

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1673		
Policy Title	Infliximab for Progressive Pulmonary Sarcoidosis Proposal <u>not for routine commission</u> (ref A3.1)		
Lead Commissioner	Kathy Blacker	Clinical Lead	Prof Ling Pei Ho
Finance Lead	Keith Moulds	Analytical Lead	Craig Charlton

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.	3 per 100,000 <i>with sarcoidosis, of these 0.7 to 2.1 per 100,000 will have progressive pulmonary sarcoidosis</i> <i>Source: Policy Proposition section 6 BLF data check reference</i> <i>BLF Battle for Breath Report 2016</i> <i>ATS Statement on Sarcoidosis 1999</i>				
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	3 <i>Source: Policy proposition</i> Please specify Policy proposition Post engagement – section 6 – Epidemiology and Needs assessment				
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	<u>Adults</u> Please specify Age 18 and over				
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	N/A				
A1.5 How is the population currently distributed geographically?	<u>Evenly</u> If unevenly, estimate regional distribution by %: <table border="1" style="width: 100%;"> <tr> <td>North</td><td>enter %</td></tr> <tr> <td>Midlands & East</td><td>enter %</td></tr> </table>	North	enter %	Midlands & East	enter %
North	enter %				
Midlands & East	enter %				

	<table border="1"> <tr> <td>London</td><td>enter %</td></tr> <tr> <td>South</td><td>enter %</td></tr> </table> <p>Source: Policy Proposition section 6 Craig to work percentages Please specify BLF Battle for Breath Report 2016</p>	London	enter %	South	enter %				
London	enter %								
South	enter %								
A2 Future Patient Population & Demography									
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><u>Other - detail below</u></p> <p>If other, Marginal increase Source: Policy Proposition section 6 BLF Battle for Breath Report 2016</p>								
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><u>No</u></p> <p>Please specify Not routinely commissioned Source: Policy Proposition section 6/other</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?	<table border="1"> <tr> <td>YR2 +/-</td><td>0</td></tr> <tr> <td>YR3 +/-</td><td>0</td></tr> <tr> <td>YR4 +/-</td><td>0</td></tr> <tr> <td>YR5 +/-</td><td>0</td></tr> </table>	YR2 +/-	0	YR3 +/-	0	YR4 +/-	0	YR5 +/-	0
YR2 +/-	0								
YR3 +/-	0								
YR4 +/-	0								
YR5 +/-	0								

<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"> <tr> <td>YR10 +/-</td> <td>0</td> </tr> </table>	YR10 +/-	0	<p>Source: Service specification proposition section 3.1</p> <p><u>Yes</u></p>
YR10 +/-	0			
<p>A3 Activity</p>				
<p>A3.1 What is the purpose of new policy?</p>	<p><u>Confirm non-routine commissioning position of an additional new treatment</u></p>			
<p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p>	<p>None as not routinely commissioned Please specify Policy Proposition section 6 Epidemiology and needs assessment</p>			
<p>A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?</p>	<p>None as not routinely commissioned Please specify Policy Proposition section 6 Epidemiology and needs assessment</p>			
<p>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.</p>	<p>Not applicable</p>			
<p>A4 Existing Patient Pathway</p>				

<p>A4.1 Existing pathway: Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates. 	<p>For progressive pulmonary sarcoidosis, patient is typically referred from secondary care to a tertiary ILD service for assessment at outpatient. Oral corticosteroid (Prednisolone) is the first line therapy for patients with progressive disease or end-organ dysfunction, with a maintenance dose for a period of 6-24 months. Assessment for response would usually take 3-6 outpatient appointments. Other immunosuppressants treatments are considered when corticosteroids fail to control disease progression, or when corticosteroids are contraindicated (typically when patients also have diabetes mellitus and osteoporosis), and if side effects are intolerable. Azathioprine, Mycophenolate and Methotrexate are the second line drugs of choice. Assessment for response to second line drugs will take a further 3-6 outpatient appointments. Patients may require home oxygen and on average will require inpatient admission, usually for concomitant chest infection.</p> <p>If progression cannot be halted patients may be considered for lung transplantation.</p>
<p>A4.2. What are the current treatment access and stopping criteria?</p>	<p>Secondary care treatment with corticosteroids and second line drugs. Stopping criteria would be with a positive response to treatment, stabilisation of disease, and inactive disease after that.</p> <p><i>Source: American Thoracic Society Statement on Sarcoidosis 1999</i></p>
<p>A4.3 What percentage of the total eligible population is expected to:</p> <ol style="list-style-type: none"> Be clinically assessed for treatment Be considered to meet an exclusion criteria following assessment Choose to initiate treatment Comply with treatment Complete treatment? 	<p>If not known, please specify</p> <ol style="list-style-type: none"> 10-30% 10-20% of (a) 80% of (a) 50-80% of (c) 70-100% of (d) <p><i>Source: Expert clinical experience</i></p>

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:

- Be clinically assessed for treatment
- Be considered to meet an exclusion criteria following assessment
- Choose to initiate treatment
- Comply with treatment
- Complete treatment?

