Professional and NHS organisation submission template

Cefiderocol 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 | xxxxxxxxxxxxxx |
| 2. Name of organisation | UK Clinical Pharmacy Association (UKCPA) – Infection Committee |
| 3. Job title or position | xxxxxxxxxxxxxx – xxxxxxxxxxxx |
| 4. Are you (please tick all that apply): | X 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). | UKCPA are a not-for-profit pharmacy organisation that provide opportunities for networking, collaborations, sharing best practice and inspiring innovation amongst pharmacists. This includes Practitioner-led education and training, providing peer support and pioneering national initiatives for pharmacy including curriculum development and professional recognition of advanced practice. |
| 4b. 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 cure of severe G-ve infection and avoidance of relapse of infection or development of cefiderocol resistance. |
| 7. What do you consider a clinically significant treatment response? | Resolution or substantial improvement signs and symptoms of infection towards baseline and improvement or lack of progression from an imaging perspective if applicable and microbiological eradication where this is deemed to be appropriate e.g BSI |
| 8. In your view, is there an unmet need for patients and healthcare professionals? | Yes - infections due to multidrug-resistant Gram-negative bacteria, especially when carbapenem resistant, are very difficult to treat due to the paucity of therapeutic options. Currently available options such as polymyxins, aminoglycosides, are useful in presence or resistance to all other classes, have some disadvantages that healthcare professionals would like to pts to avoid, such as toxicity (e.g nephrotoxicity) and possible suboptimal pharmacokinetics in some sites of infection (e.g chest infections). |
| 9. How is the condition currently treated in the NHS? | With best available therapy, which includes combination antibiotics dependent on resistance profile and site of infection. This may or may not have optimal pharmacokinetics for that site of infection and associated with significant risks of toxicity in protracted courses. |
| * Are any clinical guidelines used in the treatment of the condition, and if so, which? | No – dependent on resistance profile + patient factors e.g allergies + antibiotic availability to guide decision on best treatment.  There is some consensus nationally and internationally on how these infections should be broadly treated:  <https://academic.oup.com/jacamr/article/2/3/dlaa075/5917871>  <https://www.idsociety.org/practice-guideline/amr-guidance/> |
| * 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 varies between organisations dependent on level of expertise and availability of antimicrobials. |
| * What impact would the technology have on the current pathway of care? | It would allow equitable access to this drug where deemed to be best treatment for the pathogen/site of infection. Therefore, it may be utilised earlier on in treatment rather than as salvage therapy. |
| **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? | It is already in use in some organisations where severe gram-negative infections are commonly encountered and will continue to be used in this population. |
| * To what extent and in which population(s) is the technology being used in your local health economy? | It is used infrequently in severe gram-negative infections where there are limited treatment options in hospitalised patients. |
| * How does healthcare resource use differ between the technology and current care? | N/A |
| * What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.) |  |
| 11. Do you expect the technology to provide clinically meaningful benefits compared with current care? | Yes – improved patient outcomes e.g reduced toxicity, days of therapy etc |
| * 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 – Currently not licensed in paediatrics and minimal data to support appropriate dosing structure in this cohort. |
| 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.) | Yes – in some cases will be able to use single agent as opposed to dual. This will limit nursing resources with administration of intravenous therapy, reduction in drug toxicity for patients, possible reduction in days due to effectiveness of therapy. Overall will save on nursing time and bed days.  The technology is administered as a 3 hour infusion up to four times a day – this may be less preferential for the pt as this associated with increased infusion time. |
| 14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing? | Confirmation of cefiderocol susceptibility via lab testing.  There may have to be certain criteria for initiation/stopping of this drug to avoid overuse and minimise its impact in antimicrobial resistance. |
| 15. What is the outcome of any evaluations or audits of the use of the technology? | N/A |
| **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? | N/A |
| * What, in your view, are the most important outcomes, and were they measured in the trials? | Yes in the CREDIBLE-CR study – All cause mortality and development of resistance. |
| * If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes? | N/A |
| * 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? | It is quite often used in infections outside of HAP/VAP/CAP/BSI/sepsis/cUTI such as bone infections, intra-abdominal infections which was not assessed in the clinical trials. |
| **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. | N/A |
| **Key messages** |  |
| 21. In up to 5 bullet points, please summarise the key messages of your submission. |  |

Thank you for your time.

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