

NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. **Name of the proposal (policy, proposition, programme, proposal or initiative):**
2012 Rituximab for patients with idiopathic membranous nephropathy (Adults)

2. **Brief summary of the proposal in a few sentences**

Idiopathic Membranous Nephropathy (IMN) is an autoimmune disease of the kidney, specifically the glomerulus. Autoimmune diseases refers to problems with the immune system that usually fights off viruses, bacteria and infection. IMN is a result of the immune cells attacking the body by mistake. These diseases can affect almost any part of the body but with IMN, the disease is specific to the Kidney. The risk with IMN is that the disease progresses to end stage renal disease meaning patients may require dialysis and kidney transplant.

The current standard treatment for people with less severe IMN is a period of monitored supportive care.

If partial or complete remission is not achieved within 6 months, immunosuppressive therapy is then started with continuation of supportive care.

People presenting with severe disease (life-threatening fluid overload, rapidly declining kidney function, or thromboembolic disease) receive supportive care and immediate immunosuppression. Immunosuppressive therapy for IMN involves using alkylating agents (cyclophosphamide or chlorambucil) with corticosteroids, or calcineurin inhibitors (tacrolimus or ciclosporin). The choice of immunosuppressive therapy is individualized to the patient and takes into consideration pre-existing health conditions (co-morbidities). If the person is intolerant or has contraindications to both calcineurin inhibitors and alkylating agents, they are offered continued treatment with supportive care only. There is an enhanced risk that such patients will develop end stage kidney disease.

The policy recommends the use of Rituximab, given as an injection, to be administered in a renal centre. Rituximab is currently not commissioned by NHS England for IMN. The policy recommends that Rituximab should be a commissioned treatment for patients with IMN who have defined contraindications (risk factors) to receiving therapy with cytotoxics and calcineurin inhibitors. The use of both cytotoxics and calcineurin inhibitors are not recommended in some patients; however, commissioning the prescribing of Rituximab will make treatment available to a wider group of patients, and potentially increase the number of patients in remission and reduce the development of end stage renal disease in some patients. In essence, the policy suggests that patients who have contraindications to the use of cytotoxic therapy or calcineurin inhibitors should have access to Rituximab as first line treatment.

From a patient perspective, key benefits of the commissioning of Rituximab will include:

- Achieving remission of disease (partial or complete remission - which determines control of disease and symptoms) and
- Reduction in risk of developing end stage kidney disease which in turn leads to the need for renal replacement therapy (in form of dialysis or transplantation)
- Improvement in life expectancy for some patients

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A** if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age: older people; middle years; early years; children and young people.	Idiopathic membranous nephropathy (IMN) is one of the most common causes of primary nephrotic syndrome in adults. However, it is a relatively rare entity in the paediatric population and there is a paucity of data about the incidence, prognosis, and optimal treatment of IMN in children and adolescents. Less than	Given the rare incidence of IMN in children, an individual case by case decision would be required to avoid harm in children and young people. Rituximab to be used as first line treatment for adults where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>5% of all nephrotic syndrome patients (of which IMN is one type in children) will be because of IMN. It is rare for nephrotic syndrome in children to progress to end stage renal disease.</p> <p>Achieving remission of disease.</p> <p>The policy is for all adults as currently Rituximab is not licensed for the treatment of IMN in children.</p>	<p>IMN and who have contraindications to current treatments.</p>
<p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>Achieving remission of disease.</p> <p>Positive impact on long term conditions management by the improvement in chronic health for patients at risk of developing end stage renal disease who require dialysis or transplant.</p> <p>Access to transplant (because of tissue matching is problematical and patients stay on the waiting list and receiving dialysis for a long time. Rituximab will potentially ensure some patients do not develop end stage renal disease and improve their quality of life significantly.</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>
<p>Gender Reassignment and/or people who identify as Transgender</p>	<p>N/A</p>	

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Marriage & Civil Partnership: people married or in a civil partnership.	N/A	
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The Summary of Product Characteristics (SmPC) should be referred to when considering treating patients with rituximab, in particular the sections outlining contraindications, cautions, special warnings, precautions for use, and fertility, pregnancy, and lactation. As with most drugs, studies will not have been conducted in pregnant or lactating women, hence each case must be considered on its merits.	
Race and ethnicity¹	Achieving remission of disease. For some ethnic groups receiving a kidney transplant takes longer due to specific tissue typing requirements. This can find patients stay on the waiting list longer. This drug will potentially reduce the need for a transplant in some patients. Equally some ethnic groups	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.

¹ Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	have a higher prevalence of dialysis; and so treatment and prevention of end stage kidney disease will reduce the length of wait for some patients.	
Religion and belief: people with different religions/faiths or beliefs, or none.	May reduce the need for a kidney transplant in a small number of patients who because of beliefs may not wish to have a transplant.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.
Sex: men; women	N/A	
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	N/A	

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A** if your proposal will not impact on patients who experience health inequalities.