Not applicable

A6 New Patient Pathway

A6.1 What percentage of the total eligible population is expected to:

- Be clinically assessed for treatment
- Be considered to meet an exclusion criteria following assessment
- Choose to initiate treatment
- Comply with treatment

Not applicable

e) Complete treatment?																				
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	Not applicable																			
A7 Treatment Setting																				
A7.1 How is this treatment delivered to the patient?	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Emergency/Urgent care attendance</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: day patient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Acute Trust: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: inpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health provider: outpatient</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Community setting</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Homecare</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table> <p>Please specify: Not applicable</p>		Emergency/Urgent care attendance	<input type="checkbox"/>	Acute Trust: inpatient	<input 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"/>
Emergency/Urgent care attendance	<input type="checkbox"/>																			
Acute Trust: inpatient	<input 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"/>																			
A7.2 What is the current number of contracted providers for the eligible population by region?	<table border="1"> <tr> <td>NORTH</td> <td>5</td> </tr> <tr> <td>MIDLANDS & EAST</td> <td>8</td> </tr> <tr> <td>LONDON</td> <td>4</td> </tr> </table>		NORTH	5	MIDLANDS & EAST	8	LONDON	4												
NORTH	5																			
MIDLANDS & EAST	8																			
LONDON	4																			

	SOUTH	6																				
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	No Please specify: The policy is not to routinely commission																					
A8 Coding																						
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical Database**</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table> <p>**If National Return, Clinical database or other selected, please specify: NRC</p>		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 type="checkbox"/>
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 type="checkbox"/>																					

<p>A8.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Treatment function code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input type="checkbox"/></td> </tr> </table>	OPCS v4.8	<input checked="" 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"/>
OPCS v4.8	<input checked="" 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>A8.3 Identification Rules for Drugs: How are drug costs captured?</p>	<p><u>Not applicable</u></p> <p>If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:</p> <p>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:</p>														
<p>A8.4 Identification Rules for Devices: How are device costs captured?</p>	<p><u>Not applicable</u></p> <p>If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).</p> <p>If the device is not excluded from Tariff nor covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.</p>														

A8.5 Identification Rules for Activity: How are activity costs captured?	<p><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>If activity costs are already captured please specify whether this service needs a separate code.</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.</p> <p>If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team.</p>						
A9 Monitoring							
A9.1 Contracts Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	<u>None</u>						
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	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Drugs or Device MDS</td> <td><input 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 type="checkbox"/>	Blueteq	<input type="checkbox"/>	Other prior approval	<input type="checkbox"/>
Drugs or Device MDS	<input type="checkbox"/>						
Blueteq	<input type="checkbox"/>						
Other prior approval	<input type="checkbox"/>						

systems.	
A9.3 Business intelligence Is there potential for duplicate reporting?	<u>No</u>
A9.4 Contract monitoring Is this part of routine contract monitoring?	<u>No</u>
A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention?	<u>No</u> If no, will one be developed? Not applicable
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?	<u>No</u>
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Tertiary ILD centres
B1.2 Will the proposition change the way the commissioned service is organised?	<u>No</u> Please specify: Not routinely commissioned

	<i>Source: required</i>								
B1.3 Will the proposition require a new approach to the organisation of care?	<p><u>No change to delivery of care</u></p> <p>Please specify: Not routinely commissioned</p>								
B2 Geography & Access									
B2.1 Where do current referrals come from?	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>GP</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Secondary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Tertiary care</td><td><input type="checkbox"/></td></tr> <tr> <td>Other</td><td><input type="checkbox"/></td></tr> </table>	GP	<input checked="" type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input checked="" type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of referral?	<p><u>No impact</u></p> <p>Please specify: Treatment is not currently commissioned</p>								
B2.3 Is the new policy likely to improve equity of access?	<p><u>No impact</u></p> <p>Please specify: Treatment is not currently commissioned</p>								
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<p><u>No impact</u></p> <p>Please specify: Treatment is not currently commissioned</p>								

B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<u>No action required</u> Please specify: Circular to be published
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	<u>No - go to B3.4</u> 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?	Not applicable
B3.4 Is a change in provider physical infrastructure required?	<u>No</u>
B3.5 Is a change in provider staffing required?	<u>No</u>
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<u>No</u>
B3.7 Are there changes in the support services that need to be in place?	<u>No</u>

