NHS England

Clinical Priorities Advisory Group Summary Report

Agenda item	2.2
Date of Meeting	11/05/-13/05/2026
Title of the Proposition	Lenacapavir for multi-drug resistant (MDR) Human Immunodeficiency Virus 1 (HIV-1) (adults)
Unique Reference Number	2344
Programme of Care	Blood & Infection
Clinical Reference Group	HIV
Service/treatment status	delegated

Action requested

Support the adoption of the policy proposition

Recommended its relative prioritisation.

Summary of the proposition:

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 antiretrovirals (ARTs), for the treatment of adults with multidrug resistant (MDR) 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. There is currently one other treatment available for the MDR HIV-1; this is fostemsavir, an oral medicine. Lenacapavir offers an alternative option for this cohort of patients, with the added benefit that it is a 6-monthly injectable therapy.

Lenacapavir will be delivered in existing commissioned HIV service providers. Children are not included within the lenacapavir policy proposition due to the safety profile of the drug not being established in this population. However, if approved, post-adolescent children and young adults could access the intervention as per the NHS England Policy 170001/P Commissioning Medicines for Children in Specialised Services.

Clinical Panel recommendation:

The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy.

Assurances

The committee is asked to receive the following assurance:		
1.	The Deputy Director of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of developmental and governance steps.	
2.	The Deputy Director of Acute Programmes confirms the proposition is supported by the following documentation (please tick the box where applicable)	
	Draft Clinical Commissioning policy proposition	☒
	Evidence Review	☒
	Public Health Evidence Report	☐
	Evidence to Decision Making (EtD) Summary	☒
	Equalities and Heath Inequalities Assessment (EHIA)	☒
	Prior Approval Form	☒
	Engagement Report	☒
	13Q Assessment and Patient & Public Voice Assurance	☒
	Clinical Panel Report	☒
	Policy Working Group membership	☒
	Other (please state if required)	☐

3.	The Deputy Director of Finance (Specialised Commissioning) confirms that the Impact Assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Director of Clinical Commissioning (Specialised Commissioning) confirms that the Service and Operational Impact Assessments have been completed.
5.	The Deputy Director of Quality and Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined (where applicable).

Evidence Review Summary

In individuals with MDR HIV-1 infection who have limited or no therapeutic options available to construct a fully suppressive viral regimen from existing antiretroviral treatment (ART), what is the clinical effectiveness and safety of adding lenacapavir to the optimised ART regimen compared with the optimised ART regimen alone?

Outcome	Evidence statement
○ Clinical effectiveness	
Critical outcomes	
Virological suppression **Certainty of evidence:** Very low	Virological suppression is important to patients because it reflects treatment effect (either suppression or failure) of an ART regimen. If virological suppression is achieved, an individual has zero ability to transmit the virus to others and low risk of disease progression. If virological failure is seen, consideration is given to alter the current ART regimen to achieve viral suppression. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to virological suppression measured at 26 weeks and 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. At week 52 in cohort 1 in the single arm phase of CAPELLA, virological suppression of less than 50 copies per millilitre HIV-1 RNA occurred in 30/36 participants receiving lenacapavir (83%, 95% CI 67% to 94%). A less strict virological suppression of less than 200 copies per millilitre occurred in 31/36 participants (86%, 95% CI 71% to 95%). Similar results were seen at week 26. No comparator was available for this time point and statistical analyses could not be undertaken for these secondary outcomes. **(VERY LOW)** At week 52 in cohorts 1 and 2 of CAPELLA combined, virological suppression of less than 50 copies per millilitre HIV-1 RNA occurred in 56/72 participants receiving lenacapavir (78%, 95% CI 66% to 87%). A less strict virological suppression of less than 200 copies per millilitre occurred in 59/72 participants (82%, 95% CI 71% to 90%). Similar results were seen in cohorts 1 (above) and 2 individually. No comparator was available for this

