NHS England: 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): Abatacept for autoimmune complications of primary immunodeficiencies caused by CTLA-4 or LRBA genetic mutation (aged 2 years and over) [2309]

2. Brief summary of the proposal in a few sentences

Primary immunodeficiency disease (PID) is a rare inherited condition where the body's immune system does not work properly and in some cases attacks itself. The illness can affect one or many parts of the immune system and the genetic causal mechanisms can vary greatly. One of the presentations of PID is dysfunction of the regulatory T (T_{Reg}) cell which is essential for preventing autoimmunity. Genetic causes for these immune deficiencies have been identified in some patients, including monogenic deficiency of the LRBA and CTLA-4 proteins which are responsible for normal regulation of the T_{Reg} cell.

Abatacept is a biological drug that specifically targets the CTLA-4 receptor on T_{Reg} cells. Abatacept is proposed to be used long-term to treat the autoimmune or inflammatory complications such as granulomatous inflammatory lung disease, arthritis, inflammatory bowel disease and autoimmune cytopenias that arise due to T_{Reg} cell dysfunction. This proposed use of abatacept is off label. This policy is for patients aged 2 years and above in line with licensed indications for abatacept.

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.	PID due to T-$_{Reg}$ cell dysfunction can occur at any age, although they mainly tend to present in childhood. However, the manifestations of the disease can continue long into adulthood. This policy is expected to have a positive effect on the overall outcomes of all eligible patients regardless of age. This policy is proposed to be restricted to children and adults aged 2 years and over in line with licensed indications for abatacept. There is insufficient safety data for use of intravenous abatacept in children <2 years old. Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection; to minimize the impact of known socio-demographic predictors of inequality in access to healthcare, both formulation options are made available to maximise potential for positive impact.	This policy proposes that treatment is initiated and reviewed by a specialist multidisciplinary team (MDT). This will enable the appropriate selection of patients who will benefit from the intervention and mean the drug will be stopped in those gaining no benefit or where the side effect profile is too great. This should mean the greatest benefit is gained from improving physical and mental health and reducing the impact of a long-term condition.
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Patients with T_{Reg} cell dysfunction can experience severe autoimmune complications as a result of the condition.	This policy proposes that treatment is initiated and reviewed by a specialist MDT. This will enable the appropriate selection of patients who will benefit from the intervention and mean the drug will be stopped in those gaining no benefit or where the

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 includes progressive lung fibrosis which can render patients incapacitated. Abatacept is expected to have a positive impact on patients and aims to reduce the complications of disease.	side effect profile is too great. This should mean the greatest benefit is gained from improving physical and mental health and reducing the impact of a long-term condition.
Gender Reassignment and/or people who identify as Transgender	Gender reassignment and being transgender are not known to be risk factors for T_{Reg} cell deficiency. This policy is expected to have a positive effect on the overall outcomes of all eligible patients, regardless of gender reassignment and being transgender.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Marriage & Civil Partnership: people married or in a civil partnership.	Marriage status is not known to be a risk factor for T_{Reg} cell deficiency. This policy will promote access to abatacept regardless of marriage status.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Pregnancy is not known to be a risk factor for T_{Reg} cell dysfunction. However, as they can affect people of all ages, women of childbearing potential may be at risk of developing T_{Reg} cell dysfunction.	There is limited evidence of safe use of abatacept in pregnancy and breast feeding. Patients of childbearing potential should work with their clinicians to ensure adequate contraception is used during treatment with abatacept or that treatment is stopped, if necessary, during pregnancy and breast feeding.

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]	Race and ethnicity have not been identified as risk factors for T_{Reg} cell dysfunction. There should be equitable access to this treatment regardless of race or ethnicity.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Religion and belief: people with different religions/faiths or beliefs, or none.	Religion is not known to be a risk factor for T_{Reg} cell dysfunction. This policy will promote access to abatacept regardless of religion.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Sex: men; women	Sex is not known to be a risk factor for T_{Reg} cell dysfunction. This policy will promote access to abatacept regardless of sex.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation is not known to be a risk factor for T_{Reg} cell dysfunction. This policy will promote access to abatacept regardless of sexual orientation.	All patients who meet the inclusion criteria would be considered for abatacept treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

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

[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.

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	T_{Reg} cell dysfunction tends to present in childhood with disease manifestations, if not well treated or controlled, lasting long into adulthood. Children are therefore more likely to benefit from treatment with abatacept, as it may be able to prevent long-term complications as a result of their disease. This policy is restricted to children and adults aged 2 years and over in line with licensed indications for abatacept.	The specialist MDT will include clinicians who manage children and young people. The individual health, physical, mental, emotional, educational, and developmental needs of the patient will be taken into consideration if abatacept was proposed as a treatment option. Access to an injected treatment will need managing for those in care who need special arrangements.
Carers of patients: unpaid, family members.	Abatacept has the potential to improve an individual's health status and reduce morbidity. Abatacept may reduce the care needs of patients, allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with T_{Reg} cell dysfunction by reducing the assistance required to complete work, family, and personal tasks and reduce the need for emergency or unscheduled care or	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.

