

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):** Clinical Commissioning Policy: Abatacept for treatment of refractory idiopathic inflammatory myopathies (adults and children aged 2 years and over)
- 2. Brief summary of the proposal in a few sentences**

This clinical commissioning policy recommends the use of abatacept for the treatment of patients with refractory idiopathic inflammatory myopathy in adults and children.

'Idiopathic inflammatory myopathies' (IIM) are chronic inflammatory conditions characterised by muscle inflammation. This leads to weakness which has significant impact on patients' mobility and quality of life. IIMs are said to be 'heterogenous'; which means that the severity and symptoms of the disease vary from person to person. Other features include: damage to skin, joints, lungs, heart, stomach and gut. IIMs affect both children and adults. Children most commonly experience both skin and muscle features, such as muscle weakness and skin ulcers. In children the condition is called juvenile idiopathic inflammatory myopathy (juvenile IIM) or juvenile dermatomyositis. Skin involvement in children can be severe, leading to painful ulceration. In the long-term, people with IIM are at increased risk for stroke, heart attack and osteoporosis.

The intended patient groups for this policy are those who have refractory IIM. Refractory IIM is defined as the intolerance to or an inadequate response to glucocorticoids and at least two other conventional immunosuppressive or immunomodulatory agents (1st line treatment), and rituximab second line (which can be given to patients with myositis-specific or myositis-associated antibodies).

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>This policy makes abatacept available for people aged 2 years and above. There is a higher prevalence of IIMs among the older age group (>40 years of age) (Malik et al 2016). In the long-term, people with IIM are at increased risk for stroke, heart attack and osteoporosis.</p> <p>Children most commonly experience both skin and muscle features, such as muscle weakness and skin ulcers. In children the condition is called juvenile idiopathic inflammatory myopathy (juvenile IIM) or juvenile dermatomyositis. Skin involvement in children can be severe, leading to painful ulceration.</p> <p>The availability of abatacept provides an additional treatment option for adults and children 2 years and over with severe disease which does not respond</p>	<p>Abatacept to be made available as a treatment option for patients aged 2 years and over fulfilling the clinical criteria.</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>to glucocorticoids and other conventional immunosuppressive or immunomodulatory agents. Treatment with abatacept will help to improve patient quality of life, muscle strength and reduce disease activity.</p> <p>The policy does limit the use of abatacept to children aged 2 years and above, due to restrictions of the license for abatacept.</p>	
<p>Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.</p>	<p>IIM can result in progressive weakening of muscles. Patients complain of difficulty getting up from a chair, climbing stairs, lifting things, and combing hair. It is usually painless, but pain can be a significant feature with acute disease and subcutaneous calcifications. Some patients develop shortness of breath related to interstitial lung disease or ventilatory muscle weakness, and difficulty swallowing due to oesophageal or pharyngeal involvement. Patients can develop congestive heart failure or cardiac arrhythmia from inflammation of the heart muscle, and gastrointestinal bleeding due to inflammation of the</p>	<p>Abatacept to be made available as a treatment option for patients aged 2 years and over in line with the license for the product.</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
	vessels of the gut. The availability of abatacept would provide an additional treatment option for these patients, with potential improvement in function and ability to carry out daily activities.	
Gender Reassignment and/or people who identify as Transgender	N/A	N/A
Marriage & Civil Partnership: people married or in a civil partnership.	N/A	N/A
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The summary of product characteristics for abatacept advises to avoid this medicine in patients who are pregnant or breastfeeding, therefore this group would not be eligible for treatment on safety grounds.	The policy criteria reflect the safety profile of the product so no changes will be made.
Race and ethnicity¹	IIM has been reported as being more common in the United States within the Black population, with poorer prognosis factors include patients from African-American race. No studies have been published relating to prevalence for different races in the UK.	N/A

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.	N/A	N/A
Sex: men; women	There is a higher preponderance of IIM in women (Malik et al 2016). This policy will have a positive impact on this group which is disproportionately affected by this disabling disease.	N/A
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	N/A	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	N/A	N/A
Carers of patients: unpaid, family members.	N/A	N/A

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
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	N/A	N/A
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	N/A	N/A
People with addictions and/or substance misuse issues	N/A	N/A
People or families on a low income	N/A	N/A
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	N/A	N/A
People living in deprived areas	N/A	N/A
People living in remote, rural and island locations	IIM is a rare disease, often managed in specialist centres. Abatacept can be administered subcutaneously and thereby allows for home administration, reducing patient day case attendances at specialist centres. The patient pathway is proposing treatment is approved by a regional network MDT, with a review that can be virtual. This has the potential to improve access to treatment for patients living in more remote areas, negating the need for travel to specialist centres.	Provision of virtual MDT review to facilitate decision-making, widening access to specialist care.

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
Refugees, asylum seekers or those experiencing modern slavery	N/A	N/A
Other groups experiencing health inequalities (please describe)	N/A	N/A

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		

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	Specialised Rheumatology CRG stakeholder list reviewed to ensure relevant groups consulted. Responses were received from clinicians, societies, an advisory group and a provider. Five out of the 6 respondents (83%) supported the policy proposition and deemed that it would have a positive impact upon patients. The respondent who did not support the policy proposition was concerned that the treatment may be used earlier in the pathway than proposed. Stakeholder's main	June 2021

		findings resulted in amendments to the route for data collection on outcomes, clarifications on the pathway, including review periods and role in response to Covid-19.	
2	Public consultation	Not planned following review of stakeholder engagement and completion of 13Q form.	
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	Malik A, Hayat G, Kalia JS, Guzman MA. Idiopathic Inflammatory Myopathies: Clinical Approach and Management. Front Neurol. 2016;7:64. Published 2016 May 20. doi:10.3389/fneur.2016.00064	The rarity of the condition limits the evidence base available.
Consultation and involvement findings	There was no additional evidence identified by stakeholders	
Research		
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	Policy working group comprised of consultant rheumatologists, a consultant dermatologist, and a public health specialist.	

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?		
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
2		
3		

10. Summary assessment of this EHIA findings

This policy has the potential to advance equality, by providing a treatment option for a rare disease which can cause significant disability. The patient pathway has taken account of patients living in remote areas, by allowing for virtual MDT review to approve initiation of treatment and home administration of the medicine.

11. Contact details re this EHIA

Team/Unit name:	Internal Medicine Programme of Care
Division name:	Specialised commissioning
Directorate name:	Finance, Performance and Planning
Date EHIA agreed:	28/07/2020
Date EHIA published if appropriate:	11/2021