Engagement Report

Topic details

Title of policy or policy statement:	Abatacept for refractory idiopathic inflammatory myopathies (adults and children aged 2 and over)
Programme of Care:	Internal Medicine
Clinical Reference Group:	Specialised Rheumatology
URN:	1925

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. The policy proposition went out to stakeholder engagement between the 15th to 30th June 2021. There were 6 responses.

2. Background

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 cause of IIMs is not fully understood, but they are thought to be 'autoimmune' diseases. In autoimmune disease, the body's immune system incorrectly attacks and damages its own cells.

Abatacept belongs to a group of medicines called biological therapies. It is a protein which interrupts the interaction between T cells, a type of white blood cell involved in inflammation, and the other immune cells which activate these T cells. This results in decreased T cell activation, and therefore decreased inflammation, a key process of the disease activity in IIMs.

Abatacept is proposed for routine commissioning for the treatment of refractory idiopathic inflammatory myopathies (adults and children aged 2 years and over).

This policy proposition has been developed by a Policy Working Group made up of clinicians, a pharmacist, a public health lead and commissioners.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 15th June to 30th June 2021. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

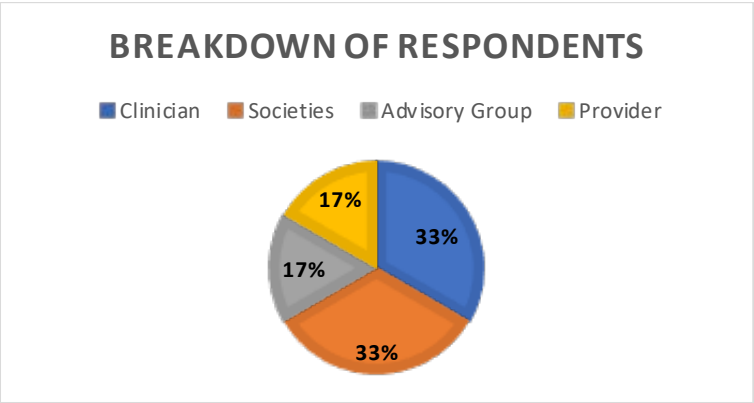
Respondents were asked the following questions:

- Do you support the proposition for abatacept for refractory idiopathic inflammatory myopathies (adults and children aged 2 and over) to be available through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
- Do you have any further comments on the proposition? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- Please declare any conflict of interests relating to this document or service area.
- Do you support the Equality and Health Inequalities Impact Assessment?

A 13Q assessment has been completed following stakeholder testing. The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

Six responses were received from clinicians, societies, and advisory group and a provider. The breakdown is as follows:



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. Abatacept is proposed to be commissioned as third line treatment to patients who are refractory to first and second line. Rituximab is second line therapy. Therefore, abatacept will not be commissioned to be used before or instead of rituximab but only if they are refractory to it or if they have had an adverse event with rituximab and/or secondary nonresponse to rituximab. In line with the 13Q assessment, it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Internal Medicine Programme of Care. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
Agreement that the relevant evidence had been reviewed for the proposition.	Noted.
It was suggested that there was some emerging evidence that abatacept had better outcomes than rituximab in patients with COVID-19.	This is accepted and the following sentence was added to the policy proposition: in light of the COVID-19 pandemic then the regional MDT may decide it is appropriate to start patients on abatacept instead of rituximab.
The evidence showed a reported improvement at 3-month that is lost at 6-month.	This is accepted and a 3-month initial review has been included in the policy proposition and a 6-month Blueteq® continuation form.
Current Patient Pathway	
Concern was raised that the treatment may be used earlier in the pathway than proposed.	Abatacept is proposed to be commissioned as third line treatment to patients who are refractory to first and second line. Rituximab is second line therapy. Therefore, abatacept will not be commissioned to be used before or instead of rituximab only if they are refractory to it or who have had an adverse event with rituximab and/or secondary nonresponse to rituximab.
Changes/addition to policy	
The proposition included the collection of outcome data for adults but not for paediatrics.	This is accepted and the Juvenile Dermatomyositis Cohort Biomarker Study and Repository (JDCBSR) has been added for data collection for paediatrics.
Highlighted that the proposition should consider including existing patients on IvIg to switch to Abatacept in selected cases.	This is accepted and the following sentence has been added to the starting criteria:

	Any patients transitioning from IVIg (see appendix 1). Appendix 1 has been included which provides a proven process for switching.
IV loading of Abatacept can be considered at initiation.	This is accepted and the following sentence has been added to the starting criteria: IV loading can be used at initiation.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following changes based on the engagement responses have been made to the policy proposition:

- The following sentences have been added to the policy proposition:
  - in light of the COVID-19 pandemic then the regional MDT may decide it is appropriate to start patients on abatacept instead of rituximab.
  - Any patients transitioning from IVIg (see appendix 1). Appendix 1 has been included which provides a proven process for switching.
  - IV loading can be used at initiation.
- A 3-month initial review has been included in the policy proposition and a 6-month Blueteq® continuation form.
- The Juvenile Dermatomyositis Cohort Biomarker Study and Repository (JDCBSR) has been added for data collection for paediatrics.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

There are no remaining concerns outstanding following consultation.