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 IgM paraproteinaemic demyelinating peripheral neuropathy (PDPN) in adults [NHS England URN: 1910]

2. Brief summary of the proposal in a few sentences

This policy introduces rituximab as a primary or secondary treatment option for PDPN which is associated with a range of pre-cancerous and cancerous blood conditions. The current standard treatment for PDPN focuses on suppressing the blood cancer which is the underlying cause of PDPN. Current treatments include the use of intravenous immunoglobulin (IVIg) corticosteroids, plasmapheresis, interferon-2-alpha, cyclophosphamide and chlorambucil to suppress or modulate the immune response. The introduction of rituximab for the treatment of PDPN applies to all patient groups with protected characteristics.

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.	The peak decade of onset of PDPN neuropathy is of 70-79 years and the mean age of onset is 58.2 years. PDPN does not occur in children. This policy aims to improve the quality of life	The policy will enable eligible patients to be offered up to 4 cycles of rituximab with regular reviews of their response to treatment every four to 12 months.

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
	of people with PDPN by introducing rituximab as a primary or secondary treatment option to stabilise the condition and prevent further deterioration in disability. To be eligible for treatment with rituximab patients should have had the condition for less than 5 years and should have been assessed as having a degree of disability above a pre-defined threshold. The alternative criteria for eligibility are that patients have had progression of haematological disease (MGUS, lymphocytoplasmic leukaemia or non-Hodgkin’s lymphoma) with a significant increase in plasma paraprotein trending over time. It is thought that patients who meet these criteria are the ones most likely to benefit from treatment with rituximab.	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.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Patients with PDPN typically become disabled, losing their strength and balance. Affected individuals progressively lose strength and sensation and they may be prevented from performing day-today activities and their occupational roles.	In addition to the option of treatment with rituximab eligible patients will be offered standard care which would include physiotherapy, orthotics, podiatry, occupational therapy and other supportive care.

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
	This policy aims to improve the quality of life of people with the condition by introducing rituximab as a primary or secondary treatment option to stabilise the condition and prevent further deterioration in disability.	
Gender Reassignment and/or people who identify as Transgender	There is no known correlation between PDPN and gender reassignment or between PDPN and people who identify as transgender.	n/a
Marriage & Civil Partnership: people married or in a civil partnership.	There is no known correlation between PDPN 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 unless the benefit to the mother outweighs the risk of B-lymphocyte depletion in the foetus. Women who are breastfeeding are advised not to breastfeed for 12 months following rituximab treatment. Women of childbearing potential are advised to use effective contraceptive methods during and for 12 months following treatment with rituximab.	Women who are pregnant or breastfeeding and who have PDPN are offered physiotherapy and occupational therapy. For some women it may be also be possible to offer IVIg as an alternative to treatment with rituximab. To note, 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.

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
Race and ethnicity[1]	PDPN affects people of all ethnicities.	n/a
Religion and belief: people with different religions/faiths or beliefs, or none.	There is no known correlation between PDPN and religion and belief.	n/a
Sex: men; women	PDPN is more common in men than in women. 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 PDPN and sexual orientation.	n/a

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[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.

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 PDPN and looked after children and young people.	n/a
Carers of patients: unpaid, family members.	As patients with PDPN may 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 and reduce the level of disability of people with PDPN 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. Compared to treatment with alternative therapies, for example IVIg, treatment with rituximab requires fewer hospital visits. The use of rituximab may stabilize PDPN in some patients and this may mean a reduction in the number of hospital follow-up appointments for these patients. This may save patients and their carers the time and expense of arranging transport to and from hospital.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	There is no known correlation between PDPN and homeless people.	n/a

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[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
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	There is no known correlation between PDPN and people involved in the criminal justice system.	n/a
People with addictions and/or substance misuse issues	There is no known correlation between PDPN and people with addictions and/or substance misuse issues.	n/a
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 PDPN on their day to day activities, their ability to work and their financial stability. PDPN causes significant disability. This policy proposition aims to improve the quality of life of people with the condition by introducing rituximab as a primary treatment option to stabilise the condition and prevent further deterioration in disability.	The use of rituximab may enable more people with PDPN to benefit from a greater improvement in their symptoms compared to current alternative treatments This may contribute towards improving the ability of those who are on low incomes to seek employment. It will also decrease the number of hospital visits compared to IVIg decreasing associated expenses and increasing quality of life.
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 struggle to a greater degree to cope with the negative impact of the	The use of rituximab may enable more people with PDPN to benefit from a greater improvement in their symptoms compared to current alternative