	time point and statistical analyses could not be undertaken. Also, outcomes in cohort 2 (and, therefore, the total population) are exploratory only. **(VERY LOW)** **The single arm phase of CAPELLA provides very low certainty evidence that maintenance treatment with lenacapavir plus optimised ART suppresses viral load to less than 50 copies per millilitre and to less than 200 copies per millilitre in about 80% of people with MDR HIV-1 at 52 weeks. No comparator was available at this time point.**
Reduction in viral load **Certainty of evidence:** Very low	Reduction in viral load is important to patients because it reflects a measure of clinical effectiveness of the treatment. A reduction in viral load correlates with reducing the risk HIV transmission to others and a lower risk of disease progression. A reduction in viral load of 0.5 $\log_{10}$ copies per millilitre is considered to be clinically important. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to viral load measured at 15 days, 26 weeks and 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. At day 15 in the randomised controlled phase of the CAPELLA trial (cohort 1), a statistically significant and clinically important reduction in viral load of at least at least 0.5 $\log_{10}$ copies per millilitre HIV-1 RNA from baseline was seen with lenacapavir compared with placebo (primary outcome). In the lenacapavir group, 21/24 participants (88%) experienced the reduction compared with 2/12 participants (17%) in the placebo group (absolute difference 71%; 95% CI 35% to 90%, p<0.001). **(VERY LOW)** At week 52 in the single arm phase of the study in cohort 1, mean viral load was reduced from baseline by a mean –2.57 (SD 1.0) $\log_{10}$ copies per millilitre HIV-1 RNA (exploratory outcome). No comparator was available for this time point and statistical analyses could not be undertaken. **(VERY LOW)** **The randomised controlled phase of CAPELLA provides very low certainty evidence that statistically significantly more participants achieve a clinically significant reduction in viral load at 15 days with 3 loading doses of oral lenacapavir plus failing ART compared with placebo plus failing ART. About 90% of people with MDR HIV-1 taking lenacapavir had a clinically important reduction compared with about 20% of people taking placebo. All participants continued their failing ART for this period and it is not known if the results would have been the same if ART had been optimised.** **The CAPELLA study also provides very low certainty evidence that ongoing maintenance treatment with subcutaneous lenacapavir 6-monthly plus optimised ART reduces mean viral load in people with MDR HIV-1 at week 52. No comparator was available at this time point and this outcome was exploratory only.**
Increase in baseline CD4 cell counts	Increase in CD4 counts is important to patients because it reflects the overall immune function of a person living with HIV. The CD4 measurements are critical in establishing thresholds for initiation and

Certainty of evidence: Very low	discontinuation of opportunistic infection prophylaxis. Increased CD4 counts correlate with the reduced risk of disease progression occurrence of AIDS defining illnesses and reduced rates of death. A 30% change in the absolute CD4 count or an increase or decrease of 3% is considered to be clinically important. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to CD4 counts measured over 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. At week 52 in the single arm phase of CAPELLA, CD4 counts increased from baseline to week 52 by a mean of 82 cells per microlitre (95% CI 43 to 122 cells per microlitre) in cohort 1 and 113 cells per microlitre (95% CI 70 to 156 cells per microlitre) in cohort 2 (exploratory outcome). These improvements from baseline are likely to be clinically important. No comparator was available for this time point and statistical analyses could not be undertaken. **(VERY LOW)** **The CAPELLA study provides very low certainty evidence that ongoing maintenance treatment with subcutaneous lenacapavir 6-monthly plus optimised ART improves CD4 counts in people with MDR HIV-1 by a clinically important amount at week 52. No comparator was available at this time point and this outcome was exploratory only.**
Important outcomes	
Mortality **Certainty of evidence:** Very low	Mortality is important to patients because individuals with advanced HIV have a high mortality rate because of progressive viral replication and advanced immunosuppression. Interventions which improve the survival outcome are important markers of effective HIV treatment. Mortality was not a prespecified outcome in the phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) included in the evidence review. However, the number of deaths was reported. No deaths were reported in cohort 1 of CAPELLA. In cohort 2, 1 person died from cancer at week 10 and another died from pneumonia at week 82. Neither of the deaths was considered related to lenacapavir treatment. **(VERY LOW)** **Very low certainty evidence from CAPELLA suggests lenacapavir does not impact mortality in people with MDR HIV-1 over 52 weeks. However, the study may have been too small and too short to detect rare events.**
Quality of life **Certainty of evidence:** Not applicable	Quality of life is important to patients because it provides an indication of an individual's general health and self-perceived well-being and their ability to participate in activities of daily living. **No evidence was identified for this outcome.**

