Patient organisation submission

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 evaluation.You can provide a unique perspective on the impact of life-threatening drug-resistant infections that is not typically available from other sources. If you would like help with your submission or somebody to read a draft for you, please contact PIP@nice.org.uk or Mandy.Tonkinson@nice.org.uk You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type. Please note that declarations of interests relevant to this topic are compulsory.**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
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* Your response should not be longer than 10 pages.
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| **About you** |  |
| 1.Your name  | xxxxxxxxxxxxxxx  |
| 2. Name of organisation | Anthony Nolan  |
| 3. Job title or position  | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx   |
| 4a. Brief description of the organisation (including who funds it). How many members does it have?  | Anthony Nolan saves the lives of people with blood cancer. Founded in 1974 as the world’s first stem cell register, we’re motivated by a mother’s determination to save her son, Anthony. Now saving three lives every day, our charity is a lifesaving legacy. By growing our register of potential stem cell donors, conducting ground-breaking research into improving transplant outcomes, and providing outstanding support and clinical care for patients and their families, Anthony Nolan cures people’s blood cancer and blood disorders. The responses in our submission relate specifically to the impact of life-threatening drug-resistant infections on people who require, or who have received, a stem cell transplant. A stem cell transplant is a potentially curative treatment for patients with blood cancers and blood disorders, and usually their last chance of survival. Anthony Nolan’s main source of income is the provision of stem cells for transplant, collected from volunteer donors. Voluntary income (and fundraising events through Anthony Nolan Trading Ltd (ANTL)) comes from a wide variety of generous supporters, including individual giving, legacies, community and events fundraising, corporate support, and charitable trusts. This helps to fund our ground-breaking scientific research, and growth and diversity of the stem cell donor register. |
| 4b. Has the organisation received any funding from the manufacturer(s) of the treatment 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. | Pfizer - £10,000 grant contract dated 29th April 2020 to be used to support the Institution's existing activities, any increased demands on its services and its continued work to support Patients and the wider community during the COVID-19 pandemic.  Merk Sharp & Dohme (MSD) - £10,000 contract dated 23rd October 2020 to fund a policy online roundtable event.   Gilead - £15,000 grant contract dated 18th April 2020 to be used to save lives during the COVID-19 Pandemic.   Gilead - £10,000 grant contract dated 11th August 2020 for addressing the Health Inequality exposed for minority ethnic communities by COVID-19.  |
| 4c. Do you have any direct or indirect links with, or funding from, the tobacco industry? | None |
| 5. How did you gather information about the experiences of patients and carers to include in your submission? | We reached out to the stem cell transplant patient and carer community via our Patients and Families Panel (PFP), and our online support groups. Through this, we have been able to speak directly with people who have been personally affected by a severe drug-resistant infection and have based our submission on virtual conversations and written information received from patients and carers in response to our request for information. We also consulted experts from the clinical community, gathering evidence on the impact of a severe drug-resistant infection on stem cell transplant patients and carers, particularly for questions related to hospitalisation and treatment.  |
| Experience of infection |  |
| 6. What is it like for patients who experience severe, drug-resistant infection? This refers to an infection which requires urgent treatment in hospital, for which there are limited antibiotics that work. These infections can be life threatening. For example, sepsis (blood stream infection), hospital-acquired pneumonia, or complicated urinary tract infection. Please include details of the type of infections including location in the body, the type of bacteria that caused the infection, and how many courses of antibiotics might be used. | Severe drug-resistant infections can be life-threatening and cause extreme distress and anxiety to patients who have received a stem cell transplant. Often patients may develop multiple infections which leaves them feeling scared and helpless, particularly as the drug-resistant nature of these infections leaves few treatment options that are likely to work.    One carer we spoke to described constant trips to A&E for treatment as ‘horrific’. They described the person they were caring for feeling frustrated and demoralised at being constantly unwell and helpless. The drug-resistant infections often required them to be isolated in a private room and they described long waits in the hospital (sometimes over 10 hours), made worse by severe pain, and bouts of confusion.    They also described the ‘never ending’ hospital visits, being prescribed more antibiotics each time with longer stays in hospital. Increasing doses of antibiotics caused progressively worse side-effects, impacting their wellbeing both physically and mentally.   |
| 7. How long on average do patients spend in hospital receiving treatment for drug-resistant infections? | The amount of time spent in hospital for people experiencing a severe-drug resistant infection varies greatly and is dependent on numerous factors, including the severity and the type of drug-resistant infection.   The patient representatives we spoke to noted that in their experience, hospital stays were generally between 10 days to two weeks in length, with clinical representatives commenting that some infections can lead to extended treatment pathways taking over 6 weeks.   One carer commented that their loved one experienced one stay of almost two months, caused by repeated severe infections.  Often patients might develop multiple infections, meaning that even if the time spent in hospital for each infection is short, the cumulative time hospitalised adds up to significant stays.  For some extended treatment regimes, drug administration can sometimes be performed in an outpatient setting if the patient is well enough. This could include continuing treatment through oral or home IV antibiotic administration.   |
| 8. Are patients required to isolate in hospital (that is be in a room on their own) to reduce the risk of passing on infection to other patients? If yes, can you provide examples of the duration and impact on patients.  | People who contract a severe-drug resistant infection are often required to isolate in hospital. Isolation is used to reduce infection spread to others in the hospital and may apply to both inpatient and out-patient hospitalisation. Often, those undergoing a stem cell transplant will also need to complete long periods of hospital isolation during the conditioning and transplant recovery process, meaning that if a severe infection develops, patients may experience prolonged periods of isolation, sometimes in an acute hospital setting. One patient we spoke to commented that they felt lonely during their isolation and cut off from normality, adding to the anxiety and stress they experienced.  We spoke to the parent of a child who had to isolate following a severe drug-resistant infection. This was particularly challenging as isolation prevented them being allowed to access shared play areas. Isolation also impacts carers themselves, causing significant stress and anxiety. Further, to prevent infection spread, medical staff can be required to wear increased PPE, which may be unfamiliar and scary, particularly for people experiencing confusion or if the patient is a child.  |