From a patient perspective, key benefits of the commissioning of Rituximab will include:

- Achieving remission of disease (partial or complete remission - which determines control of disease and symptoms)
- Reduction in risk of developing end stage kidney disease which in turn leads to the need for renal replacement therapy (in form of dialysis or transplantation)
- Improvement in life expectancy for some patients

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
<p>Looked after children and young people</p>	<p>The policy is for all adults as currently Rituximab is not licensed for the treatment of IMN in children.</p> <p>IMN is one of the most common causes of primary nephrotic syndrome in adults. However, it is a relatively rare entity in the paediatric population and there is a paucity of data about the incidence, prognosis, and optimal treatment of IMN in children and adolescents. Less than 5% of all nephrotic syndrome patients (of which IMN is one type in children) will be because of IMN. It is rare for nephrotic syndrome in children to progress to end stage renal disease.</p>	<p>Given the rare incidence of IMN in children, an individual case by case decision would be required to avoid harm in children and young people.</p>

² Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>Achieving remission of disease.</p> <p>Potential positive impact for a small number of people whose potentially long-term health and social care needs would be reduced by avoiding lifelong management of dialysis or transplant.</p> <p>Promote healthy living and reduction in long term health care needs.</p> <p>Increased choices in life by avoiding dialysis.</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>
<p>Carers of patients: unpaid, family members.</p>	<p>Achieving remission of disease.</p> <p>Potential positive impact for a small number of carers with family members with complex needs. This would be achieved by avoiding lifelong management of dialysis or transplant in family members with IMN.</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>
<p>Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.</p>	<p>Achieving remission of disease.</p> <p>Potential positive impact for a small number of people whose health and</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with</p>

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	social care needs would be reduced by avoiding lifelong management of dialysis or transplant. The main benefits in terms of access to this group is that only two doses are required (two visits to the hospital for infusions) with possible further dosing at 6 months.	IMN and who have contraindications to current treatments.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Achieving remission of disease. Potential positive impact for a small number of people whose needs would be enhanced by avoiding lifelong management of dialysis or transplant. Some prisons provide dialysis, but some do not.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.
People with addictions and/or substance misuse issues	Achieving remission of disease. Potential positive impact for a small number of people whose health and social care needs would be enhanced by avoiding lifelong management of dialysis or transplant. The main benefits in terms of access to this group is that only two doses are required (two visits to the hospital for infusions) with possible further dosing at 6 months.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.
People or families on a low income	Achieving remission of disease.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This

Groups who face health inequalities ²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	Positive impact. May facilitate improved employment opportunities by avoiding the need for dialysis three times per week, reducing the cost and time of travel.	increases the treatment options for patients with IMN and who have contraindications to current treatments.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Achieving remission of disease. Potential positive impact for a small number of people whose needs would be reduced by avoiding lifelong management of dialysis or transplant.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.
People living in deprived areas	Achieving remission of disease. Potential positive impact for a small number of people would avoid lifelong management of dialysis or transplant. People from deprived areas have a higher prevalence for end stage kidney disease and the drug will help reduce the requirement for dialysis for a small number of patients. The main benefits in terms of access to this group is that only two doses are required (two visits to the hospital for infusions) with possible further dosing at 6 months.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.
People living in remote, rural and island locations	Achieving remission of disease.	Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This

Groups who face health inequalities²	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	<p>Potential positive impact for a small number of people whose potentially complex health and social needs would be reduced by avoiding lifelong management of dialysis or transplant.</p> <p>On occasions this can mean long trips to a dialysis unit three times per week.</p>	<p>increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>
Refugees, asylum seekers or those experiencing modern slavery	<p>Achieving remission of disease.</p> <p>Potential positive impact for a small number of people whose potentially complex health and social needs would be reduced by avoiding lifelong management of dialysis or transplant. The main benefits in terms of access to this group is that only two doses are required (two visits to the hospital for infusions) with possible further dosing at 6 months.</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>
Other groups experiencing health inequalities (please describe)	<p>Achieving remission of disease.</p> <p>Positive impact in the long term for patients on the kidney transplant waiting list. This will reduce the demand for transplants albeit by a relatively small number.</p>	<p>Rituximab to be used as first line treatment for patients where other types of treatment for IMN are contraindicated in their specific health needs. This increases the treatment options for patients with IMN and who have contraindications to current treatments.</p>

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes X	No	Do Not Know
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b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	Focus groups involving patients/carers and professionals to support the Renal Transformation	The impact of dialysis and also time awaiting transplant has been reviewed as part of the service transformation review. Experiences of families and patients living with end stage kidney disease has been explored as a theme.	2019/20
2	Stakeholder engagement planned	As part of the policy development engagement with key patient groups will take place.	2022
3	Public Consultation	After refinement of the policy following stakeholder engagement, the proposal may go out for public consultation. Post PPAVG review and NPOC assurance review public consultation not required.	2022

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An external literature review has been conducted, a summary of which will be in the final document.	
Consultation and involvement findings	Stakeholder engagement has been completed using the listed renal services stakeholder list provided by NHS England.	
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	There is a policy working group that is developing the policy. In addition, the CRG is formally reviewing the policy which contains patient and public representation.	

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?		X	
The proposal may support?			
Uncertain whether the proposal will support?			

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	X	
The proposal may support?		

Uncertain if the proposal will support?		
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9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1	
2	
3	

10. Summary assessment of this EHIA findings

This policy will ensure that there is equity of access to the drug for the primary treatment of IMN, as currently some MHS Trusts are prescribing and some are not.

11. Contact details re this EHIA

Team/Unit name:	Internal Medicine Programme of Care
Division name:	Acute Services Programme
Directorate name:	
Date EHIA agreed:	

Date ERIA published if appropriate:	
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