Treatment failure **Certainty of evidence:** Very low	Treatment failure is important to patients because it reflects the effectiveness of the intervention. Consideration and analysis in those with treatment failure can assist with understanding of developing genotypic and phenotypic resistance patterns to ART agents. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to treatment failure measured at 26 weeks and 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. Of 22/72 participants (11 in each cohort) who met the prespecified criteria for resistance analysis, 8 had resistance-associated mutations to lenacapavir by week 26 and a further person by week 52 (9 in total, 4 in cohort 1 and 5 in cohort 2). Of these, 4/9 had no fully active drugs in their optimised ART and 5/9 had inadequate adherence to ART (including the person who developed emerging resistance between week 26 and week 52). Despite emerging resistance, 4/9 resuppressed (HIV-1 RNA less than 50 copies per millilitre) while continuing lenacapavir (2 with a change in optimised ART and 2 without a change in ART). **(VERY LOW)** At week 52, 16 participants did not have HIV-1 RNA of less than 50 copies per millilitre. Of these, 10 had HIV-1 RNA of 50 copies per millilitre or more suggesting virological suppression was incomplete or failing. **(VERY LOW)** **The CAPELLA study provides very low certainty evidence that lenacapavir resistance may emerge within 26 weeks in people with MDR HIV-1 receiving lenacapavir plus optimised ART**. **Resistance and subsequent treatment failure may be driven by a lack of other fully active ARTs in the optimised background regimen and/or poor adherence to optimised ART. No comparator was available at this time point and this outcome was exploratory only.**
Treatment adherence **Certainty of evidence:** Very low	Adherence to treatment is important to patients as it provides an indication of how the treatment is tolerated. Effective treatment requires long-term adherence to ART regimens to achieve viral suppression and immune regulation. Poor adherence can increase the risk of treatment failure and add to viral resistant strain development and transmission. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to treatment adherence measured at 26 weeks and 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. 5/9 participants with emerging resistance to lenacapavir had inadequate adherence to their optimised ART (determined from plasma concentrations of key ARTs). 1 person in cohort 2 was withdrawn by the investigator at week 16 because of ‘non-compliance’. **(VERY LOW)** **In the CAPELLA study, there were no reports of lack of adherence to lenacapavir treatment, probably because maintenance treatment is given by subcutaneous injection every 6 months. However, lack of**

	adherence to optimised background ART regimens was reported, which may increase the risk of lenacapavir resistance emerging and subsequent treatment failure. This outcome was exploratory, and the evidence provided by CAPELLA is of very low certainty.
○ **Safety**	
Frequency of adverse events **Certainty of evidence:** Very low	Safety of lenacapavir is an important to patients because it allows comparison of interventional approaches in this highly complex patient cohort. Treatment-emergent adverse events are those that occur during treatment, which were not present beforehand or which worsen during the study. However, they may not be due to the treatment being studied (lenacapavir). For example, they may be due to the person's condition worsening or another treatment they are taking. Treatment-related adverse events are adverse events that the investigators think have definitely or probably been caused by the treatment they are studying (a side effect of lenacapavir). One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to safety of lenacapavir over 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. In the placebo controlled 14-day period in cohort 1, at least 1 treatment-emergent adverse event was reported in 9/24 participants (38%) in the lenacapavir group and in 3/12 participants (25%) in the placebo group. In that period, nausea was the only adverse event reported in more than 1 participant taking lenacapavir (3/24 participants, 13% compared with 0/12 participants taking placebo). No statistical analyses were reported. **(VERY LOW)** In cohorts 1 and 2 combined over 52 weeks, 47/72 participants (66%) had at least 1 injection site reaction with lenacapavir, including swelling (26/72, 37%), pain (22/72, 31%), erythema (22/72, 31%) and SC nodules (18/72, 25%). **(VERY LOW)** Excluding injection site reactions, 17/72 participants (24%) had at least 1 treatment-related adverse event over 52 weeks. These were nausea, diarrhoea, headache, myalgia, pyrexia, rash, somnolence and vomiting (all n=2, except nausea n=3). **(VERY LOW)** **The CAPELLA study provides very low certainty evidence that, over 52 weeks, around two thirds of people with MDR HIV-1 experience injection site reactions with lenacapavir, and around a quarter of people experience other lenacapavir-related adverse events.**
Frequency of serious adverse events **Certainty of evidence:** Very low	Serious treatment-emergent adverse events include those that result in death or hospitalisation, or cause persistent or significant disability or incapacity. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to safety of lenacapavir over 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and

	optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. In the placebo controlled 14-day period in cohort 1, no serious adverse events were reported in either group. **(VERY LOW)** In cohorts 1 and 2 combined over 52 weeks, 10 participants had serious adverse events, none of which were considered related to lenacapavir**. (VERY LOW)** **No serious adverse events considered related to lenacapavir were reported in CAPELLA. The study provides very low certainty evidence that, over 52 weeks, most adverse events related to lenacapavir are likely to be mild or moderate in people with MDR HIV-1. However, the study may have been too small and too short to detect rare adverse events.**
Frequency of adverse events leading to discontinuation **Certainty of evidence:** Very low	Stopping treatment because of adverse events is important to patients with MDR HIV-1 because it limits their treatment options further. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to safety of lenacapavir over 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART. In the placebo controlled 14-day period in cohort 1, no participants in either group discontinued treatment because of an adverse event. **(VERY LOW)** In cohorts 1 and 2 combined over 52 weeks, only 1 participant discontinued treatment because of an adverse event related to lenacapavir (a subcutaneous nodule, grade 1). **(VERY LOW)** **The CAPELLA study provides very low certainty evidence that, over 52 weeks, adverse events seen with lenacapavir rarely lead to treatment being stopped in people with MDR HIV-1. However, the study may have been too small and too short to detect rare adverse events.**
Frequency of grade 3 to 4 laboratory abnormalities **Certainty of evidence:** Very low	Grading is another way of reporting adverse events, which relates to the intensity of the adverse event, rather than the actual outcome of the event. Grade 3 adverse events are severe and undesirable adverse events, such as those needing hospitalisation, and grade 4 adverse events are life threatening. One phase 2/3 study (Segal-Maurer et al. 2022 and Ogbuagu et al. 2023; CAPELLA) provided evidence relating to safety of lenacapavir over 52 weeks. Participants in cohort 1 were randomised to receive oral lenacapavir or placebo plus their current failing ART for 14 days then, from day 15, all participants received subcutaneous lenacapavir 6-monthly and optimised ART. All participants in cohort 2 received lenacapavir plus optimised ART.

	In the placebo controlled 14-day period in cohort 1, no adverse events of grade 3 or higher were reported. **(VERY LOW)** In cohorts 1 and 2 combined over 52 weeks, grade 3 or higher laboratory abnormalities occurred in 23/72 participants (32%). Of the 5 participants with grade 4 laboratory abnormalities, 2 had elevated aspartate aminotransferase, 2 had elevated creatinine, and 1 had fasting hyperglycaemia). **(VERY LOW)** **The CAPELLA study provided very low certainty evidence that, over 52 weeks, grade 3 or 4 treatment-emergent adverse events occur in about 30% of people with MDR HIV-1 who are taking lenacapavir in combination with ART.**
Occurrence of new or recurrent clinical event(s) indicating severe immunodeficiency **Certainty of evidence:** Not applicable	**No evidence was identified for this safety outcome.**
Abbreviations ART, antiretroviral treatment; CD4, cluster of differentiation 4; CI, confidence interval; HIV-1, Human Immunodeficiency Virus 1; MDR, multi-drug resistant; p, p-value; RNA, ribonucleic acid; SC, subcutaneous; SD, standard deviation	

In individuals with MDR HIV-1 infection who have limited or no therapeutic options available to construct a fully suppressive viral regimen from existing ART, what is the cost effectiveness of adding lenacapavir to the optimised ART regimen compared with the optimised ART regimen alone?

Outcome	Evidence statement
Cost effectiveness	**No evidence was identified regarding the cost effectiveness of lenacapavir for individuals with MDR HIV-1 infection who have limited or no therapeutic options available to construct a fully suppressive viral regimen from existing ART.**
Abbreviations ART, antiretroviral treatment; HIV-1, Human Immunodeficiency Virus 1; MDR, multi-drug resistant	

From the evidence selected, are there any subgroups of patients that may benefit from lenacapavir more than the wider population of interest?

No evidence was identified regarding any subgroups of patients who would benefit more from treatment with lenacapavir than the wider population of interest. However, 2 subgroup analyses provide additional data to support decision-making.

Subgroup	Evidence statement
Those who become virologically supressed (<50 copies HIV RNA per mL) compared with those who remain virologically unsuppressed (>50 HIV RNA copies per mL)	At week 52 in cohorts 1 and 2 of CAPELLA combined, virological suppression (less than 50 copies per millilitre HIV-1 RNA) occurred in 56/72 participants receiving lenacapavir (78%). Of the 16 participants (22%) who did not have virological suppression at week 52 while receiving lenacapavir, 10 had HIV-1 RNA of 50 copies per millilitre or more. Of these, 1 had virological rebound (viral load at least 50 copies per millilitre after a previous measure of less than 50 copies per millilitre), 5 never had virological suppression, and 4 later resuppressed with no change in optimised background ART. Of the other 6, 4 discontinued treatment (3 with last available HIV-1 RNA of less than 50 copies per millilitre; 1 with last available HIV-1 RNA of at least 50 copies per millilitre), 1 died and 1 had missing data. Resistance analysis showed 9 people (4 of whom later resuppressed) in the study had lenacapavir resistant mutations at week 52. All 9 were at high risk of developing resistance because of a lack of fully active background ART options or poor adherence. **From the CAPELLA study data, it is likely that most people without virological suppression at week 52 had developed lenacapavir resistant mutations.**
People with no ART options available compared with those with 1 or 2 ART fully or partially virological suppressed ART options available	In cohorts 1 and 2 in the CAPELLA study at week 52, HIV-1 RNA was less than 50 copies per millilitre in 9/12 participants (75%) with no fully active ARTs available, 20/26 participants (77%) with 1 fully active ART available, and 27/34 participants (80%) with at least 2 fully active ARTs available. **Results of the CAPELLA study suggest that the efficacy of lenacapavir was generally similar regardless of number of fully active ARTs in the optimised background ART regimen. Resistance analysis showed that a lack of fully active background ART options was a risk factor for developing lenacapavir resistance.**
Abbreviations ART, antiretroviral treatment; HIV-1, Human Immunodeficiency Virus 1; MDR, multi-drug resistant; RNA, ribonucleic acid	

