NHS England

Engagement Report

Topic details

Title of policy or policy statement:	**Lenacapavir for multi-drug resistant Human Immunodeficiency Virus 1 (adults)**
Programme of Care:	**Blood and Infection**
Clinical Reference Group:	**HIV**
URN:	**2344**

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.

2. Background

Human immunodeficiency virus type 1 (HIV-1) attacks the immune system destroying CD4 positive (CD4+) T cells, a type of white blood cell that is vital for fighting infection. The reduction of these cells leaves people living with HIV less able to fight off infections (also known as being immunosuppressed), making them susceptible to other diseases including cancers. If HIV is untreated, a high viral load (high level of virus) can be observed, meaning the HIV is not suppressed (under control). This can increase the chance of HIV being transmitted, as well as cause significant morbidity and mortality for the person living with HIV. There are two main types of HIV: HIV-1 and HIV-2. Most cases in the UK are caused by HIV-1, which is considered more transmissible than HIV-2.

Treatment for HIV-1 involves life-long antiretroviral treatment (ART), which stops the virus replicating in the body and destroying CD4+ T cells. There is no cure for HIV, but ART enables most people to live a long and healthy life with an undetectable viral load. An undetectable viral load eliminates the risk of transmitting infection. Combination antiretroviral therapy has transformed HIV-1 infection into a manageable chronic condition for many people living with HIV. However, for some individuals, finding effective ART is not always possible. A suitable regimen may no longer exist because of multidrug resistance (MDR), meaning that the virus does not respond or only partially responds to the drugs. Contraindications, previous intolerances, treatment history, adherence issues, drug-to-drug interactions, or drug resistance patterns are other reasons why an individual might have MDR HIV-1 infection.

The standard of care is treatment with a drug regimen comprising at least two agents offered immediately after a diagnosis to limit viral replication. People typically start on a two or three drug regimen and only move to another if there is lack of virological response,

treatment failure, or tolerability issues. Additional issues include pill burden and dose frequency, which may affect adherence. Considerations related to potential for drug-drug interactions are particularly relevant as people living with HIV now have a near-normal life expectancy, which means they may take other medication for age-related comorbidities. Effective treatment is one that suppresses viral replication and maintains an undetectable viral load. In addition to preventing progression of HIV infection to immunosuppression and life-threatening illness, effective treatment also prevents onward HIV transmission, which is a key government ambition to eliminate HIV transmission in England by 2030.

Lenacapavir is the first of a new class of drugs called capsid inhibitors for the treatment of HIV. Lenacapavir works by blocking the HIV-1 viral capsid, interfering with essential steps of the virus's lifecycle. It is licensed in combination with other ARTs, for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen. It is taken as an oral tablet initially, before switching to a maintenance 6 monthly subcutaneous injection.

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 underwent a four-week stakeholder testing between the 18th July and 14th August 2024 with registered stakeholders from the following Clinical Reference Groups:

- Infectious diseases
- HIV
- Specialised paediatric allergy, immunology and infectious diseases

Respondents were asked the following consultation questions:

- Do you support the proposal for lenacapavir for multi-drug resistant HIV-1 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?
- 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?
- Do you have any further comments on the proposal?
- Do you support the Equality and Health Inequalities Impact Assessment (EHIA)?
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any potential conflict of interest relating to this document or service area?

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.

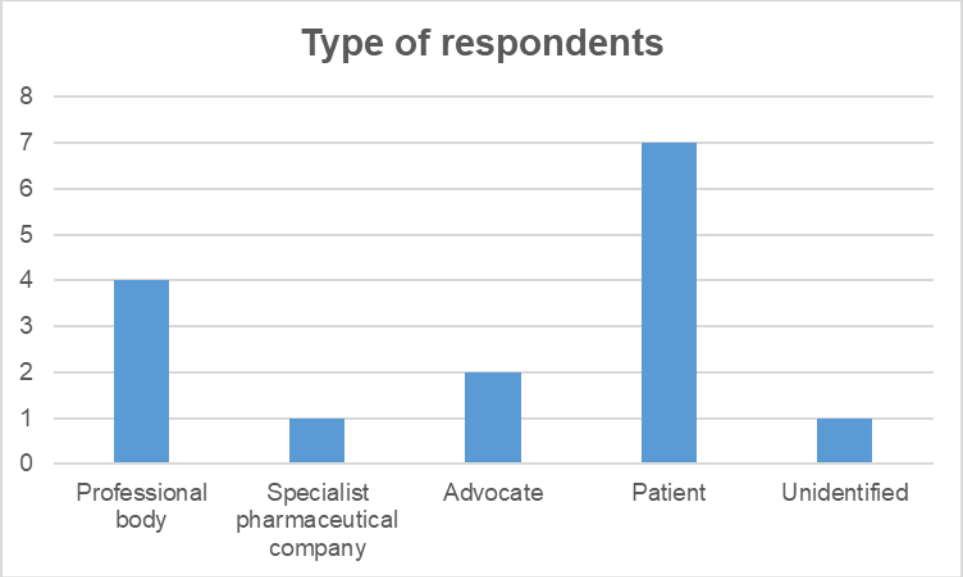
A 13Q assessment has been completed following stakeholder testing.

