NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus (Review of TA397) [ID1591]

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation

1.	Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

Stakeholders commented:

- Systemic lupus erythematosus (SLE) is more common in people of African-Caribbean and Asian family backgrounds and as a group these people tend to have poorer health outcomes than people from other ethnic groups.
- The condition predominantly affects women, particularly those of child-bearing age. There is a risk of infertility and teratogenicity with some treatments used in SLE and there is limited data on the use of belimumab in pregnant women.
- Childhood SLE is relatively rare but usually has more severe disease presentation than in adults. It may have a significant impact on a child's education and future prospects and introduce significant caring requirements for parents.
- The eligibility criteria defined in NICE TA397 may discriminate against people who are less likely to have anti-double-stranded DNA antibodies, such as people of African descent, or those who previously received cyclophosphamide or rituximab (but still have active disease and may have permanent disability from lupus).

- The current administration of intravenous belimumab within a specialist centre may present a barrier to access to treatment because a person may live far and find it difficult to take time off work to have regular infusions.

Considerations by committee:

- Issues about differences in the prevalence or incidence of a condition and healthcare implementation cannot be addressed in a technology appraisal.
- The new subcutaneous formulation of belimumab can be self-administered which may improve access to treatment, if belimumab is recommended by the committee.
- The new population presented by the company for this appraisal requires only 1 of the 2 biomarkers (either positive anti-double-stranded DNA or low complement) to be eligible for treatment with belimumab, if recommended by the committee.
- The presence of comorbidities and disability in people with systemic lupus erythematosus should not affect access to treatment with belimumab, if recommended by the committee.

2.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the committee addressed these?
No other equalities issues were identified.	

3.	Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?
No other equalities issues were identified by the committee.	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other

	groups? If so, what are the barriers to, or difficulties with, access for the specific group?
Not applicable.	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
Not applicable.	

6.	Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
Not applicable.	

7.	Have the committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
Equality issues considered by the committee are included in the committee discussion section of the appraisal consultation document.	

Approved by Associate Director (name): …Linda Landells……

Date: 24 May 2021

Final appraisal determination

(when an ACD issued)

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?
Stakeholders commented that if belimumab was not recommended for routine commissioning this may increase inequalities in access to rituximab. This is because rituximab is only available as an intravenous infusion administered at a specialist centre and some people may struggle to access these centres. Furthermore, rituximab is currently not commissioned for use in children who have not started puberty. The committee concluded that issues around healthcare implementation cannot be addressed in a technology appraisal. Furthermore, these equalities issues relate to the recommendation being negative, but it is now positive.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No.	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No.	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified

	in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
Not applicable.	

5.	Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
See section 3.18 of the FAD.	

Approved by Associate Director (name): ……Linda Landells……

Date: 28 October 2021