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):

Rituximab for the treatment of nodal/paranodal antibody positive inflammatory/autoimmune neuropathy in adults and post-pubescent children [NHS England URN: 2001]

2. Brief summary of the proposal in a few sentences

This policy introduces rituximab as a primary or secondary treatment option for nodal/paranodal antibody positive inflammatory/autoimmune neuropathy, a physically debilitating progressive condition which causes loss of strength and balance. The core diagnostic feature of the condition is the presence of nodal or paranodal autoantibodies directed against cell adhesion molecules present at the node of Ranvier or surrounding paranode of myelinated nerve fibres. It is thought that people with nodal/paranodal antibody positive inflammatory/autoimmune neuropathy will have an improved and sustained response to treatment with rituximab compared with currently used alternative therapies.

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.	Patients with nodal/paranodal antibody-mediated neuropathies, a subset of chronic inflammatory neuropathies	As pre-pubescent children can be affected by nodal/paranodal antibody-mediated neuropathies, following the completion of the evidence review,

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
	generally tend to be middle aged or older. The policy is for adults and post-pubescent children.	the policy working group (PWG) proposed a paper for review, De Simoni et al, 2020. This paper was not included in the evidence review. The paper was reviewed by the PWG's public health lead who concluded that the new evidence from the paper is helpful in providing some evidence of effectiveness for pre-pubescent children and therefore may allow a wider age range for the policy. However, the paper does not materially change the evidence on effectiveness from the evidence review. The paper supports the evidence review and enhances the proposed age range for the policy. On this basis the PWG decided that the policy would not be altered as a consequence of the evidence in the Simoni et al. paper.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Patients with chronic inflammatory demyelinating polyneuropathies (CIDPs) typically become disabled, losing their strength and balance. This makes simple day-to-day tasks difficult or even impossible. Patients with nodal/paranodal antibody-mediated neuropathies, a subset of chronic inflammatory neuropathies, often have more severe and aggressive diseases and tend to respond less well to the usual CIDP treatments.	Nodal/paranodal antibody positive inflammatory/autoimmune neuropathy causes significant disability. This policy aims to improve the quality of life of people with the condition by introducing rituximab as a primary or secondary treatment option. For patients who do not meet the eligibility criteria for treatment with rituximab it is proposed to offer standard supportive care which would include physiotherapy, orthotics, podiatry and occupational therapy.

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
	Affected individuals progressively lose strength and sensation, with ongoing deterioration continuing beyond 8 weeks after onset. Rituximab will be given to patients with nodal/paranodal antibody positive inflammatory/autoimmune neuropathy who meet the criteria stated in the policy under 'Inclusion criteria' as these are the patients who are thought to be most likely to benefit.	
Gender Reassignment and/or people who identify as Transgender	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and gender reassignment or between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and people who identify as transgender.	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and marriage and civil partnership.	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Rituximab is contraindicated in women who are pregnant or breast-feeding. Women who are breastfeeding are advised not to breastfeed for 12 months following rituximab treatment.	Women who are pregnant or breastfeeding and who have nodal/paranodal antibody-mediated neuropathies are offered physiotherapy and occupational therapy. For some women it may be

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
	Women of childbearing potential are advised to use effective contraceptive methods during and for 12 months following treatment with rituximab.	also be possible to offer intravenous immunoglobulin (IVIG). (Although the safety of IVIG for use in human pregnancy has not been established in controlled clinical trials, clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected. No negative effects on the breastfed newborns/infants are anticipated.)
Race and ethnicity[1]	Nodal/paranodal antibody positive inflammatory/autoimmune neuropathy affects people of all ethnicities. A registry of people with this condition is not maintained and therefore the proportions of people of various ethnicities who are affected is not known with certainty. Anecdotally it is thought that the ethnicities of people who are affected by nodal/paranodal inflammatory/autoimmune are in approximately the same proportions as in the general population.	N/A

[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
Religion and belief: people with different religions/faiths or beliefs, or none.	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and religion and belief.	N/A
Sex: men; women	Nodal/paranodal antibody positive inflammatory/autoimmune neuropathy predominantly affects men more than women in a ratio of 2 to 1. There are no known differences between the sexes in terms of the degree of severity of the condition or the response to rituximab.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and sexual orientation.	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.**

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
Looked after children and young people	There is no known correlation between nodal/paranodal antibody positive and looked after children and young people.	N/A

[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
Carers of patients: unpaid, family members.	As patients with nodal/paranodal antibody positive inflammatory/autoimmune neuropathy have severe reductions in their mobility, dexterity and quality of life, the burden on family members who care for them is considerable. The policy aims to improve the quality of life of and reduce the level of disability of people with nodal/paranodal antibody positive inflammatory/autoimmune neuropathy by introducing rituximab as a primary or secondary treatment option.	The use of rituximab may enable more people with the condition to benefit from a greater improvement in their symptoms compared to current alternative treatments, thereby reducing the burden on family members of caring for patients.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and homeless people.	N/A
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and people involved in the criminal justice system.	N/A
People with addictions and/or substance misuse issues	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and people with addictions and/or substance misuse issues.	N/A

