Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A03X03		
Policy Title	Rituximab for Primary Sjogren's Syndrome		
Accountable Commissioner	Debbie Hart	**Clinical Lead**	Simon Bowman
Finance Lead	Craig Holmes	**Analytical Lead**	Jay Emin

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 This policy proposes to **not routinely commission** the use of in adult patients with Primary Sjogrens Syndrome. Primary Sjogrens Syndrome is a rare condition with an estimated prevalence of 700 patients in the UK Women are 13 times as likely to be affected as men.
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 This policy proposes to not routinely commission the use of rituximab in adult patients with Primary Sjogrens Syndrome. The cohort covered by the policy is those patients with unresponsive Primary Sjogrens Syndrome that could be suitable for rituximab. The number of adult patients that would have had unresponsive Primary Sjogrens Syndrome is estimated to be approximately 100 (or about 10% of the prevalent population).[i]

	A1.3 What age group is the treatment indicated for?	A1.3 This treatment is indicated for adults (ages 18 and above).
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 Primary Sjogrens Syndrome can affect people of any age, however, it is rare in children. The average age at which people are diagnosed is around 40-45.[ii]
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 Rituximab is currently not routinely commissioned for Primary Sjogrens Syndrome. Current activity for **rituximab** is difficult to estimate and only very few patients might have access to it. One individual funding request (IFR) for the drug was submitted in 2015/16 [iii]
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 There were no disease-specific growth rates identified (please also see A2.2). However, the prevalence would grow in line with demographic growth.
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	A1.7 Without routine commissioning, new patients would not receive rituximab as a treatment option in future. These patients are likely to use other treatments including high cost treatments
	A1.8 How is the population currently distributed geographically?	A1.8 Across England - no significant geographical differences have been identified.
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently	A2.1 The policy moves to a 'non-routine commissioning' position for rituximab in adult patients with Primary Sjogrens

	routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	Syndrome.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	Therefore, no specific factors affecting growth of the patient population other than demographic factors were identified.
	A2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	A2.3 None identified.
	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?	A2.4 The proposed policy establishes a 'not routinely commissioned' proposal for the relevant population (the specific cohort set out in A1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.
A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	A3.1 Current activity is described in A1.5.
	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.	A3.2 The proposed policy establishes a 'not routinely commissioned' proposal for the relevant population (the specific cohort set out in A1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small. As such, the target population is expected to undergo comparator treatments

		in future. The number of new patients undergoing treatment with comparators is therefore estimated in the region of 120 in future years.[iv]
	A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	A3.3 If the policy were not implemented, 'do nothing' activity figures would be as set out in A1.7; patients would use SSAs.
A4 Existing Patient Pathway	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.	A4.1 – A4.3 There are three treatment options for patients diagnosed with Primary Sjogrens Syndrome: The majority of cases may have some level of response to conventional immunosuppressant therapy. 9% of the above registry cohort were on one of the following conventional immunosuppressant therapies (Azathioprine, Methotrexate, Sulfasalazine, Leflunomide, Ciclosporin, Mycophenolate, Tacrolimus). 2% were on Rituximab, cyclophosphamide, intravenous immunoglobulins, chlorambucil or other chemotherapeutic agent. Currently patients may be receiving therapies such as azathioprine or mycophenolate requiring frequent hospital monitoring visits associated with an existing cost and a small number receiving rituximab through an IFR or by local arrangement (data not known).
	A4.2. What are the current treatment access criteria?	A4.2. Patients diagnosed with Primary Sjogrens Syndrome.
	A4.3 What are the current treatment stopping points?	A4.3 Treatment response

A5 Comparator (next best alternative treatment) Patient Pathway	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.	A5.1 Yes (see A4.1).
	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 after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A5.2 Not applicable.
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	A6.1 Not applicable – no new pathway proposed.
	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.	A6.2 Not applicable – no new pathway proposed.
A7 Treatment Setting	A7.1 How is this	A7.1 Rituximab is administered in an

	treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery	outpatient setting by IV injection
	A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.2 No
A8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	A8.1 Rituximab is a high cost drug excluded from tariff, so it would be captured in the high cost drug dataset for routine commissioning.
	A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.2 Not applicable as position is to not routinely commission.
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 Not applicable.
	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 Not applicable.
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 Not applicable.

	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 Not applicable.
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 Not applicable.
	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 Not applicable.
	A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in C1 below*	A9.7 Not applicable.
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 Rheumatology Service has around 30 Adult Specialist Endocrinology Centres that provide services to patients; some deliver these services in more local hospitals through networking arrangements (Manual for prescribed specialised services, 2013/14, page 35)
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 No changes proposed.

B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Patients present in various settings, often when seeking treatment for co-morbidities associated with Primary Sjogrens Syndrome (incl. diabetes mellitus, hypertension, arthritis, sleep apnoea and cardiovascular disease). They are diagnosed after referral to Specialist Rheumatology Centres but may be referred through a number of specialties
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 No – no changes proposed.
	B2.3 Is the new policy likely to improve equity of access?	B2.3 – No.
	B2.4 Is the new policy likely to improve equality of access / outcomes?	
B3 Implementation	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?	B3.1 No – no lead in time required.
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 No change in provider physical infrastructure.
	B3.3 Is there a change in provider staffing required?	B3.3 No – no changes required.
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 No – no changes required.

	B3.5 Are there changes in the support services that need to be in place?	B3.5 No – no changes needed.
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 No – no changes required.
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 No – no new policy proposed.
	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)	B3.8 Not applicable.
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)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 No, see C1.2.
	C1.2 Is this treatment excluded from national prices?	C1.2 Rituximab is a high cost drug excluded from tariff.

	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?	C1.3 As an excluded drug, the price is subject to local negotiations.
	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?	C1.4 No new price is proposed.
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 Not applicable
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 Not applicable.
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 As the policy proposes not to routinely commission rituximab, for Primary Sjogrens Syndrome, there would be no revenue impact.
	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 For reference, the costs per patient in future years are not likely to change and are assumed to be as set out in C2.1.
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	C3.1 Cost neutral, as the policy is to not routinely commission rituximab, and there is little identified activity for rituximab in the 'do-nothing' scenario (see A1.5).
	C3.2 Where this has not	C3.2 Not applicable.

	been identified, set out the reasons why this cannot be measured.	
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	C4.1 Cost neutral for the reasons given in C3.1.
	C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	C4.2 Cost neutral for the reasons given in C3.1.
	C4.3 Where this has not been identified, set out the reasons why this cannot be measured.	C4.3 Not applicable.
	C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.4 Not applicable.
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*	C5.1 Not applicable.
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy?	C6.1 Not applicable.
	C6.2 Can these be mitigated, if so how?	C6.2 Not applicable.
	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best	C6.3 Not applicable.

	case, worst case and most likely total cost scenarios?	
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature* C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.1 and C7.2 No published and peer reviewed studies have evaluated cost effectiveness of rituximab treatment when compared to other therapies.
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs* C8.2 If so, confirm the source of funds to meet these costs.	C8.1 None identified. C8.2 Not applicable.

[i] Based on discussions with the policy working group.

[iii] Based on data extracted from the national IFR database.