Professional and NHS organisation submission template

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

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| 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.
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| **About you** |  |
| 1. Your name | xxxxxxxxxxx |
| 2. Name of organisation | Leeds Teaching Hospitals NHS Trust |
| 3. Job title or position | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |
| 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). | Teaching hospital, a tertiary centre with complex infection patients, central funding from the government |
| 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. | No |
| 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?  | Clinical recovery and reducing morbidity and mortality from infectionReducing AMR by appropriate treatment of priority pathogens |
| 7. What do you consider a clinically significant treatment response?  | Clinical and/or microbiological cure, reducing hospital stay and adverse outcomes |
| 8. In your view, is there an unmet need for patients and healthcare professionals? | Yes, limited options for MDR Gram negative infections which have high morbidity & mortality |
| 9. How is the condition currently treated in the NHS?  | Combination of antibioticsMeropenem, Colistin, Aminoglycosides, Temocillin, Fosfomycin, Aztreonam |
| * Are any clinical guidelines used in the treatment of the condition, and if so, which?
 | BSAC/HIS guidelineLeeds Teaching Hospitals antimicrobial stewardship guidelines |
| * 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.)
 | Standardisation difficult, the international definition of MDR is complex, very few good-quality comparative randomized clinical trials to support treatment regimens which can lead to differences in professional opinions |
| * What impact would the technology have on the current pathway of care?
 | Standardised and consistent care pathway for complex patients with such infections, reducing AMR and improving quality of patient care |
| **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?  | Currently being used as restricted antibiotic under the advice of infection specialists in certain patients in high risk settingsLaboratory testing revels specific resistance mechanisms or sensitivity pattern |
| * To what extent and in which population(s) is the technology being used in syour local health economy?
 | MDR Gram negative infections in VAP, UTI, cIAI and infections with limited treatment options |
| * How does healthcare resource use differ between the technology and current care?
 | Adds to pharmacy/antimicrobial budget for the individual trust based on the volumes of antibiotic prescribed |
| * What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)
 | Staff educationLaboratory resources for rapid detection of resistance genes, CPE screening and automated sensitivity testingAntimicrobial surveillance to guide empiric use on certain settings |
| 11. Do you expect the technology to provide clinically meaningful benefits compared with current care?  | Yes, standardised pathway |
| * Do you expect the technology to increase length of life more than current care?
 | Difficult to predict |
| * Do you expect the technology to increase health-related quality of life more than current care?
 | Likely outcome |
| 12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?  | Optimal usage in complex patients who present with red flags for sepsis and have risk factors for antibiotic resistance, patients with multiple hospital admissions with prolonged stay, patients needing critical care, can fit with Start smart & then focus strategy hereDirected therapy based on antibiotic resistance mechanism in patients with positive microbiology including blood cultures |
| 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.)  | It should improve compliance with guidelines by providing a standard pathway |
| 14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing? | Restricted antibiotic on formulary, empiric use as advised by infection specialistsDirected use based on culture results and antibiotic testingLaboratory resources needed for CPE screening and additional resistance gene testing |
| 15. What is the outcome of any evaluations or audits of the use of the technology? |  |
| **Sources of evidence** |  |
| 16. Do the clinical trials on the technology reflect current UK clinical practice? | Yes, for some of the licensed indications |
| * If not, how could the results be extrapolated to the UK setting?
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| * What, in your view, are the most important outcomes, and were they measured in the trials?
 | Clinical efficacy has been compared to currently used antimicrobials Meropenem and Colistin |
| * If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?
 | NO |
| * Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?
 | Emergence of resistant strains |
| 17. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?  | NA |
| 18. How do data on real-world experience compare with the trial data? | Given limited options, use has been extended beyond licensed indications |
| **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. | * Improve antimicrobial stewardship and reduce AMR
* Standard pathway for clinical management of patients with severe Gram negative infections with limited treatment options
* Reduce variation in professional practice
* Reduce mortality & morbidity with Gram negative infections
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Thank you for your time.

Please log in to your NICE Docs account to upload your completed submission.

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

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