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
People or families on a low income	People or families on a low income have few resources and, compared to families on higher incomes, may struggle to a greater degree to cope with the negative impact of the condition on their day to day activities, their ability to work and their financial stability.	The use of rituximab expands the range of treatment options for people with the condition and may be a more effective treatment for some people than the current alternatives. It is anticipated that more people will benefit from a greater reduction in disability.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	People with poor literacy may struggle to access services generally.	Patients with poor language skills will be able to consult with clinicians via interpreters provided by the NHS to discuss their eligibility for access to treatment with rituximab.
People living in deprived areas	People living in deprived areas may have fewer resources and less support within their community to cope with the impact of the condition on their daily lives compared to people living in more affluent areas.	The introduction of rituximab as a treatment option expands the range of treatment options for people with the condition and may be a more effective treatment for some people than the current alternatives. It is anticipated that more people will benefit from a greater reduction in disability.
People living in remote, rural and island locations	Treatment with rituximab requires fewer hospital visits compared to treatment with IVIG, one of the main alternative treatments. Two doses of rituximab are administered 2 weeks apart and then further doses may be administered at intervals ranging from 6 months to 5 years.	Compared to treatment with IVIG, one of the treatment options for the condition, treatment with rituximab requires fewer hospital visits. This will benefit patients who live in remote, rural and island locations.

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
Refugees, asylum seekers or those experiencing modern slavery	There is no known correlation between nodal/paranodal antibody positive inflammatory/autoimmune neuropathy and people experiencing modern slavery.	N/A
Other groups experiencing health inequalities (please describe)	There are anecdotal reports that frail elderly people have more difficulty gaining access to therapeutic treatment for nodal/paranodal antibody-mediated neuropathies compared to younger, less frail people.	Treatment with rituximab requires fewer hospital visits compared to treatment with IVIG, one of the current treatment options for nodal/paranodal antibody-mediated neuropathies. This may benefit frail, elderly patients who may have significant co-morbidities and who may also face logistical difficulties arranging transport to and from hospital.

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**	**Don't know**

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	Discussion with PWG members.	The equalities health impact of the policy was discussed at the PWG meeting on 8th October 2020.	**Oct 2020**

2	Discussion with the Chief Executive of the GAIN charity for people with inflammatory neuropathies.	The Chief Executive of GAIN charity provided information about the equality health impact of the policy on 20/10/2020.	**Oct 2020**
3	Stakeholder testing from January 28th to February 12th 2021.	The stakeholder testing comments included suggested amendments to the policy proposition improving the clarity of how the policy is to be implemented and suggested a further research paper for review. The comments resulted in edits to the policy.	**Jan-Feb 2021**

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	There is published evidence. However, the quality of the evidence is of low certainty and is based on case series.	The evidence review that was undertaken independently as part of the policy development included several papers with low numbers of participants. None of the papers included qualitative research on the impact of the condition on the quality of life of the patients affected. As the number of patients affected by the condition in the UK is low (about 150 a year of whom 10-20 are suitable for treatment with rituximab), it is difficult to draw any conclusions on the demographic characteristics of the patients affected and the way in which the condition affects population subgroups.
Consultation and involvement findings	The stakeholder testing comments included suggestions for improving the clarity of how the policy is to be	No key gaps in evidence were identified.

Evidence Type	Key sources of available evidence	Key gaps in evidence
	implemented and suggested a further research paper for review.	
Research	The stakeholder testing identified a further research paper for review. The research paper identified during stakeholder testing has not yet been published and it does not meet the evidence review criteria. The paper does not expand the range of antibodies currently considered within the policy/evidence review and does not provide a higher quality of evidence than currently within the evidence review. Following the evidence review, the PWG identified a paper published in 2020 which provides evidence on the effectiveness of treating pre-pubescent children with rituximab. This was reviewed by the PWG's public health lead who concluded that this new evidence is helpful in providing some evidence of effectiveness for pre-pubescent children and therefore may allow a wider age range for the policy, but it does not materially change the evidence on effectiveness from the evidence review. The paper supports the evidence review and supports the proposed age range.	No gaps in evidence were identified.

Evidence Type	Key sources of available evidence	Key gaps in evidence
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Consultation with clinicians and with the chief executive of GAIN charity.	There is no registry of people with the condition and the numbers of those affected are low. Therefore, it is difficult to identify with any certainty the demographic characteristics of those affected and the impact on people with protected characteristics.

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?			
The proposal may support?		x	
Uncertain whether the proposal will support?	x		x

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?		
The proposal may support?	x	x
Uncertain if the proposal will support?		

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	N/A	N/A

10. Summary assessment of this EHIA findings

Patients with nodal/paranodal antibody-mediated neuropathies, a subset of chronic inflammatory neuropathies, often have more severe and aggressive disease than people with other forms of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and tend to respond less well to the usual treatments. This policy will contribute to reducing health inequalities by providing a further treatment option which may be more effective for some patients with nodal/paranodal antibody-mediated neuropathies than other currently available treatments. As patients with nodal/paranodal antibody positive inflammatory/autoimmune neuropathy have severe reductions in their mobility, dexterity and quality of life, the burden on family members who care for these patients is considerable. The use of rituximab may enable more people with the condition to benefit from a greater improvement in their symptoms compared to current alternative treatments. This may also benefit unpaid family carers by reducing the burden of caring for people with this condition. Rituximab requires fewer hospital visits than other available treatment options and therefore may be more accessible to people who live in remote locations, people on lower incomes, from deprived areas and/or with poor literacy than other alternative treatments.

11. Contact details re this EHIA

Team/Unit name:	National Programme of Care for Trauma
Division name:	Finance, Performance and Planning

Directorate name:	Specialised Commissioning
Date EHIA agreed:	26/10/2020
Date EHIA published if appropriate:	