NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Scoping

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.

1.	Have any potential equality issues been identified during the scoping process (draft scope consultation and scoping workshop discussion), and, if so, what are they?

- SLE affects all ethnic groups but is more common in people of African-Caribbean and Asian ethnicity, who often also have more severe disease. People from BAME communities also have higher risk of developing diabetes and hypertension and so are at higher risk of negative consequences of steroid use. Also, some ethnic groups respond better to some drugs compared with others.
- SLE is 6-9 times more common in women.
- SLE is common among women at the childbearing age. The risk of infertility from cyclophosphamide and the teratogenicity of cyclophosphamide, methotrexate and mycophenolate mofetil needs to be considered. There are a limited amount of data from the use of belimumab in pregnant women. Summary of product characteristics states that belimumab should not be used during pregnancy unless the potential benefit justifies the potential risk to the foetus. Women of childbearing potential must use effective contraception during belimumab treatment and for at least 4 months after the last treatment.
- Childhood SLE is relatively rare but usually has more severe disease presentation than in adults, with a higher incidence of major organ involvement and a more aggressive disease course. 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 TA397 (stricter than the eligibility criteria defined in the marketing authorisation) may discriminate against people who are less likely to have anti-dsDNA 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). People with cutaneous SLE manifestations do not always have low complement so would not be eligible to receive belimumab under TA387 criteria.

- The intravenous mode of administration may discriminate people who may have difficulty accessing the treatment, for example because:

    - they live far from the specialised centres that can administer the treatment, and have transport problems.

    - they have problems taking time off work on a regular basis or fear that this could negatively affect their employment. The infusions are needed every 4 weeks and last an hour plus the travel time.

2. What is the preliminary view as to what extent these potential equality issues need addressing by the Committee?
The committee may need to consider separately the impact of SLE treatments on BAME communities, women of childbearing potential and children. If a positive recommendation is reached, the committee will need to consider any equality issues related to eligibility criteria or the mode of administration in its decision-making.

3. Has any change to the draft scope been agreed to highlight potential equality issues?
No changes needed at this point.

4.	Have any additional stakeholders related to potential equality issues been identified during the scoping process, and, if so, have changes to the matrix been made?
No additional stakeholders identified.	

Approved by Associate Director (name): Linda Landells

Date: 26 August 2020