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 | British Infection Association |
| 3. Job title or position | xxxxxxxxxxxxxxxxxx |
| 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). | A group of infection specialist clinicians from across the UK. A registered charity. |
| 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? | To cure resistant infections where antibiotic options are limited by resistance. |
| 7. What do you consider a clinically significant treatment response? | Clinical and microbiological cure. |
| 8. In your view, is there an unmet need for patients and healthcare professionals? | Yes |
| 9. How is the condition currently treated in the NHS? | With alternative agents as available. |
| * Are any clinical guidelines used in the treatment of the condition, and if so, which? | This medication is used for a wide range of conditions. Useful guidelines will depend on the specific condition under consideration. |
| * 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.) | Yes the pathway of care is reasonably well defined but there will inevitably be differences of opinion. |
| * What impact would the technology have on the current pathway of care? | For a small number of patients with resistant organisms or e.g. allergy to other options it could be life-saving. |
| **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 not currently available in the NHS. |
| * To what extent and in which population(s) is the technology being used in your local health economy? | It has been used on compassionate grounds on occasion in the UK. |
| * How does healthcare resource use differ between the technology and current care? | It would provide an additional treatment option. |
| * What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.) | Lab test set up for testing of sensitivity to this agent. |
| 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 in very specific sub-groups |
| * Do you expect the technology to increase health-related quality of life more than current care? | Yes in very specific sub-groups |
| 12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population? | Yes- those with life-threatening infection (not colonisation) due to infection resistant to alternative antibiotics. |
| 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 will not be different from current care. It is administered three times a day in a similar way to other antibiotics.The associated laboratory will need to test for resistance with a specialist set up. |
| 14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing? | Yes- additional testing for resistance to this antibiotic. |
| 15. What is the outcome of any evaluations or audits of the use of the technology? | N/A as not yet available. |
| **Sources of evidence** |  |
| 16. Do the clinical trials on the technology reflect current UK clinical practice? | N/A as not yet available. |
| * If not, how could the results be extrapolated to the UK setting? | If it were available we would use trial data to inform practice. |
| * What, in your view, are the most important outcomes, and were they measured in the trials? | Atrributable mortality is the most important outcome but very hard to measure. The largest published study I am aware of was called a study rather than a trial and was descriptive- CREDIBLE-CR. This did not seek to measure mortality which is high in this group and the group in the study was wider than those in whom it may be of benefit. They measured clinical and microbiological response. |
| * If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes? | The clinical and microbiological response may predict outcomes long-term (or short-term). |
| * Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently? | I am not aware of any |
| 17. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence? | I think the data is published in reports. |
| 18. How do data on real-world experience compare with the trial data? | Not yet available in real world routinely but one case was beneficial: when used as salvage therapy.  https://academic.oup.com/cid/article/68/11/1932/5174241 |
| **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. | No |
| **Key messages** |  |
| 21. In up to 5 bullet points, please summarise the key messages of your submission. | * CREDIBLE-CR as study * Subpopulation benefit expected * Rare utility currently but expected to increase in the future |

Thank you for your time.

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

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