

Engagement Report

Topic details

Title of policy or policy statement:	Rituximab for patients with idiopathic membranous nephropathy (Adults)
Programme of Care:	Internal medicine
Clinical Reference Group (CRG):	Renal
URN:	2012

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. In total, three feedback forms have been received during the stakeholder engagement process, all supportive of the policy proposition.

2. Background

Rituximab is recommended to be available as a routine commissioning treatment option for adult patients with idiopathic membranous nephropathy within the criteria set out in the policy document. The policy proposition has been developed by a Policy Working Group (PWG), including a Clinical Lead, a Lead Commissioner, a Public Health Lead.

Idiopathic membranous nephropathy (IMN) is a rare kidney disease where the immune system attacks certain cells in the kidneys. No cause can be found. One role of the kidneys is to filter waste products and excess fluids from the blood into the urine. In IMN the filtering membrane of the kidney has become damaged and cannot function properly. This results in protein from the bloodstream leaking into the urine and the body retaining excess fluids. The condition causes distressing symptoms including severe swelling of the legs and kidney failure. The worst affected patients eventually need kidney dialysis or a kidney transplant.

Rituximab is a chimeric monoclonal antibody that depletes human B Cells and is given as an intravenous infusion. B cells are central in the production of antibodies and therefore rituximab has been widely used for the treatment of autoimmune conditions, where antibodies play a key role in the development of disease. Rituximab is currently licensed for the treatment of certain lymphomas and leukaemias, and autoimmune conditions such as rheumatoid arthritis and vasculitis.

In recent years, rituximab has surfaced as a potential treatment option and may be superior to CNI therapy in inducing a complete or partial remission of IMN. This policy proposition therefore suggests that Rituximab should be offered as the primary immunosuppressive therapy to patients with IMN who are intolerant or have contraindications to cytotoxic therapy.

Primary immunosuppressive therapy with rituximab can be considered for patients who meet all of the following inclusion criteria:

- 1) Diagnosis of IMN. Diagnosis is made by a combination of antibody tests (anti-PLA2R or anti-THSD7A antibodies) and kidney biopsy.
- 2) Contraindications or intolerances to cytotoxic or steroid therapy OR inability to comply with the monitoring requirements for cytotoxic therapy.
- 3) eGFR >20mls/min/1.73m².
- 4) Multi-disciplinary team (MDT) agreement, that rituximab at the specified frequency and dose is the most appropriate treatment option.

The decision to commence treatment with rituximab must be made in conjunction with the patient and by the MDT. Individual providers will have policies for the prescription and administration of rituximab prescription, which should be followed.

Treatment with rituximab should be stopped in any of the following circumstances:

- Adverse events (particularly infusion associated reactions) where harm exceeds the benefit at any time during treatment.
- The patient is unable to tolerate the side effects of treatment. Reference should be made to the SmPC, especially the criteria for permanent discontinuation of treatment with rituximab.

Two doses of 1000mg of intravenous rituximab at baseline, with further re-dosing after 4-6 months. Re-dosing will not be given to those patients who have no evidence of treatment response, specifically a reduction in proteinuria. The decision to re-dose should be made by the MDT. Rituximab will be given as a day case infusion.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 3 May 2022 to 17 May 2022. Three responses were received. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you support the proposal for rituximab to be available for adult patients with idiopathic membranous nephropathy through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
- Do you have any further comments on the proposition? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.

- Please declare any conflict of interests relating to this document or service area.
- Do you support the Equality and Health Inequalities Impact Assessment?

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

Respondents were asked the following consultation questions:

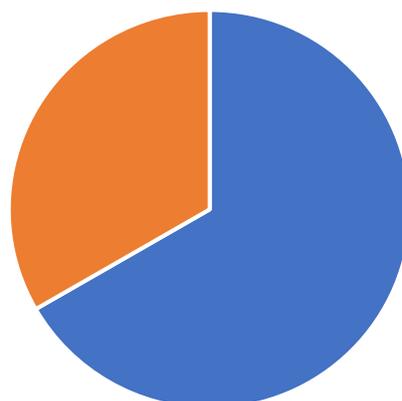
- RC: Do you support the proposition for Rituximab for patients with idiopathic membranous nephropathy (Adults) to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- NRC: Do you support the proposition that Rituximab for patients with idiopathic membranous nephropathy (Adults) will not be routinely commissioned based on the evidence review and the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- The impact assessment has been completed to identify the impact of moving from current pathways of care to the one(s) proposed in the draft policy proposition taking into account the anticipated patient numbers, treatment, cost of the treatment and capacity within providers, Do you think that the impact assessment fairly reflects the likely patient numbers, treatment, cost of treatment and the capacity within providers? If not, what do you think is inaccurate?
- The patient pathway describes the patient's journey through the health system to receive current treatment for this condition. Do you think that the policy proposition accurately describes the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential positive and negative impacts on equality and health inequalities which might arise as a result of the proposed policy that have been described?
- Are there any changes or additions you think need to be made to this document, and why?
- Did you comment on the stakeholder testing for this policy proposition (only relevant for Public Consultation questionnaire if required)?

