NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date:	17/07/19
Intervention:	Plerixafor
Indication:	Stem cell mobilisation in adults and children
ID:	1902
Gateway:	2, Round 1.
Programme:	Blood and Infection
CRG:	Blood and Marrow transplant

Information provided to the panel

Policy proposition

CPAG Summary Report

Evidence review x 2

Prior approval form

Key elements discussed

Panel noted that it was intended that the policy proposition would replace two existing published clinical commissioning policies and in addition, provide a commissioning position for some additional indications, including non-haematological tumours.

Panel were presented with two evidence reviews, one for adults with non-haematological tumours and one for haematological tumours, both of which attempted to identify the clinical effectiveness, cost effectiveness, safety and any specific patient subgroups.

Evidence for adults with non-haematological tumours consisted of two retrospective case series including 54 adults with various non-haematological tumours. 70% of patients received plerixafor following unsuccessful treatment and 30% received plerixafor pre-emptively. In total, 83% achieved successful mobilisation although no data was provided on successful engraftment. No serious adverse events relating to plerixafor were reported. Panel highlighted that the case series were retrospective and the drug was used compassionately across different sites likely to have differing protocols in place for the use of the drug, although noted that an RCT would be difficult to conduct in this situation. Panel noted that the evidence suggested that the use of plerixafor was effective for patients with solid tumours types in this population and that it was well tolerated.

Evidence for haematological disease consisted of a single retrospective case series focusing on patients with multiple myeloma and lymphoma (for which plerixafor is already commissioned) and amyloidosis. Patients received plerixafor as a rescue treatment and all achieved successful mobilisation and engraftment. Some toxicities were identified which were not considered to be related to plerixafor. Panel noted that this was a small, retrospective care series of three patients which may be prone to bias. Of this limited evidence, data was available only for a single condition (amyloidosis) not covered by the existing published policies.

Overall, no evidence was identified by either evidence review to help identify patient subgroups who may benefit.

Panel noted that the license for plerixafor cautioned its use in patients with leukaemia, as it may cause mobilisation of leukaemic cells. The SPC states that: 'In a compassionate use programme, plerixafor and G-CSF have been administered to patients with acute myelogenous leukaemia and plasma cell leukaemia. In some instances, these patients experienced an increase in the number of circulating leukaemia cells. For the purpose of haematopoietic stem cell mobilisation, plerixafor may cause mobilisation of leukaemic cells and subsequent contamination of the apheresis product. Therefore, plerixafor is not recommended for haematopoietic stem cell mobilisation and harvest in patients with leukaemia.'

Recommendation

Panel requested that the amendments outlined below were made before the policy was resubmitted to the next meeting of the Clinical Panel for approval.

Why the panel made these recommendations

The Panel considered whether it was possible to extrapolate from the evidence identified to cover all haematological and solid tumour types and ages of patients. The evidence reviews presented do not provide a basis for extending plerixafor to the eligible population but do provide a small amount of data to justify treatment. However, the Panel identified that these patients may suffer from significant harm as a result of the transplant and the addition of plerixafor was unlikely to cause additional harm. As such, the Panel agreed that taking a pragmatic approach to support a routine commissioning position was appropriate.

Documentation amendments required

The PWG were asked to consider the following amendments:

1) The specific types of solid tumours to be considered should be specified.
2) The glossary should be amended to align with the eligibility criteria outlined and should remove reference to 'benign' tumours.
3) All references to haematological cancers should clearly state that warning and precautions in the licence in relation to the use of plerixafor in patients with leukaemia. These patients should be included in the exclusion criteria.
4) Appendix 1 should be removed and a reference included.
5) The criteria should include reference to when clinical judgement is used and reference to the MDT for decision making.
6) Substantial revisions were needed to the CPAG Summary Report to include a single table summarising the evidence across the two reviews.

Post Panel Note

Please note that the Blood & Infection Programme of Care have incorporated and completed the above amendments required following Clinical Panel in July, 2019.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, Medical Director