

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A14/X/04		
Policy Title	Rituximab for Interstitial Lung Disease		
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Section A - Activity Impact			
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 Prevalence of the combination of a defined connective tissue disease and interstitial lung disease is < 1 in 100 000.	
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 N/A.	
	A1.3 What age group is the treatment indicated for?	A1.3 All ages.	
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 Most are aged 18-60.	

	<p>A1.5 What is the current activity associated with currently routinely commissioned care for this group?</p> <p>A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?</p> <p>A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?</p> <p>A1.8 How is the population currently distributed geographically?</p>	<p>A1.5 N/A</p> <p>A1.6 Annual incidence of approximately 1 in 1 000 000.</p> <p>A1.7 No projected growth.</p> <p>A1.8 Evenly distributed across England.</p>
<p>A2 Future Patient Population & Demography</p>	<p>A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p> <p>A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g.</p>	<p>A2.1 Move to a not routinely commissioned position.</p> <p>A2.2 Not anticipated</p>

	<p>increased disease prevalence, increased survival).</p> <p>A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.</p> <p>A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>A2.3 Not anticipated</p> <p>A2.4 No change - Move to a not routinely commissioned position.</p>
A3 Activity	<p>A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.</p> <p>A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.</p> <p>A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted?</p>	<p>A3.1 Move to a not routinely commissioned position</p> <p>A3.2 No change - Move to a not routinely commissioned position</p> <p>A3.3 N/A</p>

	Please details in accompanying excel sheet.	
A4 Existing Patient Pathway	<p>A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p>	<p>A4.1 N/A - Move to a not routinely commissioned position</p> <p>A4.2 N/A</p> <p>A4.3 N/A</p>
A5 Comparator (next best alternative treatment) Patient Pathway	<p>A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment</p>	<p>A5.1 Not applicable</p> <p>A5.2 Not applicable</p>

	<p>after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	
A6 New Patient Pathway	<p>A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p> <p>A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>A6.1 Not applicable</p> <p>A6.2 Not applicable</p>
A7 Treatment Setting	<p>A7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting 	A7.1 Not applicable.

	<ul style="list-style-type: none"> ○ Homecare delivery <p>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	A7.2 Not applicable.
A8 Coding	<p>A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>A8.1 Not applicable.</p> <p>A8.2 Not applicable.</p>
A9 Monitoring	<p>A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>A9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>A9.3 What analytical information /monitoring/ reporting is required?</p> <p>A9.4 What contract monitoring is required by supplier managers? What changes need to</p>	<p>A9.1 Not applicable.</p> <p>A9.2 Not applicable.</p> <p>A9.3 Not applicable.</p> <p>A9.4 Not applicable.</p>

	<p>be in place?</p> <p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i></p>	<p>A9.5 Not applicable.</p> <p>A9.6 Not applicable.</p> <p>A9.7 Not applicable.</p>
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Section B - Service Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 Tertiary centres
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 No change proposed

<p>B2 Geography & Access</p>	<p>B2.1 Where do current referrals come from?</p> <p>B2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>B2.3 Is the new policy likely to improve equity of access?</p> <p>B2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>B2.1 Primary and secondary care</p> <p>B2.2 No change</p> <p>B2.3 Not applicable – move to not routinely commissioned policy</p> <p>B2.4 Not applicable – move to not routinely commissioned policy</p>
<p>B3 Implementation</p>	<p>B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> <p>B3.2 Is there a change in provider physical infrastructure required?</p> <p>B3.3 Is there a change in provider staffing required?</p> <p>B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p>	<p>B3.1 No</p> <p>B3.2 No</p> <p>B3.3 No</p> <p>B3.4 No</p>

	<p>B3.5 Are there changes in the support services that need to be in place?</p> <p>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)</p>	<p>B3.5 No</p> <p>B3.6 Not required</p> <p>B3.7 No</p> <p>B3.8 No</p>
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 No
Section C - Finance Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)

<p>C1 Tariff</p>	<p>C1.1 Is this treatment paid under a national prices*, and if so which?</p> <p>C1.2 Is this treatment excluded from national prices?</p> <p>C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?</p> <p>C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?</p> <p>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>C1.1 No</p> <p>C1.2 Rituximab is a high cost drug excluded from tariff</p> <p>C1.3 If applicable Rituximab would be negotiated under local arrangements. The list price for MabThera is £873.15 (not including VAT) for 500mg/50ml.</p> <p>C1.4 No new price is proposed</p> <p>C1.5 VAT would be payable as it is envisaged the drug would be administered in a day case setting.</p> <p>C1.6 Not applicable</p>
<p>C2 Average Cost per Patient</p>	<p>C2.1 What is the revenue cost per patient in year 1?</p>	<p>C2.1 As the policy proposes not to routinely commission there would be no revenue impact.</p>

	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 Not applicable.
C3 Overall Cost Impact of this Policy to NHS England	<p>C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>C3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>	<p>C3.1 Neutral as move to not routinely commissioned policy.</p> <p>C3.2 Not applicable.</p>
C4 Overall cost impact of this policy to the NHS as a whole	<p>C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).</p> <p>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p> <p>C4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>C4.1 Neutral as move to not routinely commissioned policy.</p> <p>C4.2 Neutral.</p> <p>C4.3 Not applicable.</p> <p>C4.4 Neutral.</p>
C5 Funding	C5.1 Where a cost	C5.1 Not applicable.

	pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning less clinically or cost-effective services</i>	
C6 Financial Risks Associated with Implementing this Policy	<p>C6.1 What are the material financial risks to implementing this policy?</p> <p>C6.2 Can these be mitigated, if so how?</p> <p>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>C6.1 None identified.</p> <p>C6.2 Not applicable.</p> <p>C6.3 Not applicable.</p>
C7 Value for Money	<p>C7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>C7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>C7.1 Not applicable as move to not routinely commissioned policy</p> <p>C7.2 Not applicable</p>
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	C8.1 None as move to not routinely commissioned policy

	C8.2 If so, confirm the source of funds to meet these costs.	C8.2 Not applicable
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For public consultation