NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Project (RPP) decision paper

Review of TA323; Erythropoiesis-stimulating agents (epoetin and darbepoetin) for the treatment of cancer-treatment induced anaemia

Final recommendation post consultation
The guidance should be transferred to the 'static guidance list'.

1. Background

This guidance was issued in November 2014.

At the Guidance Executive meeting of 14 November 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be transferred to the 'static guidance list'. That we consult on this proposal.

3. Rationale for selecting this proposal

There has been no substantial change in the wordings of the marketing authorisation of the technologies, recommended in the technology appraisal guidance 323, concerning chemotherapy-induced anaemia. Some biosimilars have received European marketing authorisation since the publication of TA323 for example Abseamed and Epoetin Alfa Hexal (epoetin alfa), Biopoin (epoetin theta) and Silapo (epoetin zeta). However these products are currently not available in the UK. Teva UK has confirmed that they are no longer marketing Eportio

(epoetin theta), one of the recommended options in TA323, in the UK. The list prices for the recommended technologies have not substantially changed since the publication of TA323 in November 2014.
The evidence review during the development of TA323 established that erythropoiesis-stimulating agents were effective in increasing haemoglobin concentrations, improving haematological responses thereby reducing the need for blood transfusions and improving health-related quality of life. The main concerns were their effect on overall survival, tumour growth, and adverse reactions particularly high risk of thromboembolism.
Studies published since the searches were last run during the development of TA323 (December 2013), reconfirm the earlier conclusion. Owing to the potential negative effect on survival, tumour progression, the use of erythropoiesis-stimulating agents has gone out of favour as a standalone treatment of chemotherapy-induced anaemia (Weigl et al, 2017).
As the regulatory agencies in Europe have not issued any new safety warning, it is expected that clinicians will adhere to the instructions stipulated in the section 4.4 'Special warnings and precautions for use' in respective summaries of the product characteristics regarding starting, stopping and, dose adjustments taking into account haemoglobin level, to mitigate the risk of harm.
As there is no evidence which could have an impact on the previous recommendations, it is recommended to move the guidance on the static list.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: Amgen **Response to proposal:** Agree Amgen support the recommendation proposed by the Institute that TA323 should be transferred to the 'static guidance list' as there is no evidence which could have an impact on the previous recommendations.	**Comment from Technology Appraisals** Comment noted. Thanks

Paper signed off by: Elisabeth George, 17 January 2018

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