

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):** Bortezomib for the treatment in acute immune Thrombotic Thrombocytopenic Purpura (TTP) and elective therapy to prevent immune TTP relapse in patients who are refractory or intolerant to rituximab (all ages) [2301]

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

This policy proposition is focused on the drug bortezomib as both acute treatment of immune thrombotic thrombocytopenic purpura (TTP) and as elective therapy to prevent acute immune TTP relapse. Immune TTP is a critical medical condition requiring immediate transfer for treatment; 50% require critical care admission and without treatment, the mortality in acute immune TTP is >90%. There are approximately 100-150 new cases of acute immune TTP per year across the UK. Of those cases, approximately 10% relapse, requiring further treatment. Roughly 10-30 patients a year requiring further treatment will be refractory or intolerant to rituximab, thus requiring alternative therapy.

The clinical policy proposition 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 proposition does not recommend that bortezomib is made available at this time, due to the lack of evidence identified.

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 Registry).	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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).	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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).	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.

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	Being of black race is a risk factor for TTP (BMJ Best Practice). Therefore, this policy proposition will disproportionately impact people of black race who develop TTP.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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 proposition is focused on bortezomib, 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.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
Sex: men; women	TTP affects both males and females but two-thirds of the patients with TTP are females (TTP Registry).	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this 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
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.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
Carers of patients: unpaid, family members.	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.

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

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
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 proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
People with addictions and/or substance misuse issues	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
People or families on a low income	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
People living in deprived areas	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
People living in remote, rural and island locations	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
Refugees, asylum seekers or those experiencing modern slavery	There are no identified potential positive or adverse impacts of this proposition on this group.	There is insufficient evidence to support the commissioning of Bortezomib, so there is no change in the impact on this group.
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	No	Do Not Know X
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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	Stakeholder testing (planned)	This will involve clinical staff, professional groups, patients, patient groups and industry groups who have expressed an interest in this topic area.	
2	Public consultation (planned)		
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	An external review of available clinical evidence was undertaken to inform this proposition.	Clinical effectiveness in acute TTP and as elective therapy to prevent TTP relapse. Cost effectiveness of treatment.
Consultation and involvement findings	Planned	
Research	No pending research is known	Clinical effectiveness in acute TTP and as elective therapy to prevent TTP relapse.

Evidence Type	Key sources of available evidence	Key gaps in evidence
		Cost effectiveness of treatment.
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which included TTP specialists, a range of medical clinicians, a public health specialist, a pharmacist and a patient and public voice representative.	

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?	X	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?		
Uncertain if the proposal will support?	X	X

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
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1	Cost effectiveness of intervention versus usual care	Research
2	Clinical effectiveness of the intervention versus usual care in acute TTP.	Research
3	Clinical effectiveness of the intervention versus usual care as elective therapy to prevent relapse.	

10. Summary assessment of this EHIA findings

There is insufficient evidence to support the treatment of TTP with bortezomib. Consequently, there is no change to the current treatment pathway, as it is not currently commissioned and therefore no impact on patients.

11. Contact details re this EHIA

Team/Unit name:	Clinical policy team
Division name:	Specialised Commissioning, NHS England
Directorate name:	Chief Finance Officer
Date EHIA agreed:	
Date EHIA published if appropriate:	