not Known</td></tr><tr><td>MIDLANDS & EAST</td><td>Not Known</td></tr><tr><td>LONDON</td><td>Not Known</td></tr><tr><td>SOUTH</td><td>Not Known</td></tr></table>

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** *Source: Policy Proposition section 9*
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: Click here to enter text.
A8.2 Specify how the activity related to the new patient pathway will be identified.	*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>
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<u>Already specified in current NHS England Drugs List document</u>** Anakinra is commissioned currently for a number of conditions on the NHS England Drug List which will need to be updated to reflect new policy. The coding of anakinra has been discussed with the pharmacy and Information lead for Specialised Commissioning
A8.4 **Identification Rules for Devices:** How are device costs captured?	**<u>Not applicable</u>**
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**<u>Not captured by an existing specialised service line</u>** 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>**
A9 Monitoring	

<table>
<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>Yes - other</u>
Treatment centres will use a prior approval system to track and audit use of anakinra and tocilizumab, in order to ensure it is administered according to the criteria for commissioning.</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:
Click here to enter text.</td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
Drugs used are part of routine contract monitoring as excluded from tariff</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u></td></tr>
<tr><td>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?</td><td><u>No</u></td></tr>
<tr><td colspan="2">Section B - Service Impact</td></tr>
</table>

<table>
<tr><th colspan="2">B1 Service Organisation</th></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)</td><td>Tertiary Centres with specialist rheumatology and immunology services
Source: Service Specifications for Specialised Immunology and Rheumatology</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u></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></td></tr>
<tr><th colspan="2">B2 Geography & Access</th></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>Patients are referred to tertiary specialist centres for investigation of AOSD symptoms</td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>
Patients are already referred to tertiary centres for diagnosis of AOSD</td></tr>
</table>

B2.3 Is the new policy likely to improve equity of access?	**Increase** There is currently a funded patient cohort from pre 2015 when funding arrangements changed and an unfunded patient cohort post 2015. This policy will ensure equality of access. *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Increase** The policy will improve health outcomes for those with AOSD whom the condition is not presently controlled by corticosteroids or DMARDs. 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**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
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** If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No**

<table>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u></td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u></td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>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</td><td><u>No change</u>
Please complete table:
<table>
<tr><th>Region</th><th>Current no. of providers</th><th>Future
State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North</td><td></td><td></td><td>select</td></tr>
<tr><td>Midlands & East</td><td></td><td></td><td>select</td></tr>
<tr><td>London</td><td></td><td></td><td>select</td></tr>
<tr><td>South</td><td></td><td></td><td>select</td></tr>
<tr><td>Total</td><td></td><td></td><td>select</td></tr>
</table>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS</td><td>Select all that apply:</td></tr>
</table>

England as the responsible commissioner.	<table><tr><td>Publication and notification of new policy</td><td>☐</td></tr><tr><td>Market intervention required</td><td>☐</td></tr><tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr><tr><td>Any qualified provider</td><td>☒</td></tr><tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr><tr><td>Procurement</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table> 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	☐
	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.	Anakinra costs £9,850/annum per patient to provide 100mg per day in a homecare setting this value includes VAT at the standard 20% rate, which is inclusive of delivery and administration charges. Tocilizumab is administered as an intravenous infusion usually given in a hospital setting every 4 to 6 weeks and costs [redacted] for the drug this value includes VAT at the standard 20% rate plus £1680/annum day care costs.
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the	N/A

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.	
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 %)	A&E attendances priced at an average of Type 1 & 2 departments at £158 per attendance (VB01Z – VB99Z) OP attendances are priced at Rheumatology OP rates against WF01B single professional first attendance £246 and WF01A single professional follow up £111. Inpatient attendances are costed using an average rate of adults £2,783 against HRG`s HD23D- HD23J, dependent upon complication and comorbidity score MFF is then applied at 8.075%.
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.	N/A
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	N/A
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**Yes** Please specify: Blueteq
C2 Average Cost per Patient	

<table>
<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>11,087</td></tr><tr><td>YR2</td><td>11,094</td></tr><tr><td>YR3</td><td>11,094</td></tr><tr><td>YR4</td><td>11,086</td></tr><tr><td>YR5</td><td>11,094</td></tr></table>
No</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 saving</u>
Please specify:
It is anticipated that the use of Anakinra or tocilizumab will reduce attendances in specialist outpatient appointments and regularity of inpatient stays including ICU to care for patients due to symptoms of AOSD and complications of taking high dose corticosteroids and DMARDs</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>N/A</td></tr>
<tr><td>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?</td><td>N/A</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy to the NHS as a whole</td></tr>
</table>

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost saving** Budget impact for providers: **Cost saving** Please specify: It is anticipated that the use of Anakinra/tocilizumab will reduce the reliance on A&E attendances and regularity of inpatient stays to care for patients do to symptoms of AOSD and complications of taking high dose corticosteroids and DMARDs
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost saving** Please specify: It would be expected the budget impact as a whole across the NHS would equate to a cost saving over 10 years.
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?	**Yes** Please specify: It would be expected that patients with controlled symptoms would be able to work and not require benefits for sickness or disability.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of	N/A

funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	Nil
C6.2 How can these risks be mitigated?	N/A
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	The impact of the disease over 10 years has been modelled for patients who are treated with anakinra or tocilizumab, and those that are refractory to second line treatments and have uncontrolled symptoms and side effects to condition and of high dose corticosteroids and DMARDs
C6.4 What scenario has been approved and why?	It is more cost effective to treat AOSD patients with anakinra or tocilizumab then present pathway for patient's refractory to 2nd line treatments.
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** Evidence review found no information regards cost effectiveness of treatment
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 | ☐
	Please specify: Click here to enter text.
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