Patient Impact assessment

The condition has the following impacts on the patient's everyday life:

- **mobility:** Patients have severe difficulties in walking about
- **ability to provide self-care:** Patients have severe problems in washing or dressing
- **undertaking usual activities:** Patients have severe problems in doing their usual activities
- **experience of pain/discomfort:** Patients have severe pain or discomfort
- **experience of anxiety/depression:** Patients may be severely anxious or depressed

Further details of impact upon patients:

The lived experience of people living with HIV is varied. For long-term survivors, HIV can have a severe impact because of side effects related to early medication, and the long-lasting impact of opportunistic infections and a severely damaged immune system.

People living with multi-drug resistant HIV-1 infection (MDR HIV-1) have limited treatment options and the HIV virus is not controlled. This means that individuals have issues related to a poor functioning immune system and are at high risk of infection and developing serious health problems such as certain types of cancers and AIDS defining illnesses. When the virus is not suppressed, people living with HIV can pass the virus onto others. This can add to psychological distress. Furthermore, peripheral neuropathy and lipodystrophy from older HIV treatments are severely disabling and likely to be present in people with MDR HIV, as is unresolved trauma from long-time HIV infection, its social stigma in the past and numerous losses of friends and community

As the virus is not controlled, individuals may develop health problems which can limit their participation and functioning in daily activities. This can also mean the individual may need to spend time in hospital, if they have serious infections. and may lead to death. This can have a significant emotional and psychological impact for patients and their families. HIV currently does not have any cure, though normally, individuals will have a near normal life if the ART controls the virus. This is not the case with MDR HIV-1 infection, which is difficult to treat. This can further exacerbate the psychological impact this diagnosis has.

Further details of impact upon carers:
Carers most likely will have been with the patient throughout their HIV journey, from the initial diagnosis, through trials of different ART medications and then potentially into the complications of immunosuppression.

This can place a significant emotional and psychological burden on patients, carers and their wider families as they may require more assistance, have greater care needs and require help to complete household activities. Patients and their families must also live with the uncertainty of MDR HIV-1 infection and the limited treatment options.

Considerations

Equality and Health Inequalities Impact Assessment (EHIA)	
Summary of any potential impacts of the proposal	This Policy Proposition is not considered to unfairly discriminate those with a protected characteristic. The Policy Proposition could provide an alternative treatment option for patients who are currently experiencing the consequences of HIV-1 infection which has currently limited or no treatment options to control the virus. These patients have a large unmet need for an effective intervention and may experience

	the consequences of unregulated viral control with advanced immunosuppression, AIDS defining illness and also increased mortality. This policy is informed by the evidence base and the clinical expertise of the Policy Working Group. A national clinical commissioning policy will reduce variation in clinical practice promoting an equity of care for those in which this intervention is indicated.

13Q Assessment

PPVAG outcome	No consultation required
Were PPVAG assured of the level of stakeholder testing?	Yes

Rare Disease Advisory Group

Not Applicable

Pharmaceutical

Yes

This clinical commissioning policy proposition is for the use of lenacapavir as a treatment option for multi-drug resistant HIV1 infection in adults. The recommendation is aligned to the marketing authorisation for lenacapavir. Lenacapavir may also be used in post-pubescent children by application of the NHS England's Policy 170001/P Commissioning Medicines for Children in Specialised Services (commissioning medicines children). Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined, using separate prior approval forms for registration of adults and children.

Lenacapavir is on the NHS Payment Scheme Annex A, that is, it is a high-cost drug.

National Programme of Care

The proposal received the full support of the Blood and Infection National Programme of Care Assurance Group.