NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA) template

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. Name of the proposal (policy, proposition, programme, proposal or initiative)[1]: Clinical Commissioning Policy Proposal: Lenacapavir for the treatment of multi-drug resistant HIV-1 infection (adults). URN 2344.

2. Brief summary of the proposal in a few sentences

This Clinical Commissioning Policy outlines the commissioning criteria for the use of lenacapavir in multi-drug resistant (MDR) HIV-1 infection. Lenacapavir is a first in class, capsid inhibitor 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. Multi-drug resistant HIV-1 infection affects a minority of people living with HIV, but in whom there are limited remaining approved and fully active antiretrovirals (ART) to form a viable ART regimen which induces viral suppression. This could be as a result of drug resistance (screening or historical resistance or both) and/or additional factors (e.g. ART tolerability, ART availability, ART safety concerns and/or drug contraindications) which affect the ability to use remaining ART drugs. The aim of lenacapavir is to supress the virus, reducing the consequences of immunosuppression which include increased mortality, morbidity and poor health related quality of life. If the virus is undetectable, it is untransmissible.

The clinical policy was developed through conducting an externally conducted evidence review and by a Policy Working Group (PWG) consisting of HIV experts, virologist, a public health specialist and specialised commissioner for NHS England. This policy

[1] Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.

recommends that lenacapavir is made available as an option for adults with multi-drug resistant HIV-1 infection who meet the criteria outlined in the Clinical Commissioning Policy.

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age: older people; middle years; early years; children and young people.	According to UKHSA, there were 94,397 people living with diagnosed HIV infection and accessing care in England in 2022. Overall, 98% of people living with HIV in England in 2022 were virally suppressed and therefore unable to pass on the virus. The age profile of newly diagnosed individuals with HIV demonstrates different risk profiles within patient population groups. There has also been a change in the age profile of newly diagnosed individuals over the past 10 years, with males over 50 years increasing, whilst	Children are not included within the lenacapavir policy due to the safety profile of the drug not being established in this population. 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. There will be a positive impact on older people because older people make up a higher proportion of those presenting late with HIV which can be more difficult to treat, and this

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	other at risk groups in younger age brackets decreasing. Half of people diagnosed with HIV were aged 50 years or over in 2022 compared to 27% in 2012. Similarly, older individuals feature as a higher proportion presenting late with HIV and subsequently have a higher mortality. This is important for the intervention proposed as with age also increases medical complexity. This can limit the available suitable antiretroviral (ART) options, making HIV (for a small number of patients), more difficult to treat. Children do not feature as a significant proportion of individuals with multi-drug resistant (MDR)-HIV-1 infection, with the majority of children virally suppressed on ART. This summary is supported by UK Health Security Agency (UKHSA) 2022 data in HIV populations.[2]	intervention will offer an additional treatment option for these individuals. The population of individuals with multi-drug resistance (MDR) is estimated to be small in the UK and is often associated with complexity of care including treatment experience and other patient factors (other medical conditions) which limit the number of ART agents available. The paediatric data suggests that the predominant of children are virally suppressed. This suggests the impact of the policy to exclude children would be minimal. The patient pathway recommends regular review every 3-6 months, to ensure that lenacapavir still meets the needs of the individual. This allows for adaptions and new approaches if the health circumstances of an individual change. The pathway suggests a multi-disciplinary team (MDT) approach to capture a holistic assessment of the individual and their treatment options. This policy will be reviewed at a future specified date to consider the results of longer-term outcomes from ongoing clinical

[2] UK Health Security Agency (UKHSA). 2022. https://www.gov.uk/government/statistics/hiv-annual-data-tables

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	Overall, in 2022, 34% (246/724) of men were aged 50 years or over at the time of their diagnosis, in comparison to 23% (187/826) of women. These figures compare to 19% (253/1,320) and 10% (184/1,916) in 2009, respectively. The proportion of HIV diagnoses made at a late stage of infection increased with age largely due to the longer delay before diagnosis as well as a more rapid decline in CD4 counts among older persons. In 2022, 25% (65/259) of people aged 15 to 24 years were diagnosed late compared to 52% (275/532) and 48% (40/84) among those aged 50 to 64 years and over 65 years, respectively. Those diagnosed at a late stage in England in 2021 were 5 times more likely to die (deaths due to all causes among people with HIV) within a year of their diagnosis, compared to those who were diagnosed promptly. This is similar to 2019. In 2020, those diagnosed late were 13 times more likely to die within a year of diagnosis compared to those diagnosed promptly, which reflects the impact of	trials to ensure the commissioning criteria reflect the most up to date evidence base.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	COVID-19 prior to the availability of vaccinations. The paediatric summary is supported by the Collaborative HIV Paediatric Study (CHIPS): [3] Viral suppression on ART: among patients on ART through 2017 (n=571) and 2018 (n=436), the proportions with confirmed virological suppression <400 copies/ml were 84% and 90% and < 50 copies/mL 75% and 81% respectively.	
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Disability is not known to be a risk factor for MDR-HIV-1 acquisition, however if HIV is not virally suppressed it can lead to complex medical conditions which increase an individual's risk of mortality and also can create morbidity. In addition, other health co-morbidities can limit the use of some ART drugs, which may limit an individual's treatment options for HIV, making it MDR, by nature of the limited treatment that can be provided.	This policy outlines that lenacapavir provision should be initiated and reviewed by a specialist MDT consisting of professionals who are responsible for ongoing patient care. The decision to prescribe lenacapavir should be dependent on shared decision making with the patient and MDT assessment of suitability, which considers an individual's long-term health conditions and their unique circumstances and concurrent health needs.