[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
	prolonged admissions to address the consequences of advanced disease. However, the use of abatacept may increase ongoing carer support to enable attendance at hospital for those receiving the drug by intravenous infusion.	
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	This group may be less likely to enter the patient pathway due to access issues e.g., not registered with a General Practitioner. They may also find it more difficult to maintain engagement with a course of treatment. This policy will promote access to abatacept regardless of living status.	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	Being in the criminal justice system is not known to be a risk factor for T_{Reg} cell dysfunction. This policy will promote access to abatacept regardless of criminal status.	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.
People with addictions and/or substance misuse issues	Addiction and substance misuse is not known to be a risk factor for T_{Reg} cell dysfunction.	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to

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 with addiction/and or substance misuse issues might find it harder to maintain engagement with the course of treatment. This policy will promote access to abatacept regardless of addiction issues.	establish the most appropriate formulation of treatment for the patient.
People or families on a low income	Economic status is not known to be a risk factor for T_{Reg} cell dysfunction. Travel to hospital for infusions, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement. However, as abatacept is available subcutaneously, most patients will be able to have treatment from home and avoid this potential barrier to treatment. Most patients will already be receiving immunoglobulin replacement therapy and will likely use the same route of administration for abatacept. As such, apart from 2-3 training visits, additional visits may not be required. Patients may also struggle to access centres able to carry out genetic testing for CTLA-4 insufficiency or LRBA	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient. Arrangements can be made to support access to assessment and treatment in hospital, especially where travel is required. Reimbursement for travel costs is covered in the Healthcare Travel Costs Scheme.

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
	deficiency which could delay access to treatment. This will mostly be offset by laboratory confirmation of the deficiency whilst awaiting genetic confirmation. This policy will promote access to abatacept regardless of economic status.	
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. This might impact on their ability to access treatment or maintain involvement in a treatment regime.	The existence of a clear referral process into an MDT should enable access to the drug. Shared decision making should be used using appropriate mediums including verbal, written shared decision-making tools, translated, and Easy Read materials. The provision of treatment should be provided in a way to assist those with poor health or literacy skills. A holistic assessment of an individual should be undertaken by the prescribing physician to assess their suitability and understanding of compliance barriers for abatacept.
People living in deprived areas	Deprivation is not known to be a risk factor for T_{Reg} cell dysfunction. Travel to hospital for infusions, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement. However, as abatacept is available subcutaneously,	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.

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
	most patients will be able to have treatment from home and avoid this potential barrier to treatment. Most patients will already be receiving immunoglobulin replacement therapy and will likely use the same route of administration for abatacept. As such, apart from 2-3 training visits, additional visits may not be required. Patients may also struggle to access centres able to carry out genetic testing for CTLA-4 insufficiency or LRBA deficiency which could delay access to treatment. This will mostly be offset by laboratory confirmation of the deficiency whilst awaiting genetic confirmation. This policy will promote access to abatacept regardless of economic status.	Arrangements can be made to support access to assessment and treatment in hospital, especially where travel is required. Reimbursement for travel costs is covered in the Healthcare Travel Costs Scheme.
People living in remote, rural and island locations	This policy intends to ensure there is equal access to treatment regardless of location. Travel to hospital for infusions, time out of work and arrangements for childcare can be difficult and may represent a barrier to engagement. However, as	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.

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
	abatacept is available subcutaneously, most patients will be able to have treatment from home and avoid this potential barrier to treatment. Most patients will already be receiving immunoglobulin replacement therapy and will likely use the same route of administration for abatacept. As such, apart from 2-3 training visits, additional visits may not be required. Patients may also struggle to access centres able to carry out genetic testing for CTLA-4 insufficiency or LRBA deficiency which could delay access to treatment. This will mostly be offset by laboratory confirmation of the deficiency whilst awaiting genetic confirmation. This policy will promote access to abatacept regardless of area the patient lives.	Arrangements can be made to support access to assessment and treatment in hospital, especially where travel is required. Reimbursement for travel costs is covered in the Healthcare Travel Costs Scheme.
Refugees, asylum seekers or those experiencing modern slavery	Being a refugee, asylum seeker or experiencing modern slavery are not known to be risk factors for T_{Reg} cell dysfunction.	Abatacept may be given in hospital as monthly intravenous infusion or at home weekly by subcutaneous injection. Clinicians should work with the patient, together with the relevant local authorities, integrated care boards and GP to establish the most appropriate formulation of treatment for the patient.

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
	This policy will promote access to abatacept regardless of economic status.	
Other groups experiencing health inequalities (please describe)	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 testing	The policy went out to key stakeholders from the Specialised Immunology and Allergy and the Specialised Paediatric Allergy, Immunology and Infectious Disease CRGs for a 14 day period of stakeholder testing from 19 February 2024 to 5 March 2024	Feb/Mar 24
2			
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.	Hard to draw clear conclusions on clinical and cost effectiveness.
Consultation and involvement findings	The policy was sent out for stakeholder testing and amendment to the wording within the policy was made for greater clarity.	
Research	No pending research is known	
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 immunologists, 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?		X	X
Uncertain whether the proposal will support?	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	Cost effectiveness	Further research
2	Clinical effectiveness	More robust research needs to be carried out to determine clinical effectiveness of abatacept.
3		

10. Summary assessment of this EHIA findings

No specific risk factors were identified for T_{Reg} cell dysfunction. It was noted that T_{Reg} cell dysfunction can occur in all ages and equally in both sexes. A policy for abatacept for T_{Reg} cell dysfunction is anticipated to offer an improvement in the care pathway of these patients. There are no anticipated adverse impacts of commissioning abatacept for this population.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	System Development Group
Date EHIA agreed:	
Date EHIA published if appropriate:	