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.

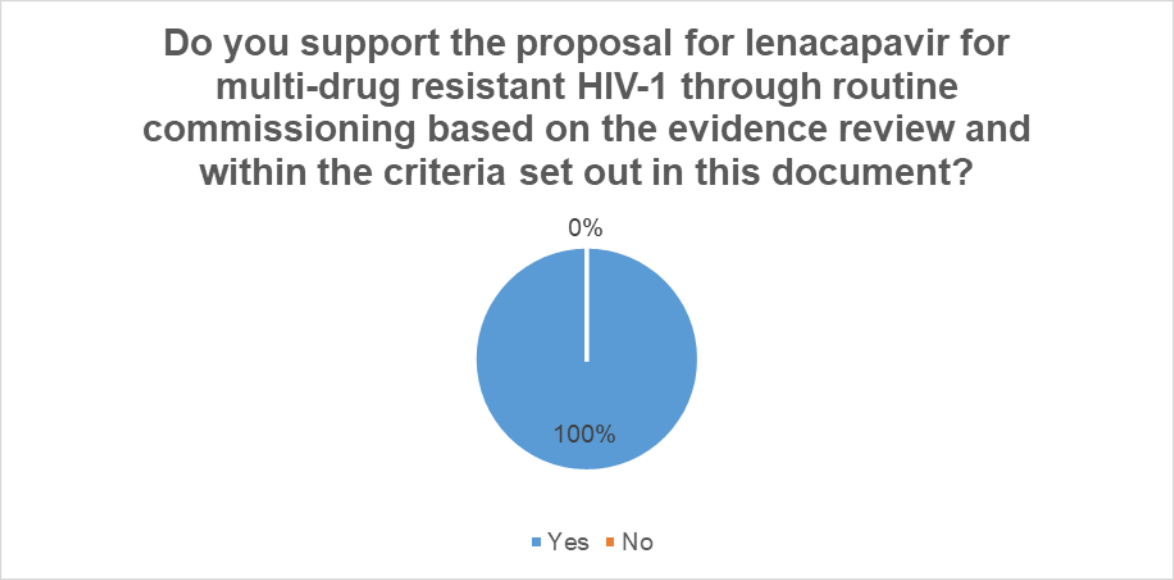
4. Engagement Results

15 stakeholders responded:

- 4 professional bodies
- 1 specialist pharmaceutical company
- 2 advocates
- 7 patients
- 1 remained unidentified



All respondents were supportive of the policy proposition.



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
Financial impact	
One respondent queried how will NHS England reduce the cost.	NHS England works to secure access to clinically effective treatments in a way that delivers the best value for taxpayers. No action was required on this basis.
Patient Impact Assessment (PIA)	
Three respondents were not supportive of the PIA, as they felt it underestimated the lived experience of those with HIV particularly in the advanced stages. One respondent was supportive but stated a similar concern around the homogeneity of the population and their lived experience.	The PIA was updated to reflect stakeholder comments regarding the effects of HIV and its treatment.
One respondent wished for carer's allowance to be increased.	Carer's allowance is outside the scope of the policy proposition and NHS England's remit.
Equalities and Health Inequalities Impact Assessment (EHIA)	
One respondent noted that the document stated a planned stakeholder testing with no date	The EHIA has been updated to include the dates that stakeholder testing took place.

All but one respondent agreed with the EHIA, stating that there should have been key engagement and consultation to support the document.	The draft proposed commissioning policy, developed by a policy working group including clinical as well as patient and public voice representatives, was published in July for a 4-week stakeholder testing period (extended due to July and August being popular holiday months). No changes were made to the policy proposal on this basis.
Changes/addition to policy	
Two respondents called for lenacapavir to be made available for children and adolescents. One called for further research in this cohort.	Research is outside of the scope of the policy proposition and something that NHS England does not commission. Though specific to adults (those aged 18 years and over), the ***NHS England Commissioning Medicines for Children in specialised commissioning policy*** could allow access to this treatment in post-pubescent children.
One respondent queried if lenacapavir would be available for those not tolerating other anti-retroviral therapy.	The inclusion and exclusion criteria are clearly defined in the policy proposition, and have been based on the available evidence for this intervention and proposal submitted by the Clinical Reference Group (CRG).
Policy process and application	
One respondent asked for the urgent approval of Lenacapavir to reduce complications of viraemia.	The policy proposition methods are published on the NHS England website; this is not considered to be an urgent policy proposition.
One respondent stated that they strongly support the availability of Lenacapavir throughout the UK.	Health is a national devolved responsibility, therefore this policy proposition only applies to England covering the population articulated in the document.

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

EHIA and PIA	
Minor amends have been made to the PIA and EHIA.	Please see the above table for more detailed information on these changes.

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

No.