Clinical and NHS commissioning expert statement

Ceftazidime with avibactam for treating severe aerobic Gram-negative bacterial infections

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

You can provide a unique perspective on ceftazidime with avibactam 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 | Marisa Lanzman |
| 2. Name of organisation | UK Clinical Pharmacy Association (UKCPA) – Infection Committee |
| 3. Job title or position | Senior Pharmacist Microbiology - Royal Free London NHS Foundation Trust Committee member UKCPA infection committee |
| 4. Please specify your role from the examples given: | An employee or representative of a healthcare professional organisation that represents clinicians  A specialist in the treatment of people with this condition  A specialist in the clinical evidence base for this condition or ceftazidime with avibactam  Commissioning services for a CCG or NHS England in general  Commissioning services for a CCG or NHS England for the condition for which NICE is considering ceftazidime with avibactam  Responsible 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 | UK Clinical Pharmacy Association (UKCPA) |
| 6. Did your nominating organisation make a submission? | Yes |
| 7. Did you write your nominating organisation’s submission? | Yes |
| 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. |  |
| **Current treatment of severe gram-negative infections, where resistance is suspected/confirmed** |  |
| 9. What is the main aim of treatment? | The main aim of treatment is clinical cure of the patient |
| 10. What do you consider a clinically significant treatment response? | A significant treatment response would be that the patient is able to stop receiving antibiotics without relapsing |
| 11. How are severe gram-negative infections, where resistance is suspected/confirmed, currently treated in the NHS? | Treatment is usually hospital based and requires the administration of one or more intravenous antibiotics. |
| a) Are any clinical guidelines used, and if so, which? | There may be local clinical guidelines in place, which allow for the use of this antibiotic on the recommendation of a consultant microbiologist or infectious diseases clinician.  The Infectious Diseases Society of America have recently published guidelines on the treatment of gram-negative infections <https://www.idsociety.org/globalassets/idsa/practice-guidelines/amr-guidance/idsa-amr-guidance.pdf> The UKCPA has recently produced a guide to treating infections caused by carbapenemase-producing Enterobacterales (CPE) which includes ceftazidime-avibactam:   *Stephen Hughes, Mark Gilchrist, Katie Heard, Ryan Hamilton, Jacqueline Sneddon*, Treating infections caused by carbapenemase-producing Enterobacterales (CPE): a pragmatic approach to antimicrobial stewardship on behalf of the UKCPA Pharmacy Infection Network (PIN), JAC-Antimicrobial Resistance, Volume 2, Issue 3, September 2020, dlaa075, <https://doi.org/10.1093/jacamr/dlaa075> |
| 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.) | The pathway of care is fairly well defined; treatment may vary from institution to institution and some antibiotics may not be suitable for certain patients or may not be available |
| 1. What impact would ceftazidime with avibactam have on the current pathway of care? | The technology is currently available to NHS patients and Trusts. Some Trusts may have a cap on the number of patients that can receive this medication. |
| Using ceftazidime with avibactam in clinical practice |  |
| 12. To what extent and in which population(s) is ceftazidime with avibactam currently being used in your local health economy? | This medication is currently used in hospital inpatient settings |
| 13. Will ceftazidime with avibactam be used (or is it already used) in the same way as current care in NHS clinical practice? | Yes |
| 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 will vary between organisations |
| 15. If information about the pathogen is very limited (ie susceptibility data and gene testing results are not yet available) – what specific rules/criteria determine that it’s appropriate to use ceftazidime with avibactam in the risk-based empiric treatment setting? | Use is likely to be restricted to approval from infection teams if used empiricial |
| 16. Will ceftazidime with avibactam 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) | Use of ceftazidime-avibactam may result in the reduction in the number of antibiotics to be given in a treatment course including those that require therapeutic drug monitoring. Therefore use of this antibiotic may be easier for the patient and healthcare professional. |
| Benefits of ceftazidime with avibactam |  |
| 17. Do you expect ceftazidime with avibactam to provide clinically meaningful benefits compared with current care? | Yes |
| 18. Please comment on the potential benefits of ceftazidime with avibactam 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/about/what-we-do/life-sciences/scientific-advice/models-for-the-evaluation-and-purchase-of-antimicrobials/ceftazidime-with-avibactam). |  |
| 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. |  |
| 1. Enablement value (enabling other treatments and procedures to take place eg 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? |  |
| 1. Spectrum value (benefits of replacing broad spectrum antimicrobials with narrow spectrum antimicrobials). |  |
| 1. Insurance value (having antimicrobials available for sudden increase of infections with pathogens resistant to existing antimicrobials). |  |
| 1. Diversity value (having a range of treatment options available) |  |
| 19. Which of these elements of value (transmission, enablement, spectrum, insurance, diversity) does ceftazidime with avibactam have the greatest potential to impact? That is, the greatest potential to improve population health outcomes? |  |
| 20. Are there any groups of people for whom ceftazidime with avibactam would be more or less effective (or appropriate) than the general population? | No |
| 21. How do any side effects or adverse effects of ceftazidime with avibactam affect the management of infection and the patient’s quality of life? | If side or adverse effects are overwhelming or unmanageable the antibiotic would need to be stopped which could impact the infection management |
| **Sources of evidence** |  |
| 22. Do the clinical trials on ceftazidime with avibactam reflect current UK clinical practice? | Yes |
| 1. If not, how could the results be extrapolated to the UK setting? |  |
| 1. What, in your view, are the most important outcomes, and were they measured in the trials? | Clinical response is the most important outcome – this was measured in the trials |
| 1. If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes? | NA |
| 1. Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently? | No |
| 23. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence? | No |
| 24. How do data on real-world experience compare with the trial data? | Real-world data is a favourable; clinical cure can be achieved if this antibiotic is started at the correct time. |
| **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? | No |
| 25b. Consider whether these issues are different from issues with current care and why. | NA |
| **Key messages** |  |
| 26. In up to 5 bullet points, please summarise the key messages of your statement. | * This is a useful antibiotic that is currently available in clinical practice in England * The antibiotic is licensed for a wide range of infections and can be used to treat infections caused by a variety of gram-negative pathogens * The cost of this antibiotic is likely to lead to a restriction on its use currently. Restrictions will also be in place to ensure that the antibiotic is not overused which could cause resistance |

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.

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

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