

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):** Etanercept and adalimumab for deficiency of adenosine deaminase 2 (DADA2) (aged 5 years and older) [2319]
- 2. Brief summary of the proposal in a few sentences**

This is a clinical commissioning policy which proposes the use of etanercept or adalimumab for deficiency of adenosine deaminase 2 (DADA2).

Deficiency of adenosine deaminase type 2 (DADA2) is a rare, inherited disorder caused by autosomal recessive mutations in the ADA2 gene. DADA2 is characterised by abnormal inflammation, and immune system function. Inflammatory features include intermittent fevers, rash, pain and/or inflammation in the muscles and the joints, and importantly, strokes in infancy or childhood. Problems with normal blood cell development may also begin early in life or in late adulthood, and include severe anaemia, low white blood cells, or low blood platelets.

Vasculitis is one of the most predominant features of DADA2 and often begins early in infancy or childhood, with many patients experiencing early-onset strokes or peripheral vascular disease before the age of 10 years. In severe cases these strokes can be debilitating, leading to irreversible brain damage, or fatal; and the peripheral vascular disease can lead to loss of fingers, toes, testicles or damage to organs such as the kidneys and liver. High blood pressure and organomegaly (enlarged organs) are also often seen in early childhood and persist into adulthood. Patients are highly susceptible to infections and cancers as a result of their immunodeficiency. Untreated, the disease can lead to permanent disability or death.

Lifelong TNF inhibitors are the standard of care to prevent strokes and other vasculitic complications. There are five TNF inhibitors used worldwide (etanercept, adalimumab, infliximab, golimumab and certolizumab), however none are licensed in DADA2. Current practice is determined at the local level with inconsistency between centres and inequity of access. Some paediatric centres have local funding in place for TNF inhibitors which is then not available when patients transition to adult services.

The only potential curative treatment available for DADA2 is haematopoietic stem cell transplantation (HSCT). However, this is only an option for a small number of patients who have bone marrow failure, and the procedure itself is associated with 20% chance of death.

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
<p>Age: older people; middle years; early years; children and young people.</p>	<p>DADA2 can affect people of all ages. The onset is usually in infancy or childhood, leading to early onset organ damage from vasculitis that carries on into adulthood.</p> <p>This policy is expected to have a positive effect on the overall survival and outcomes of both adults and children.</p> <p>This policy aims to address the current inequity of access that exists, whereby some specialist centres are able to fund and prescribe TNF inhibitors for patients with DADA2. These specialist centres are concentrated in London, and this creates geographic disparity. Additionally, some patients who receive TNF inhibitors for this indication as children may lose access to this treatment when they transition to adult services.</p>	<p>This policy aims to make etanercept and adalimumab available for all patients with DADA2 if clinically eligible. The introduction of a national clinical policy would address the existing age-related inequity of access.</p>

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
<p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>DADA2 leads to early onset strokes and vasculitis, causing permanent brain damage and potentially loss of limbs leading to lifelong disability.</p> <p>TNF inhibitors have been shown to control inflammation and prevent the severe complications of the disease such as stroke and loss of peripheral tissues from vasculitis.</p> <p>Etanercept and adalimumab are administered subcutaneously, meaning that patients can self-administer at home rather than attending hospital for repeated infusions, which may be useful in terms of accessing treatment for those with access needs due to disability.</p>	<p>Provision of etanercept and adalimumab would prevent the severe complications of the disease.</p>
<p>Gender Reassignment and/or people who identify as Transgender</p>	<p>There is no identified impact of this policy on this protected characteristic.</p>	<p>N/A</p>
<p>Marriage & Civil Partnership: people married or in a civil partnership.</p>	<p>There is no identified impact of this policy on this protected characteristic.</p>	<p>N/A</p>
<p>Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.</p>	<p>Etanercept and adalimumab are not recommended to be used in pregnancy and breast-feeding, although they are not contraindicated.</p>	<p>Clinicians should discuss the risks and benefits with each individual patient to help them make an informed decision about the treatment.</p>

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
	<p>Women of child-bearing age should consider the use of appropriate contraception during and for three weeks after stopping treatment. Additionally, consideration should be given to either stop breast feeding or stop treatment during breast feeding as etanercept and adalimumab are excreted in breast milk.</p> <p>This is a potential adverse impact of the policy but is no greater than that of the current standard of care.</p>	
Race and ethnicity ¹	<p>Race and ethnicity are not known to be a risk factor for DADA2 per se, although endogamous populations are more at risk. This policy will promote access to etanercept and adalimumab regardless of race or ethnicity.</p>	<p>This policy aims to make etanercept and adalimumab available for all patients with DADA2 who meet the criteria for access, regardless of ethnicity.</p>
Religion and belief: people with different religions/faiths or beliefs, or none.	<p>There is no identified impact of this policy on this protected characteristic.</p>	<p>N/A</p>

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
Sex: men; women	DADA2 affects males and females equally. This policy will promote access to etanercept and adalimumab regardless of sex.	This policy aims to make etanercept and adalimumab available for all patients with DADA2 who meet the criteria for access, regardless of sex.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	There is no identified impact of this policy on this protected characteristic.	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	<p>People from these groups often experience difficulties accessing services and accessing follow up.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous in this setting as it allows administration outside secondary care.</p>	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.