B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<u>No</u>																											
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	<u>No change</u> <i>Please complete table:</i> <table border="1" data-bbox="1088 333 2016 778"> <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></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> </tbody> </table>				Region	Current no. of providers	Future State expected range	Provisional or confirmed	North			select	Midlands & East			select	London			select	South			select	Total			select
Region	Current no. of providers	Future State expected range	Provisional or confirmed																									
North			select																									
Midlands & East			select																									
London			select																									
South			select																									
Total			select																									
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<i>Select all that apply:</i> <table border="1" data-bbox="1088 874 2000 1353"> <tbody> <tr> <td>Publication and notification of new policy</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Market intervention required</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Competitive selection process to secure increase or decrease provider configuration</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Price-based selection process to maximise cost effectiveness</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Any qualified provider</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Commercial Agreements e.g. drugs, devices</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Procurement</td> <td><input type="checkbox"/></td> </tr> </tbody> </table>				Publication and notification of new policy	<input 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"/>										
Publication and notification of new policy	<input 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"/>																											

	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Other</td><td style="width: 20%; text-align: center;"><input checked="" type="checkbox"/></td></tr> </table> <p>Please specify: Not applicable</p>	Other	<input checked="" type="checkbox"/>																			
Other	<input checked="" 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)	<u>No</u>																					
Section C - Finance Impact																						
C1 Tariff/Pricing																						
<p>C1.1 How is the service contracted and/or charged?</p> <p>Only specify for the relevant section of the patient pathway</p>	<p><i>Select all that apply:</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td rowspan="3" style="width: 15%; text-align: center; vertical-align: middle;">Drugs</td><td style="width: 75%;">Not separately charged – part of local or national tariffs</td><td style="width: 10%; text-align: center;"><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff – pass through</td><td style="text-align: center;"><input checked="" type="checkbox"/></td></tr> <tr> <td>Excluded from tariff - other</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td rowspan="4" style="text-align: center; vertical-align: middle;">Devices</td><td>Not separately charged – part of local or national tariffs</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff (excluding ZCM) – pass through</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td>Excluded from tariff (excluding ZCM) – other</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td>Via Zero Cost Model</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td rowspan="2" style="text-align: center; vertical-align: middle;">Activity</td><td>Paid entirely by National Tariffs</td><td style="text-align: center;"><input type="checkbox"/></td></tr> <tr> <td>Paid entirely by Local Tariffs</td><td style="text-align: center;"><input type="checkbox"/></td></tr> </table>	Drugs	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff – pass through	<input checked="" type="checkbox"/>	Excluded from tariff - other	<input type="checkbox"/>	Devices	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"/>	Activity	Paid entirely by National Tariffs	<input type="checkbox"/>	Paid entirely by Local Tariffs	<input type="checkbox"/>
Drugs	Not separately charged – part of local or national tariffs		<input type="checkbox"/>																			
	Excluded from tariff – pass through		<input checked="" type="checkbox"/>																			
	Excluded from tariff - other	<input type="checkbox"/>																				
Devices	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"/>																				
Activity	Paid entirely by National Tariffs	<input type="checkbox"/>																				
	Paid entirely by Local Tariffs	<input type="checkbox"/>																				

	<table border="1"> <tr> <td>Partially paid by National Tariffs</td><td><input type="checkbox"/></td></tr> <tr> <td>Partially paid by Local Tariffs</td><td><input type="checkbox"/></td></tr> <tr> <td>Part/fully paid under a Block arrangement</td><td><input type="checkbox"/></td></tr> <tr> <td>Part/fully paid under Pass-Through arrangements</td><td><input type="checkbox"/></td></tr> <tr> <td>Part/fully paid under Other arrangements</td><td><input type="checkbox"/></td></tr> </table>	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 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 type="checkbox"/>										
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.	Not applicable										
C1.3 Device Costs Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable										
C1.4 Activity Costs covered by National Tariffs List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Not applicable										
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	Not applicable										

if newly proposed how is has been derived, validated and tested.			
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable		
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	<u>No</u>		
C2 Average Cost per Patient			
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?	YR1	0	
	YR2	0	
	YR3	0	
	YR4	0	
	YR5	0	
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.	<u>Cost neutral</u> Please specify: Not routinely commissioned		

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: <u>No impact on CCGs</u> Budget impact for providers: <u>No impact on providers</u>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<u>Cost neutral</u> Please specify: Not for routine commissioning
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?	<u>No</u>
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.	Not applicable				
C6 Financial Risks Associated with Implementing this Policy					
C6.1 What are the material financial risks to implementing this policy?	Not applicable				
C6.2 How can these risks be mitigated?	Not applicable				
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable				
C6.4 What scenario has been approved and why?	Not applicable				
C7 Value for Money					
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	<u>There is no published evidence of cost-effectiveness</u>				
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</td><td><input 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	<input 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	<input type="checkbox"/>				

	compared to current/comparator treatment	
	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 value	<input type="checkbox"/>
	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
Please specify: Not applicable		
C8 Cost Profile		
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	<u>No</u>	
C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable	