# 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 in acute Thrombotic Thrombocytopaenic Purpura (TTP) and elective therapy to prevent TTP relapse (adults and children aged 2 years and above)**

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

This policy is focused on the drug rituximab as a) a treatment for acute immune TTP for all ages and b) an elective therapy for patients with TTP who are in clinical remission. TTP is a critical medical condition requiring immediate transfer for treatment; 50% require ICU admission and without treatment, the mortality in acute TTP is >90%. There are approximately 100-150 new cases of acute TTP per year across the UK. Rituximab is the existing treatment option for TTP, though the Prescribed Services Advisory Group (PSSAG) have requested that commissioning responsibility for the disease move from Clinical Commissioning Groups (CCGs) to NHS England (Specialised Commissioning). The aim of this shift in commissioning responsibility is to improve patient outcomes by establishing expert centres and clear pathways.

The clinical policy was developed through conducting an externally conducted evidence review and by a Policy Working Group (PWG) consisting of haematology experts, a public health specialist and specialised commissioner for NHS England. This policy recommends that rituximab is made available as an option for children and adults if they have TTP and meet the criterial outlined in the policy.

**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 | Acute immune mediated TTP can affect all ages, although it is exceedingly rare in children. The average age at diagnosis is 40 years (TTP Network).<br><br>The aim of this policy is to improve patient outcomes and includes adults and children aged 2 years and above, so will have a positive impact across all ages. | Adults and children aged 2 years and above are included in this policy. |
| **Disability:** physical, sensory and learning impairment; mental health condition; long-term conditions. | Human Immunodeficiency Virus (HIV) is a long-term condition and a risk factor for TTP, with an estimated 40-fold increased incidence of TTP in HIV-infected patients compared with that in the general population (Miller et al. 2005).<br><br>The aim of the policy is to improve patient outcomes, so will have a potential positive impact on patients with TTP and HIV and/or other co-morbidities.<br><br>However, there may be concerns about the sharing of relevant clinical information between different treatment centres. | Specific consideration needs to be given to patients with TTP with complex health needs as a result of other co-morbidities including how relevant clinical information is shared between care providers. |

| 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 |
|---|---|---|
| **Gender Reassignment and/or people who identify as Transgender** | There should be no direct negative or positive impact on this group as people who have undergone gender reassignment and/or people who identify as transgender have not been identified as a high-risk group. | Not applicable. |
| **Marriage & Civil Partnership:** people married or in a civil partnership. | There should be no direct negative or positive impact on this group as marriage/civil partnership has not been identified as a high-risk group. | Not applicable. |
| **Pregnancy and Maternity:** women before and after childbirth and who are breastfeeding. | Pregnancy/immediate post-partum period is a risk factor for TTP (McMinn & George, 2001). Therefore, in offering treatment for the condition, this policy will have a positive impact on women before and after childbirth as they are more likely to develop TTP. | Specific considerations should be given to pregnant women/women who are immediately post-partum as they may have other specific needs including issues around shared care and access to antenatal/ postnatal/ neonatal services. |
| **Race and ethnicity**[1] | Being of black race is a risk factor for TTP (BMJ Best Practice). Therefore, this policy will disproportionally impact people of black race who develop TTP. | All patients who meet the inclusion criteria would be considered for rituximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |

[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. | Included within the treatment pathway for TTP is plasma exchange (PEX). As PEX involves the transfusion of plasma, a primary component of blood, patients who are Jehovah's Witness may refuse the treatment (George et al. 2017). Although this policy is focused on rituximab, as PEX is part of the treatment pathway for TTP, this issue is important to highlight and would have an adverse impact on people who follow the Jehovah's Witness faith. | Specific considerations need to be given to alternative treatment options to PEX for patients with TTP who follow the Jehovah's Witness faith. Alternatives to PEX should be identified in the treatment pathway. |
| **Sex:** men; women | TTP affects both males and females but two-thirds of the patients with TTP are females (TTP Network). In offering treatment for the condition, this policy will have a positive impact on this protected characteristic group proportional to need. | All patients who meet the inclusion criteria would be considered for rituximab treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group. |
| **Sexual orientation:** Lesbian; Gay; Bisexual; Heterosexual. | There should be no direct negative or positive impact on people based on their sexual orientation compared to all patients with TTP. | Not applicable. |

**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** | TTP is rare in children, so impact on looked after children would be extremely small. | Not applicable. |
| **Carers of patients:** unpaid, family members. | Carers may be indirectly positively affected by this policy.<br><br>If the use of rituximab is successful, it has the potential to improve an individual's health status and reduce risk of acute relapse. This may reduce their care needs allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with TTP by reducing the assistance required to complete work, family and personal tasks.<br><br>The use of rituximab electively may require ongoing carer support to facilitate attendance at follow-up appointments. This might be offset by a reduction in emergency and unscheduled care or prolonged | The policy reflects the best available evidence for treatment to be made available for those patients that would have positive outcomes.<br><br>If this policy is adopted, a commissioning plan will set out the pathway of provision for rituximab which will include access at appropriately staffed centres. |

[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 |
|---|---|---|
| | admissions to address the consequences of acute relapse. | |
| **Homeless people.** People on the street; staying temporarily with friends /family; in hostels or B&Bs. | The lack of a permanent base for which follow-up appointments could be co-ordinated may be a challenge in this cohort of patients.<br><br>Those who are homeless could be at risk of adverse outcomes due to lack of access to services and/or incomplete follow up. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for homeless patients.<br><br>The treatment is delivered in hospital. The services provide a care coordination service for patients with TTP which will support patients who are homeless. |
| **People involved in the criminal justice system:** offenders in prison/on probation, ex-offenders. | There are no identified potential positive or adverse impacts of this policy on this group. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for people involved in the criminal justice system.<br><br>The services provide a care coordination service for patients with TTP which will support patients who are in prison. |
| **People with addictions and/or substance misuse issues** | There are no identified potential positive or adverse impacts of this policy on this group. | Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for people with addictions and/or substance misuse issues.<br><br>The services provide a care coordination service for patients with TTP which will support patients who have addictions and/or substance misuse issues. |

| 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** | There are no identified potential positive or adverse impacts of this policy on this group. | The policy will facilitate access to rituximab. Services will put in place shared care arrangements where appropriate so that patients travel costs are reduced. |
| **People with poor literacy or health Literacy:** (e.g. poor understanding of health services poor language skills). | This group may find it hard to understand their condition and the benefits and risks associated with different treatment options. It may also be harder for these individuals to understand and follow the drug directions. | Clinicians will need to ensure that patients are well informed, this can be through various mediums including verbal as well as written shared decision-making tools, translated and Easy Read materials.<br><br>The provision of rituximab involves face-to-face assessment and verbal instruction, this can assist those with poor health or literacy skills. |
| **People living in deprived areas** | A national commissioning policy attempts to ensure there is equal access to treatment regardless of location, it will reduce variation in practice. | Transferring commissioning responsibility from CCGs to NHS England (Specialised Commissioning) will reduce any regional variation in access to rituximab for TTP. |
| **People living in remote, rural and island locations** | There are no identified potential positive or adverse impacts of this policy on this group.<br><br>A national commissioning policy attempts to ensure there is equal access to treatment regardless of location. | If adopted, a commissioning plan will determine the local arrangements, which may include specialist oversight, to improve access for patients. |
| **Refugees, asylum seekers or those experiencing modern slavery** | This group may be less likely to enter the pathway, due to access issues (e.g. not registered with a General Practitioner). | NHS England is producing this policy to increase access for anyone who may benefit from the intervention. |

| 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 |
|---|---|---|
| | The lack of a permanent base for which care and follow-up and/or review appointments could be co-ordinated may be challenging in this cohort of patients.<br><br>If identified, those who are refugees, asylum seekers or those experiencing modern slavery could be at significant risk of adverse outcomes due to lack of access to services, incomplete follow-up as well as environmental conditions which may exposure individuals to be more vulnerable. | Commissioned providers should work with the patient and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for refugees, asylum seekers and those experiencing modern slavery. |
| **Other groups experiencing health inequalities (please describe)** | Not applicable. | Not applicable. |

**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 |
|---|---|---|

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** | **Stakeholder engagement for service development** | Before the service specification was published, the aim was that by having a national network of 9 centres in place mortality would reduce and establishing regional centres would increase access.<br>Ethnicity and gender will be looked at as part of service monitoring and centres will be requested to have appropriate communication approaches for patients and carers.<br>The patient group will be part of the national monitoring of the TTP service through which rituximab will be delivered. | **Sept 2018** |
| **2** | **Stakeholder engagement for policy development** | There was a 2 week stakeholder engagement with key stakeholders as per NHS England's standard methods. | **Feb 2022** |
| **3** | | | |

**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** | BMJ Best Practice. Thrombotic thrombocytopenic purpura. Available at: https://bestpractice.bmj.com/topics/en-gb/715/history-exam#riskFactors<br>George, J.N., Sandler, S.A., Stankiewicz, J. (2017). Management of thrombotic thrombocytopenic purpura without plasma exchange. Blood Advances, 1(24): 2161-2165.<br>McMinn, J.R., George, J.N. (2001). Evaluation of women with clinically suspected thrombotic thrombocytopenic purpura-hemolytic uremic syndrome during pregnancy. Journal of Clinical Apheresis, 16: 202-209.<br>Miller, R.F. et al. (2005). Thrombotic thrombocytopaenic purpura in HIV-infected patients. International Journal of STD and AIDS, 16: 538-542.<br>TTP Network. About TTP. Available at: https://www.ttpnetwork.org.uk/about-ttp/ | |
| **Consultation and involvement findings** | The service underwent public consultation between September and October 2018. During the policy development further stakeholder testing was undertaken in February 2022. | |
| **Research** | | |
| **Participant or expert knowledge**<br>For example, expertise within the team or expertise drawn on external to your team | | |

**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? | | | |

| | | | |
|---|---|---|---|
| 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 |
| 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 | | |
| 2 | | |
| 3 | | |

**10. Summary assessment of this EHIA findings**

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|---|
| The EHIA has highlighted that TTP is more common in females, people living with HIV, people of black race and in pregnancy/the post-partum period.<br><br>The main issues highlighted as a result of this EHIA relate to the balance between the need for improved patient outcomes, a clear long-term pathway and enhanced clinical expertise versus problems with long term follow-up in patient groups that may face difficulty with engagement due to access issues. |

Furthermore, people with TTP and other co-morbidities or women with TTP who are pregnant/immediately post-partum need to be assured that shared care will be an option. Additionally plans need to be in place to support alternative treatments to plasma exchange (part of the treatment pathway for TTP) for people with TTP who follow the Jehovah's Witness faith, recognising that this is likely to be a rare occurrence given the annual incidence of TTP.

The policy provides a treatment option that is already standard of care for patients as a) a treatment for acute immune TTP (for all ages) and b) an elective therapy for patients with TTP who are in clinical remission.

Adoption of the policy is considered to improve health outcomes for people with protected characteristics (based on sex, disability, race and pregnancy). The policy may also potentially impact groups who face health inequalities (carers of patients) due to possible improvements in quality of life.

A national commissioned policy will reduce variation in clinical practice promoting an equity of care for those in which this intervention is indicated.

## 11. Contact details re this EHIA

| | |
|---|---|
| Team/Unit name: | |
| Division name: | |
| Directorate name: | |
| Date EHIA agreed: | |
| Date EHIA published if appropriate: | |