4. Engagement Results

In line with the 13Q assessment it was deemed that further public consultation was not required.

In total, three feedback forms have been received during the stakeholder engagement process: 2 from consultant nephrologist and 1 from an individual (not disclosed).

Stakeholder Responses



■ Clinician ■ Individual

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following theme was raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
Nil specific	
Impact Assessment	
<p>1.The form is a useful additional resource, but it has been completed in too perfunctory a manner.</p> <p>2.The impact scale is unhelpful if used in this way. If an impact on mobility is assessed as varying from zero to severe problems, this makes no sense unless annotated (e.g. in what circumstances is the impact likely to be negligible and in what circumstances severe?). An expanded commentary seems to be essential.</p> <p>3.The abbreviated comments under 'further details of impact on patients' seem to minimise the potential level and intensity of impact, probably because of their brevity. Adequate contextualisation needs to be fuller. This is especially true in the case of carers, where the potential impact may be less immediately evident to an external audience.</p>	<p>Impact Assessments within the document do not detract from the clinical benefits described in the evidence review.</p> <p>No change recommended.</p>
Patients with active nephrotic syndrome have significant oedema which greatly impacts their quality of life and	Supports the use of rituximab therefore in reducing requirement for steroids and

<p>wellbeing. They require many frequent hospital appointments as well as the adverse effects of immunosuppression with steroids being particularly problematic. There is also the uncertainty of a response to treatment and the risk of dialysis being a considerable burden as well as a great source of anxiety.</p>	<p>consequently impact of peripheral oedema.</p> <p>No change to policy proposition recommended.</p>
<p>There is also the ease of dosing and administration of Rituximab in comparison to Cyclophosphamide to be considered</p>	<p>Supports the use of rituximab</p> <p>No change to policy proposition recommended.</p>
<p>This will certainly be a positive impact as in the absence of this policy patients and clinicians have variable levels of challenge in accessing the treatment Rituximab when it is felt that this would be the best treatment option. The paperwork required and subsequent delays often led to prolonged morbidity and in some situations no access to Rituximab treatment.</p> <p>Our experience so far has been overwhelmingly positive in terms of clinical impact and patient perception of the treatment</p>	<p>This comment supports the view that the policy proposition will reduce inequities in accessing the therapy.</p> <p>No change to policy proposition recommended.</p>
<p>Body image concerns (in fact this has been the major concern reported by our young adults)</p> <p>Patients have increased risk of clots and often have to take some form of anticoagulation such as warfarin this involves issues with need for regular monitoring often with more hospital visits, increased risk of bleeding</p> <p>Increased predilection and incidence of infections for instance cellulitis</p>	<p>Conditions described are associated with the current treatments available and the use of rituximab should reduce these side effects in some patients.</p> <p>No change recommended to policy proposition.</p>
<p>Current Patient Pathway</p>	
<p>There are many positive impacts on making rituximab available. This will provide an effective treatment in those patients in whom cyclophosphamide is undesirable (for fertility reasons or elderly frail patients), or in whom steroids should be avoided (BMI, diabetic control, psychiatric side effects).</p>	<p>Agreed</p> <p>Local and national formularies should reflect the requirement for Covid 19 vaccination as rituximab is used in many treatment protocols.</p> <p>No change to policy proposition recommended.</p>

<p>Additionally, drugs such as tacrolimus or ciclosporin are not recommended in patients with poor renal function and have a high relapse rate upon stopping. Rituximab is a very effective alternative without many side effects unlike the other medications above. It involves just 2 admissions each cycle for each infusion.</p> <p>With correct patient selection, there are very few negative impacts. Some patients with rapidly declining renal function may not be suitable and may still need a cyclophosphamide-based regime but this will be a minority of patients. Patients should ideally be vaccinated against COVID-19 pre-rituximab as there will be a prolonged period with non-response to vaccination with immunosuppression</p>	
<p>Every attempt to exclude underlying conditions such as cancer should be made prior to instituting treatment</p>	<p>Agreed. This will be by individual patient consultation. No change to policy proposition recommended.</p>
Potential impact on equality and health inequalities	
<p>stakeholder engagement (with key patient groups) should have begun earlier</p>	<p>The Stakeholder engagement began at the prescribed time in the process and guides the Internal Medicine Programme of Care as to whether additional public consultation is required and for how long.</p>
<p>patient choice needs to be given due consideration Patients need to be given appropriate information around the treatment options for this condition In some situations, rituximab would be the first choice and an option such as cyclophosphamide only used as a last resort taking into account risk benefit ratio</p>	<p>This will be provided within individual patient/clinician consultations as treatment options will be specific to the individual patient. No change to policy proposition recommended.</p>
Changes/addition to policy	
	Nil

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

No. The comments underpin the view in the equality impact assessment that access to this treatment will improve equity of access for relevant patients. The comments also

suggest the treatment may be better tolerated by patients and reduce the potential risks associated with other treatments used. That is not to say that the drug will be suitable for all patients but for the majority of new patients it will be suitable. The comments in the stakeholder engagement reflect the need for adequate consultation with the patient regarding treatment options and potential side effects for all therapies.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.