Review decision – April 2018

Review decision
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Decision to move the existing guidance to the static list

We would like to update you on the decision made regarding the review of the existing guidance on TA323; Erythropoiesis-stimulating agents (epoetin and darbepoetin) for the treatment of cancer-treatment induced anaemia

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.

NICE’s Guidance Executive has decided to proceed with this proposal without consultation.

Consequently TA323 will move to the ‘static list’ of technology appraisals.

Review decision paper