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
	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.	treatments. This may contribute towards improving the ability of those people who live in deprived areas to manage the negative impact of PDPN on their day to day activities.
People living in remote, rural and island locations	Treatment with rituximab requires fewer hospital visits compared to treatment with intravenous immunoglobulin, one of the main alternative treatments. Initially four doses of rituximab are administered over the course of one month and if the patient responds well to treatment, it is possible that no further doses may be needed.	Compared to treatment with alternative therapies, for example IVIg, treatment with rituximab requires fewer hospital visits. This will benefit patients who live in remote, rural and island locations.
Refugees, asylum seekers or those experiencing modern slavery	There is no known correlation between PDPN and refugees, asylum seekers those experiencing modern slavery.	n/a
Other groups experiencing health inequalities (please describe)	People from travelling communities may experience inequalities in access to health care. One of the reasons is that they move location frequently which means that they must register from scratch in the health and care	Initially four doses of rituximab are administered over the course of one month and, if the patient responds well to treatment, it is possible that no further doses may be needed. This may improve access to therapy as the first cycle of treatment is delivered over the course of one month.

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
	system in a new area[3]. This increases the risk that they are unable to access the care that they need. Treatment with rituximab requires fewer hospital visits compared to treatment with IVIg, one of the main alternative treatments.	

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 the clinical lead for the policy proposition.	The impact of the proposition on addressing equality and health inequalities issues was discussed with the clinical lead on 10/12/2020 and on 11/01/2021. People who have PDPN tend to be in the older age range and predominantly male with disabilities which may include significant difficulty in walking	**December 2020 / January 2021**

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[3] Friends, families and travelers. How to tackle health inequalities in gypsy, roma and traveler communities, https://www.gypsy-traveller.org/wp-content/uploads/2020/11/SS00-Health-inequalities_FINAL.pdf

		and with balance. It is widely acknowledged that patients who have had the condition for less than 5 years of disease and are progressing rapidly respond better to treatment than patients who have had the condition for a longer period of time. The eligibility criteria have been structured to identify the patient groups most likely to benefit from treatment. People with PDPN who do not meet the eligibility criteria for treatment with rituximab will be offered supportive therapies.	
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 impact of the policy on addressing equality and health inequalities issues on 16/12/2020.	**December 2020**
3	Stakeholder testing	The policy proposition was sent for stakeholder testing for 2 weeks from 02/06/2021 to 16/06/2021. 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 regarding the EHIA: • Do you support the Equality and Health Inequalities Impact Assessment?	**June 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	The evidence review that was undertaken independently as part of the policy	As the number of patients affected by the condition in the UK is low (a prevalence of 0.42

Evidence Type	Key sources of available evidence	Key gaps in evidence
	development process included a systematic review and meta-analysis.	per 100,000)[4], of whom about 50 a year might be considered eligible for treatment with rituximab, it is difficult to draw any conclusions on the demographic characteristics of patients who have PDPN and the way in which the condition affects population subgroups. The systematic review and meta-analysis by Lunn and Nobile-Orazio, 2016[5], was a relatively small study of 80 patients. The study did not identify any sub-groups of patients who would benefit more than other sub-groups from treatment with rituximab.
Consultation and involvement findings		
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Consultation took place with the lead clinician for the policy proposition and with the chief executive of GAIN charity.	There is no registry of people with the condition and the numbers of those people with PDPN 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.

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[4] Mahdi-Rodgers & Hughes found that there were 1.04 (95% CI 0.73–1.43) per 100 000 population with paraproteinaemic demyelinating neuropathy in southeast England. 15 of the 37 patients had anti-MAG IgM antibodies giving a prevalence of 0.42 patients with anti-MAG antibody positive paraproteinaemic demyelinating neuropathy.

[5] Lunn MP, Nobile-Orazio E. Immunotherapy for IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathies. Cochrane Database Syst Rev 2016; 10, CD002827.

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	x	x
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?		
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 PDPN have severe reductions in their mobility, dexterity and quality of life and the burden on family members who care for these patients is considerable. The use of rituximab as a treatment option 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 IVIg, the other main treatment option, and therefore may be more accessible than other alternative treatments to people who live in remote locations, people on lower incomes, people from deprived areas, the travelling community and people with poor literacy.

11. Contact details re this EHIA

Team/Unit name:	National Programme of Care for Trauma
Division name:	Finance
Directorate name:	Medical Directorate
Date EHIA agreed:	8/9/21
Date EHIA published if appropriate:	November 2021