

Review proposal of TA601; Bezlotoxumab for preventing recurrent Clostridium difficile infection

1. Termination advice for TA601 was published in September 2019.

Decision

2. The forthcoming [antimicrobial prescribing guideline for Clostridium difficile infection](#) will make recommendations on the use of bezlotoxumab, meaning that the termination advice in TA601 will be withdrawn at the point which the guideline is published. The current anticipated publication date for the guideline is September 2020.

Background

Proposal put to company

3. NICE was unable to recommend bezlotoxumab for preventing recurrent Clostridium difficile infection as a submission was not provided during the development of the appraisal. Consequently, the appraisal was terminated in September 2019.
4. NICE is currently developing an antimicrobial prescribing guideline for clostridium difficile infection. This guideline provides an opportunity for NICE to look for evidence on bezlotoxumab for preventing clostridium difficile infection and to produce relevant guidance
5. Consequently, we propose that recommendations on the use of bezlotoxumab should be made within the antimicrobial prescribing guideline. This would mean that the termination advice in TA601 would be withdrawn at the point which the antimicrobial prescribing guideline is published.

Company response

6. NICE contacted the company (Merck Sharp & Dohme) in December 2019. Merck Sharp & Dohme responded to confirm that they did not intend to make a submission to the NICE Technology Appraisal programme.

Decision paper sign off

Jennifer Prescott – Associate Director – Planning, Operations and Topic Selection

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Contributors to this paper

Programme Manager: Andrew Kenyon