NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Scoping

STA imlifidase for preventing kidney transplant rejection in people with chronic kidney disease

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?

Yes:

- People who are highly sensitised (that is, people on the waiting list for organ transplantation carrying antibodies to human leukocyte antigen [HLA]) may not be provided with the same access to transplantation and standard of care as non-sensitised people. This could be caused by differences in time on the waiting list when comparing these patient groups. The updated kidney allocation scheme may provide evidence for this. Imlifidase may help to ensure that this gap can be narrowed further in the future.

  Imlifidase may also offer highly sensitised patients in minority ethnic groups, who already have difficulty accessing a matched donor kidney, a desensitisation treatment option to enable access to a deceased donor kidney. These people with protected characteristics could gain access to a donor kidney sooner and, thus, are likely to have better outcomes once transplanted.

- Clinical experts at the scoping workshop indicated that one of the most common causes for a patient to be 'highly sensitised' is previous pregnancy. According to British Transplantation Society guidelines, pregnancy induced sensitisation is a major reported risk factor for early antibody mediated rejection in donor specific HLA antibody incompatibility transplantation, especially where the donor is the patient's child or the father of a child with the patient. A clinical expert indicated that, for the

most sensitised patients (with positive crossmatch through Complement Dependent Cytotoxic [CDC] test), see very different 10-year survival results by sex – approximately 67/68% (males) versus 15% (females).

This may be related to graft survival, and the clinical expert provided the following data (already presented at an international meeting):

- The graft survival for CDC positive female patients was 57.1%, 38.1% and 15% at 1-year, 5-years and 10-years respectively
- The graft survival for CDC positive male patients was 81.3%, 67.1% and 67.1% at 1-year, 5-years and 10-years, respectively
- The survival probability of CDC positive male patients is significantly greater than that of CDC positive female patients (*P<0.05)

- A patient expert at the scoping workshop noted that there has been a postcode lottery, with geographic differences in access to transplant, as the use of low risk/delisted immunologically incompatible transplant and desensitisation with plasma exchange has tended to be concentrated in a few centres.

2.	What is the preliminary view as to what extent these potential equality issues need addressing by the committee?

Minority ethnic groups having difficulty accessing a matched donor kidney:

Committee should be made aware of the likelihood of obtaining a matched donor kidney, in different ethnic groups.

Pregnancy as major cause of antibody sensitisation, limitations to finding a compatible donor as a result (especially as child or father of the child often not a good match), very different outcomes for males and females in terms of graft survival in the most highly sensitised subgroup:

Committee should be made aware of this issue, and impact on current treatment options and outcomes for males and females.

Geographic differences in access to existing desensitisation/transplant in highly sensitised patients:

	This would not need to be addressed by the committee. If a positive decision the commissioner would have to find a model balancing geographic access and expertise in this transplant area.

3.	Has any change to the draft scope been agreed to highlight potential equality issues?
No	

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	

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