Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A06X01		
Policy Title	**Rituximab for the treatment of Idiopathic Membranous Nephropathy in adults**		
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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 Membranous Nephropathy (MN) is a rare disease with an incidence of 6-10 per million population per year. 25% of MN cases are secondary to malignancy, infection, medications or systemic autoimmune disease (usually Systemic Lupus Erythematosus). In 75% of cases, no underlying associated pathology can be identified and the disease is termed idiopathic (IMN).
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 Rituximab is not routinely commissioned for IMN. The policy proposition is that Rituximab is Not Routinely Commissioned.

	A1.3 What age group is the treatment indicated for?	A1.3 N/A
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 N/A
	A1.5 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 The treatment of MN depends on the patient presentation and disease progression after diagnosis is made by biopsy (Fervenza et al. 2008). In general, most patients are given a trial of conservative therapy with renin-angiotensin system (RAS) blockade. If partial or complete remission is not achieved with 6 months of conservative management, immunomodulatory therapy is then initiated. The two leading immunomodulatory therapies used are alkylating agents (cyclophosphamide or chlorambucil) and calcineurin inhibitors (cyclosporine or tacrolimus), both typically given alongside oral or intravenous corticosteroids (Perna et al. 2004, Cattran et al. 2005,).
	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 Membranous Nephropathy (MN) is a rare disease with an incidence of 6-10 per million population per year. 75% of which are IMN.
	A1.7 What is the associated projected	A1.7 See K1.6

	growth in activity (prior to applying the new policy) in 2,5 and 10 years?	
	A1.8 How is the population currently distributed geographically?	A1.8 National
A2 Future Patient Population & Demography	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?	A2.1 Maintains current position of Not Routinely Commissioned.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 None identified
	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.	A2.3 No

	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 N/A
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 Accurate figures for prevalent IMN population not available. In general, most patients are given a trial of conservative therapy with renin-angiotensin system (RAS) blockade. If partial or complete remission is not achieved with 6 months of conservative management, immunomodulatory therapy is then initiated.(K1.5)
	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 No change
	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 See K3.1
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient	A4.1 In general, most patients are given a trial of conservative therapy with renin-angiotensin system (RAS) blockade. If partial or complete remission is not achieved

	pathway? Describe or include a figure to outline associated activity.	with 6 months of conservative management, immunomodulatory therapy is then initiated. The two leading immunomodulatory therapies used are alkylating agents (cyclophosphamide or chlorambucil) and calcineurin inhibitors (cyclosporine or tacrolimus), both typically given alongside oral or intravenous corticosteroids (Perna et al. 2004, Cattran et al. 2005,).
	A4.2. What are the current treatment access criteria?	A4.2 In contemporary observational cohort studies, where patients have received these supportive treatments, up to 70% of patients achieve partial or complete remission at 5 years. Because of this natural history, most UK physicians will adopt a supportive approach for 6-12 months after diagnosis. Clinical features that predict progressive CKD include very heavy proteinuria (>8g/day, especially where this is prolonged), impaired kidney function at diagnosis or early in the course of the disease. Where supportive therapy has failed to induce partial or complete remission of NS, immunomodulatory treatment is considered. Where there is impairment of kidney function, either at diagnosis or during supportive therapy, alkylating agents are the preferred therapy. 88-92% of patients with moderate disease will be dialysis free at 10 years if treated by an alkylating agent, compared to 32-47% of controls.

	A4.3 What are the current treatment stopping points?	A4.3 None .Treatment ongoing.
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. A5.2 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.	A5.1 See A4.1 and A4.2. A5.2 N/A
A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. A6.2 Where there are different stopping	A6.1 N/A A6.2 N/A

	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.	
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.1 N/A A7.2 N/A
A8 Coding	A8.1 In which datasets (e.g. SUS/central data	A8.1 N/A

	collections etc.) will activity related to the new patient pathway be recorded?	
	A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.2 N/A
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 N/A
	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 N/A
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 N/A
	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 N/A
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 N/A

	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 N/A
	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 M1 below*	A9.7 N/A
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
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Natonal
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 No

	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?	B2.4 No
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 N/A
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 N/A
	B3.3 Is there a change in provider staffing required?	B3.3 N/A
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 N/A
	B3.5 Are there changes in the support services that need to be in place?	B3.5 N/A
	B3.6 Is there a change	B3.6 N/A

	in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 N/A
	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 N/A
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 N/A
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	C1.1 N/A

	prices*, and if so which?	
	C1.2 Is this treatment excluded from national prices?	C1.2 N/A
	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 N/A
	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 N/A
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 N/A
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 N/A
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 N/A

	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 N/A
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. C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.1 Cost neutral C3.2 N/A
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). C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. C4.3 Where this has not been identified, set out the reasons why this cannot be measured. C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	C4.1 Cost neutral C4.2 Cost neutral C4.3 N/A C4.4 No

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 N/A
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy? C6.2 Can these be mitigated, if so how? C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.1 N/A C6.2 N/A C6.3 N/A
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 N/A C7.2 N/A
C8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs	C8.1 No

	associated with this policy? *e.g. Transitional costs, periodical costs* C8.2 If so, confirm the source of funds to meet these costs.	 C8.2 N/A