NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Blinatumomab with chemotherapy for consolidation treatment of Philadelphia-chromosome-negative CD19-positive B-cell precursor acute lymphoblastic leukaemia without minimal residual disease

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

Final draft guidance

1.	Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?
	• A stakeholder commented that the key clinical trial for blinatumomab applies an upper age limit but that the standard approach is to individualise treatment decisions on biological, personal and clinical parameters. Therefore, the evaluation should reflect clinical practice and not necessarily restrict to a clinical trial defined criteria when determining benefit. The committee considered that because its recommendation does not restrict access to blinatumomab based on a person's age that this potential equality issue was resolved. • The stakeholder also highlighted that a small group of people will not be evaluable for minimal residual disease (MRD). These people should be considered within the provisions of the final assessment and care should be taken to not structurally discriminate against this subgroup on the basis of technical factors related to MRD test assessments. The committee considered that issues around the technical nature of MRD testing could not be addressed in a technology appraisal.

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?

- The external assessment report (EAR) highlighted that the lower age limit in the key clinical trial may lead to inequality of access if blinatumomab is not recommended for younger adults below this age. The committee considered that because its recommendation does not restrict access to treatment based on a person's age that this potential equality issue was resolved.
- The EAR and clinical expert statement highlighted that if blinatumomab is recommended in this appraisal based on the MRD threshold in the key clinical trial, it may leave a population with MRD-positive disease ineligible for treatment because of differences in the MRD thresholds considered in this appraisal and NICE TA589. The committee understood from the CDF clinical lead that any gaps for treatment eligibility that arise as a result of the recommendations for blinatumomab in TA589 and in this appraisal could be addressed by NHS England.
- The clinical expert statement highlighted that older people and certain biological subgroups may not have equal access to standard MRD monitoring due to lack of an identifiable MRD marker. These people should be eligible for alternative MRD assessment approaches to ensure equitable access to MRD indicated therapy. The committee considered that issues around the accessibility of MRD testing could not be addressed in a technology appraisal.

3.	Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No other potential equality issues have been identified by the committee.

4.	Do the 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?
No.	

5.	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.	

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?
N/A.	

7.	Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?
Yes, see section 3.13 of the final draft guidance.	

Approved by Associate Director (name): Ross Dent

Date: 31/01/2025