Professional and NHS organisation submission template

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

|  |
| --- |
| Thank you for agreeing to give us your organisation’s views on this technology and its possible use in the NHS.You can provide a unique perspective on the technology 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 submission** * 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.
 |

|  |  |
| --- | --- |
| **About you** |  |
| 1. Your name | xxxxxxxxxxxxxx |
| 2. Name of organisation | UK Clinical Pharmacy Association (UKCPA) – Infection Committee |
| 3. Job title or position | xxxxxxxxxxxxxxxxxxxxxxxxxx,Royal Free London NHS Foundation Trust |
| 4. Are you (please tick all that apply): | [ ]  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 technology (for example, an investigator in clinical trials for the technology)?[ ]  commissioning services for a CCG or NHS England in general?[ ]  commissioning services for the condition for which NICE is considering this technology?[ ]  responsible for quality of service delivery in the CCG (e.g. medical director, public health director, director of nursing)?[ ]  other (please specify):  |
| 5a. Brief description of the organisation (including who funds it). | We provide hospital pharmacists with opportunities for networking, collaborations, sharing best practice and inspiring innovation. Our community is both supportive and stimulating, offering our members and event delegates the opportunity to explore, learn, innovate and flourish.We provide practitioner led education and training, peer support and leadership.We are a not-for profit organisation – we charge our members a small annual fee and receive corporate funding from a number of organisations |
| 5b. Has the organisation received any funding from the manufacturer(s) of the technology and/or comparator products in the last 12 months? [Relevant manufacturers are listed in the stakeholder list.]If so, please state the name of manufacturer, amount, and purpose of funding. | The UKCPA receives funding from a number of supporters including Pfizer.Please see details on our website: <https://ukclinicalpharmacy.org/about/supporters/>And our policy on working with industry: <https://ukclinicalpharmacy.org/wp-content/uploads/2017/01/UKCPA_policy_on_working_with_industry.pdf> |
| 5c. Do you have any direct or indirect links with, or funding from, the tobacco industry? | No |
| **Current treatment of severe gram-negative infections, where resistance is suspected/confirmed** |  |
| 6. What is the main aim of treatment?  | The main aim of treatment is clinical cure of the patient |
| 7. 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  |
| 8. In your view, is there an unmet need for patients and healthcare professionals? | Yes – there is an unmet need for both patients and healthcare professions; diagnosis of gram negative infections needs to be quicker so the most appropriate antibiotics can be started as soon as possible. The current antibiotics that are available are expensive and may not be freely available when required. |
| 9. How is the condition currently treated in the NHS?  | Treatment is usually hospital based and requires the administration of one or more intravenous antibiotics |
| * Are any clinical guidelines used in the treatment of the condition, and if so, which?
 | There are 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> |
| * 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. |
| * What impact would the technology 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. |
| **The use of the technology** |  |
| 10. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice?  | Yes |
| * To what extent and in which population(s) is the technology being used in your local health economy?
 | This medication is currently used in hospital inpatients settings |
| * How does healthcare resource use differ between the technology and current care?
 | Unable to comment |
| * What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)
 | This antibiotic is currently available but the cost may be prohibitive in some institutions |
| 11. Do you expect the technology to provide clinically meaningful benefits compared with current care?  | Yes |
| * Do you expect the technology to increase length of life more than current care?
 | Yes |
| * Do you expect the technology to increase health-related quality of life more than current care?
 | Yes |
| 12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?  | No |
| 13. Will the technology 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 needed, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)  | The medication needs to be infused over two hours so this may restrict use in hospital at home or dialysis settings |
| 14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing? | The medication will be stopped when clinical cure is achieved, infection markers are reduced or the patient deteriorates further and broader spectrum antibiotic is required.  |
| 15. What is the outcome of any evaluations or audits of the use of the technology? | NA |
| **Sources of evidence** |  |
| 16. Do the clinical trials on the technology reflect current UK clinical practice? | Yes  |
| * If not, how could the results be extrapolated to the UK setting?
 |  |
| * 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 |
| * If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?
 | NA |
| * Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?
 | No |
| 17. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?  | No |
| 18. 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** |  |
| 19. 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 this treatment? | No |
| 20. Consider whether these issues are different from issues with current care and why. | NA |
| **Key messages** |  |
| 21. In up to 5 bullet points, please summarise the key messages of your submission. | * 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 submission.

………………………………………………………………………………………………….

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.

For more information about how we process your personal data please see our [privacy notice](https://www.nice.org.uk/privacy-notice).