| 9. Do resistant infections impact other treatments? For example, does infection delay acceptance for organ transplant, other surgery or other types of treatment? | Often, a drug resistant infection may prevent or delay further treatment from taking place. This can include chemotherapy and a stem cell/bone marrow transplant. Often, treatment delays are to mitigate the risk of severe complications or progression of the infection when a patient is immunosuppressed. Further, the harsh treatments required to treat severe drug-resistant infections may cause strong side effects, toxicity and interactions with other treatments that are not tolerable or desirable. This not only impacts the treatment itself, but also may have a negative physical and mental impact on the person who is experiencing the severe drug-resistant infection.  Patients and carers who have experience of severe drug-resistant infections commented on a range of ways that their infection impacted treatment and recovery. This included altering the management of post-transplant immune suppression drugs and changing drug delivery methods due to repeated infections. Some also commented on the detrimental effect that the infection had on their recovery from a stem cell transplant, which lead to significantly extended treatment that they would not otherwise have needed.  |
| 10. What do carers experience when caring for someone who has had a severe, drug-resistant infection? | Carers described their fear and anxiety related to a severe drug-resistant infection. They commented on the strain that it put on the patient, themselves, and their families. One commented that constant infections in their partner put their relationship under ‘heart-breaking stress’. They also described their partner’s illness as ‘inescapable’, feeling that they could never relax or leave them alone, fearing their condition would worsen or that the infection would return, as it did on several occasions. They also touched on the long term impact this stress had causing anxiety. Carers also commented that repeated infections caused them to feel that their loved one was not being properly investigated at the hospital or cared for, adding to their feelings of anger and helplessness. Repeatedly visiting the hospital caused particular stress for some. This was especially difficult for those who did not live near to the hospital. Others described feeling very upset and distressed when a loved one contracted an infection following a ward outbreak. Carers stressed their helplessness, in a situation where they already felt so much is against them. It was also outlined that it is particularly hard when the individual is a child and may not fully understand what was happening to them.  |
| Current treatment of life-threatening drug-resistant infections in the NHS |  |
| 11. What do patients or carers think of current treatments and care available on the NHS? | Patients and carers feel there is currently a lack of options available on the NHS to treat severe drug-resistant infections. They also feel there is a lack of knowledge about the available treatments in the NHS. This was related both to their own knowledge and a lack of training given to staff. Some felt decisions around their care were made slowly which they felt impacted treatment.Patients and carers also commented that the treatment they received was all based in the hospital and more home-based treatment would be preferable to limit regular and prolonged hospital visits.  |
| 12. Is there an unmet need for patients who have a life-threatening, drug-resistant infection? | There is a significant unmet need in the area for people who have undergone and are waiting to undergo a stem cell transplant. People in this patient group are often immunosuppressed and vulnerable to infection. As a result, they are more likely to require frequent antibiotic administration and to develop a severe drug-resistant infection. Following a stem cell transplant, bone marrow function is often fragile and people are susceptible to bone marrow suppression from antibiotic drugs.    There is an urgent need for new and better treatments, particularly when the infection is life-threatening and there may be few treatment options available.    |
| Advantages of the treatment |
| 13. What do patients or carers think are the advantages of the treatment? | Patients and carers discussed the unmet need in this area for new medication and treatments. They commented that new and potentially effective treatments could bring relief and a ‘lifeline’ to those with have a severe drug-resistant infection and few other treatment options. Speaking about a drug resistant infection that led to their partner being hospitalised on over 10 occasions, one carer said that anything that provides effective treatment in this area will be of patient benefit.  |
| Disadvantages of the treatment |
| 14. What do patients or carers think are the disadvantages of the treatment? | Patients and carers expressed concern at the side-effects that a high-dose antimicrobial agent may come with, commenting on the condition of their health at the time of infection. Patients also discussed possibility of treatment to be delivered flexibly in locations that suited the patient.   |
| **Patient population** |
| 15. Are there any groups of patients who might benefit more or less from the treatment than others? If so, please describe them and explain why. | Patients who are immunosuppressed and who experience significant periods of hospitalisation may see particular benefit from new treatments such as this. As such, this treatment may have a particular impact on stem cell transplant patients.     |
| Equality |
| 16. 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 drug-resistant infection and the treatment? | None |
| Other issues |
| 17. Are there any other issues that you would like the committee to consider? | Patients and carers supporting this work commented on the lack of information conveyed to them during treatment causing them to feel left in the dark. They also commented on a general lack of understanding about how the infection impacted their stem cell transplant. |
| Key messages |
| 18. In up to 5 bullet points, please summarise the key messages of your submission:* Patients who have a severe drug-resistant infection often have extremely difficult experiences, feeling scared and losing hope.
* Careers experiences extreme stress and anxiety when the person that they care for has a severe drug-resistant infection, impacting their mental and physical wellbeing
* Isolation due to a severe drug-resistant infection impacts the emotional and psychological wellbeing of both patients and carers, particularly as many stem cell transplant patients will already have isolated during prior treatment.

 * Patients have a mixed experience with the length of time they are required to isolate due to their severe drug-resistant infection. This can range from a few days to several months.
* Patients and carers feel that this is an area of unmet need with a requirement for greater treatment options for patients who have few options left.
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Thank you for your time.

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