Clinical and NHS commissioning expert statement

Cefiderocol for treating severe aerobic Gram-negative bacterial infections

Thank you for agreeing to give us your views on cefiderocol and its possible use in the NHS.

You can provide a unique perspective on cefiderocol in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. **You do not have to answer every question** – they are prompts to guide you. The text boxes will expand as you type.

**Information on completing this expert statement**

* Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
* We are committed to meeting the requirements of copyright legislation. If you intend to include journal articles in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
* Your response should not be longer than 13 pages.

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| **About you** |  |
| 1. Your name | xxxxxxxxxxxx |
| 2. Name of organisation | NHS England and Improvement |
| 3. Job title or position | xxxxxxxxxxxxxxxxxxxxx |
| 4. Please specify your role from the examples given: | An employee or representative of a healthcare professional organisation that represents cliniciansA specialist in the treatment of people with this conditionA specialist in the clinical evidence base for this condition or ceftazidime with avibactamCommissioning services for a CCG or NHS England in generalCommissioning services for a CCG or NHS England for the condition for which NICE is considering ceftazidime with avibactamResponsible for quality of service delivery in a CCG (for example, medical director, public health director, director of nursing)Other (please specify) |
| 5. Name of your nominating organisation | NHS England and Improvement |
| 6. Did your nominating organisation make a submission? | Unknown |
| 7. Did you write your nominating organisation’s submission? | No |
| 8. If you did not write your nominating organisation’s submission, do you agree with its content? We would encourage you to complete this form even if you agree with your nominating organisation’s submission, but this is not compulsory. | I have not seen the content |
| **Current treatment of severe gram-negative infections, where resistance is suspected/confirmed** |  |
| 9. What is the main aim of treatment? | Treat infection with effective therapy |
| 10. What do you consider a clinically significant treatment response? | This is for clinical experts to answer |
| 11. How are severe gram-negative infections, where resistance is suspected/confirmed, currently treated in the NHS?  | This is for clinical experts to answer |
| a) Are any clinical guidelines used, and if so, which?  | Usually local guidelines depending on resistance patterns |
| 1. Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please state if your experience is from outside England.)
 | As above |
| 1. What impact would cefiderocol have on the current pathway of care?
 | This is for clinical experts to answer but this treatment is already available |
| Using cefiderocol in clinical practice |  |
| 12. To what extent and in which population(s) is cefiderocol currently being used in your local health economy? | This is for clinical experts to answer and is likely to vary between localities depending on resistance patterns |
| 13. Will cefiderocol be used (or is it already used) in the same way as current care in NHS clinical practice?  | This is for clinical experts to answer |
| 14. What rules will be used to start treatment? Do these include any additional testing that is not currently routinely available on the NHS?  | This is for clinical experts to answer and is likely to vary between localities depending on resistance patterns |
| 15. If information about the pathogen is very limited (i.e susceptibility data and gene testing results are not yet available) – what specific rules/criteria determine that it’s appropriate to use cefiderocol in the risk-based empiric treatment setting? | This is for clinical experts to answer |
| 16. Will cefiderocol be easier or more difficult to use for patients or healthcare professionals than current care? Are there any practical implications for its use (for example, any concomitant treatments, additional clinical requirements or additional monitoring needed) | This is for clinical experts to answer |
| Benefits of ceftazidime with avibactam |  |
| 17. Do you expect cefiderocol to provide clinically meaningful benefits compared with current care?  | This is for clinical experts to answer |
| 18. Please comment on the potential benefits of cefiderocol in relation to the 5 following elements of value, and how these elements of value could be quantified and captured in an economic analysis. Please be aware that more detailed definitions of these elements of value are provided in chapter 7 of the [protocol for this evaluation](https://www.nice.org.uk/Media/Default/About/what-we-do/Life-sciences/models-for-the-evaluation-and-purchase-of-antimicrobials/Cefiderocol-protocol.docx). |  |
| 1. Transmission value (avoiding onwards spread of pathogens in the population).

Please include suggestions for surrogate outcomes to measure transmission benefit, for example length of hospital stay/length of stay in an intensive care unit, and provide any available evidence that supports the link between these outcomes.  | This is for clinical experts to answer |
| 1. Enablement value (enabling other treatments and procedures to take place e.g. chemotherapy, organ transplant, surgical procedures).

Please comment on the potential for enablement value **beyond** the person being treated for the infection, considering the impact of the infection on other hospital patients and members of staff. Can you suggest a specific intensive care unit which would make a good case study for modelling enablement value?  | This is for clinical experts to answer |
| 1. Spectrum value (benefits of replacing broad spectrum antimicrobials with narrow spectrum antimicrobials).
 | This is for clinical experts to answer |
| 1. Insurance value (having antimicrobials available for sudden increase of infections with pathogens resistant to existing antimicrobials).
 | This is for clinical experts to answer |
| 1. Diversity value (having a range of treatment options available)
 | This is for clinical experts to answer |
| 19. Which of these elements of value (transmission, enablement, spectrum, insurance, diversity) does cefiderocol have the greatest potential to impact? That is, the greatest potential to improve population health outcomes? | This is for clinical experts to answer |
| 20. Are there any groups of people for whom cefiderocol would be more or less effective (or appropriate) than the general population?  | This is for clinical experts to answer |
| 21. How do any side effects or adverse effects of cefiderocol affect the management of infection and the patient’s quality of life? | This is for clinical experts to answer |
| **Sources of evidence** |  |
| 22. Do the clinical trials on cefiderocol reflect current UK clinical practice? | This is for clinical experts to answer |
| 1. If not, how could the results be extrapolated to the UK setting?
 | This is for clinical experts to answer |
| 1. What, in your view, are the most important outcomes, and were they measured in the trials?
 | This is for clinical experts to answer |
| 1. If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?
 | This is for clinical experts to answer |
| 1. Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?
 | This is for clinical experts to answer |
| 23. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?  | This is for clinical experts to answer |
| 24. How do data on real-world experience compare with the trial data? | This is for clinical experts to answer |
| **Equality** |  |
| 25a. Are there any potential [equality issues](https://www.nice.org.uk/about/who-we-are/policies-and-procedures/nice-equality-scheme) that should be taken into account when considering ceftazidime with avibactam? | This is for clinical experts to answer |
| 25b. Consider whether these issues are different from issues with current care and why. | This is for clinical experts to answer |
| **Key messages** |  |
| 26. In up to 5 bullet points, please summarise the key messages of your statement. |  |

Thank you for your time.

Please log in to your NICE Docs account to upload your completed statement, declaration of interest form and consent form.

Your privacy

The information that you provide on this form will be used to contact you about the topic above.

 [ ]  Please tick this box if you would like to receive information about other NICE topics.

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