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.	<p>This policy should have a positive impact for carers as it aims to reduce the severity of symptoms and access to emergency care.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous for carers as it allows administration outside secondary care.</p>	N/A
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	<p>People from these groups often experience difficulties accessing services and accessing follow up.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous in this setting as it allows administration outside secondary care.</p>	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	There is no identified impact of this policy on this group who face health inequalities.	N/A
People with addictions and/or substance misuse issues	There is no identified impact of this policy on this group who face health inequalities.	N/A
People or families on a low income	<p>This policy will likely reduce the financial burden on families from frequent trips to hospital.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be</p>	Arrangements can be made to support access to assessment and treatment in hospital, especially where travel is required. Reimbursement for travel

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
	<p>advantageous in this setting as it allows administration outside secondary care. Therefore, this may negate some of the travel costs associated with travelling to secondary care services.</p>	<p>costs is covered in the Healthcare Travel Costs Scheme.</p>
<p>People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).</p>	<p>There is no identified impact of this policy on this group who face health inequalities.</p>	<p>Any material required to support decisions around treatment should be current, culturally, and linguistically appropriate and available in a range of media formats (that is, not just in a written format). This material should be modified to meet the specific needs of the audience, if necessary.</p> <p>Clinical teams undertaking care and treatment for these patients should seek to understand any potential barriers to treatment uptake or compliance and include every reasonable effort to adjust treatment or care delivery for optimal patient benefit.</p>
<p>People living in deprived areas</p>	<p>This policy is expected to have a positive impact on people living in deprived areas.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous in this setting as it allows administration outside secondary care. Therefore, this may negate some of the travel costs associated with travelling to secondary care services.</p>	<p>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.</p>

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 living in remote, rural and island locations	<p>This policy should have a positive impact for people living in remote, rural and island locations as it will reduce the severity of symptoms and access to emergency care.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous in this setting as it allows administration at home.</p>	<p>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.</p>
Refugees, asylum seekers or those experiencing modern slavery	<p>People from these groups often experience difficulties accessing services and accessing follow up.</p> <p>Etanercept and adalimumab are administered subcutaneously so may be advantageous in this setting as it allows administration outside secondary care.</p>	<p>Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risks for this group.</p>
Other groups experiencing health inequalities (please describe)	<p>There are no further direct negative or positive impacts of this policy on any other groups experiencing health inequalities.</p>	<p>N/A</p>

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
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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	This policy was formally discussed with the DADA2 foundation at their international meeting, Bethesda (USA) Oct 2023. The DADA2 foundation is the international patient organisation for DADA2.	The DADA2 foundation were very supportive of a policy proposition for treatment of DADA2.	Oct 2023 and Mar 2024
2	Stakeholder testing	The policy proposition went out for a 14 day period of stakeholder testing during June 2024. Key stakeholders were identified by the Policy Working Group including those registered with the following Clinical Reference Groups: <ul style="list-style-type: none"> • Specialised immunology and allergy services • Specialised paediatric allergy, immunology and infectious disease • Adult and paediatric neurology • Renal services • Specialised rheumatology • Specialised blood disorders • Specialised paediatric renal services • Paediatric haematology 	June 2024

		• Specialised paediatric rheumatology	
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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	Please see the full evidence reviews by Solutions for Public Health.	Cost effectiveness Comparative evidence with standard of care
Consultation and involvement findings	Planned	
Research	No pending research is known	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Through the Blood and Infection Programme of Care and its Clinical Reference Group structures supporting the policy working group with its expert knowledge regarding the epidemiology and treatment of DADA2.	

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?	X	X
The proposal may support?		
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 of treatment	Further research
2 Comparative evidence	Further research
3	

10. Summary assessment of this EHIA findings

This policy aims to make etanercept and adalimumab available for all patients with DADA2 if clinically eligible, addressing the current inequity of access. Routine approval as an intervention with appropriate oversight would allow both adults and children with a rare disorder access to treatment that can prevent the debilitating impacts of disease that is currently not routinely available to them.

Etanercept and adalimumab are available subcutaneously so offer the option of self-administration at home / out of hospital, improving access to treatment for groups who may otherwise face inequalities.

No adverse impacts of this policy have been identified.

11. Contact details re this EHIA

Team/Unit name:	Blood and Infection Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Chief Finance Officer
Date EHIA agreed:	
Date EHIA published if appropriate:	