

Engagement Report

Topic details

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| Title of policy or policy statement: | Fostemsavir for multi-drug resistant (MDR) HIV-1 infection (adults) |
| Programme of Care: | Blood and infection |
| Clinical Reference Group: | HIV |
| URN: | 2108 |

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered. During stakeholder engagement, two responses were received which were supportive of the proposition. No changes were recommended to the draft document from stakeholder engagement.

2. Background

This policy proposition has been developed by a Policy Working Group made up of clinical specialists in HIV medicine, Public Health, pharmacy and Commissioning leads and a patient and public voice representative.

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition was sent for stakeholder testing for 2 weeks from 11th February to 27th February 2022. The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following questions:

- Do you support the proposition for fostemsavir for multi-drug resistant (MDR) HIV-1 infection to be available through routine commissioning based on the evidence review and within the criteria set out in this document?

- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
- Do you have any further comments on the proposition? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- Please declare any conflict of interests relating to this document or service area.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

Two responses were received in stakeholder engagement. This included a representative of industry and a peer-led network which supports people living with HIV.

Both responses were supportive of the Policy Proposition, with no changes recommended to the policy.

In line with the 13Q assessment it was deemed that further public consultation was not required.

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Blood and Infection PoC. The following themes were raised during engagement:

| Keys themes in feedback | NHS England Response |
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| Relevant Evidence | |
| <p>A respondent highlighted the challenges in performing clinical trials in a multi-drug resistant HIV-1 (MDR HIV-1) population. The response was structured around the:</p> <ul style="list-style-type: none"> • Population studied • The efficacy seen in the 96 week BRIGHTE study • Trial design of the BRIGHTE study • Safety factors identified within the BRIGHTE study | <p>NHS England recognises the challenge in treating MDR-HIV-1 infection as these individuals have often limited treatment options and experience the consequences of advanced immunosuppression and ongoing viral replication.</p> <p>In assessment of the supportive evidence base, consideration was given to the efficacy seen in this highly complex patient cohort, who require an individualised approach.</p> <p>In policy development, factors supported by the evidence have informed the inclusion/exclusion criteria. To ensure suitability for treatment with</p> |

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| | fostemsavir, a multi-disciplinary team assessment is suggested which includes informed patient consent regarding the benefits, safety and/or other factors of the proposed treatment. |
| Current Patient Pathway | |
| Both respondents could not identify any negative impacts on patient care as a result of making this treatment available and were supportive of the Policy Proposition. | <p>NHS England proposes that this intervention is offered within the current patient pathway of HIV care to suitable individuals. The inclusion and exclusion criteria are defined within the policy and fostemsavir is added to an optimised regimen of antiretroviral therapy, through an individualised approach, which is proposed to be supported through a multi-disciplinary team (MDT) assessment.</p> <p>This proposal offers a complex cohort an intervention, which is not currently available. It is not impacting on other elements of the patient pathway.</p> |
| Potential impact on equality and health inequalities | |
| <p>Both respondents highlighted the clinical need for this sub-group of people living with HIV-1 infection identifying that:</p> <ul style="list-style-type: none"> • The treatment has an individual but also a public health benefit • This proposal would address an unmet clinical need for those experiencing MDR-HIV-1 infection. • Individuals experiencing MDR HIV-1 infection have adverse outcomes such as death and morbidity related to immunosuppression and the consequence of concurrent (prophylactic/preventative) treatments. • The proposed intervention aims to address the limited treatment options and/or adverse outcomes these individuals experience. | <p>NHS England has identified in the Equalities and Health Impact Assessment (EHIA) that this policy does not negatively impact on other protected characteristics and offers a treatment option for individuals who experience the challenges of limited treatment options and advanced immunosuppression which is seen in MDR-HIV-1 infection.</p> <p>This policy aims to promote equity and addresses health inequalities in individuals experiencing MDR HIV-1 infection.</p> |
| Changes/addition to policy | |
| No changes were suggested by either respondent to the proposal. | NHS England has considered the stakeholder viewpoints and no changes to the policy were identified from the process. |

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

No changes were suggested as part of the engagement response. The viewpoints of the stakeholders were considered by the Policy Working Group and the Programme of Care and no additional actions were identified.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

There are no remaining outstanding concerns.