[3] The collaborative HIV Paediatric study (CHIPS). 2020. Annual report 19/20 [online]. Available at: Annual Report for London HIV Commissioners (chipscohort.ac.uk)

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	This could mean that individuals with MDR-HIV-1 infection may have other complex or long-term health conditions including other physical, sensory, or additional needs. The decision for receiving lenacapavir as an intervention should be holistic, and patient focused, considering the impact it may have upon concurrent health needs.	
Gender Reassignment and/or people who identify as Transgender	UKHSA 2022[4] data shows that since 2019, between 34 and 39 new HIV diagnoses have been recorded among trans[5] people: 13 diagnoses in 2019, under 5 in 2020, 9 in 2021 and 12 in 2022. Six trans people diagnosed in 2022 were aged 15 to 34 years, Six were first diagnosed in the UK and six were previously diagnosed abroad. The data is not aggregated to demonstrate if these individuals have MDR HIV-1.	All patients who meet the inclusion criteria would be considered for lenacapavir treatment. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation. The policy is therefore not considered to have an adverse impact on this protected characteristic group.
Marriage & Civil Partnership: people married or in a civil partnership.	There should be no direct negative or positive impact on this group as marriage/civil partnership has not been identified as a high-risk group.	Not applicable.

[4] UK Health Security Agency (UKHSA). 2022. https://www.gov.uk/government/statistics/hiv-annual-data-tables

[5] Trans is an umbrella term that refers to all people whose gender identity is different to the gender given at birth, this includes trans men, trans women, non-binary, and other gender identities

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Uptake of HIV screening in pregnant women who engage with antenatal care remains high. During the financial year 2017/2018, coverage exceeded 99% with 657,231 pregnant women tested for HIV. Positive HIV diagnosis remained low and 14.3 per 100,000 women were newly diagnosed with HIV during pregnancy. [6] The majority of these pregnant women newly diagnosed in 2018 were born outside the UK (78%; 88/113) and just over half of those born abroad (56%; 49/88) were of black African ethnicity. [7] There is not a high-risk association with pregnancy and maternity increasing risk factors for developing MDR-HIV-1 infection. Pregnancy would be a key time to achieve viral suppression to reduce vertical transmission to the child. Women with HIV-1 infection are encouraged to not breast feed, in order to avoid vertical HIV transmission. The risk of transmission is higher in individuals who	Lenacapavir has a limited amount of data for use in pregnancy (fewer than 300 pregnancy outcomes). The summary of product characteristics (SmPC) advises as a precautionary measure it is preferable to avoid the use of lenacapavir during pregnancy. The policy suggests that individuals' suitability is assessed and discussed by a HIV specialist MDT. This could assist with the clinical challenges of considering lenacapavir use in pregnancy for this complex cohort as MDR-HIV-1 infection (which by definition is not virally suppressed) places an individual and also child at increased risk of complications and also the child of vertical transmission. As breast-feeding is a potential risk factor for transmission and individuals with MDR-HIV-1 by definition are not virally suppressed, it would not be recommended to breast-feed. The SmPC data suggests the effects of lenacapavir excretion into breast milk are

[6] Public Health England (PHE). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)
[7] Public Health England (PHE). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	are not virally suppressed as in the case of MDR-HIV-1 infection.	unknown. Given these factors, the policy is not thought to exclude this patient cohort after appropriate discussion regarding the risks.
Race and ethnicity[8]	Race and ethnicity can have an impact on MDR-HIV-1, as there are different prevalence rates for HIV and MDR HIV-1 globally. This can impact particularly new migrants to the UK, who may have been exposed to a greater risk of HIV acquisition and/or different levels of healthcare and treatment access, which can increase the risk of MDR HIV-1 acquisition. The MDR-HIV-1 data is not broken down into race and ethnicity groupings. Race and ethnicity data is collected in new diagnosis of HIV and in some ethnic groups a higher rate of new diagnosis of HIV is seen, as well as a slower rate of decline in new cases compared to other ethnic groups. Overall, there has been a reduction in HIV diagnosis over the past 10	All patients who meet the inclusion criteria would be considered for lenacapavir treatment. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

[8] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	years. Race and ethnicity data is important to capture as some groups experience health inequities in access to care and support for HIV. These summary statements are supported by UKHSA data[9]: In 2022, 58% of newly diagnosed GBMSM were of white ethnicity. In this group, new HIV diagnoses decreased by 17% (508 to 420) between 2021 and 2022. In contrast, the number of diagnoses remained relatively stable among men of black African ethnicity (27 in 2021 and 26 in 2022) and rose slightly by 17% (75 to 88) among those of Asian ethnicity and by 25% (71 to 89) among those of mixed or other ethnicity. Black African men and women accounted for 44% (643/1,477) of new HIV diagnoses among adults who acquired HIV heterosexually in 2018, compared to 61% (1,961/3,219) of new diagnoses in 2009, representing a 67% decline (1,961 to 643).	

[9] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	Over the same time, diagnoses among black Caribbean men and women who acquired HIV heterosexually also declined, from 141 in 2009 to 46 in 2018 (67% fall). Men and women who acquired HIV heterosexually and were of white ethnicity accounted for 38% (555/1,477) of new diagnoses in 2018, compared to 24% (773/3,219) in 2009.	
Religion and belief: people with different religions/faiths or beliefs, or none.	There should be no direct negative or positive impact on this group as religion and belief have not been identified as high-risk groups.	Not applicable.
Sex: men; women	Sex is not determined to be a risk factor for MDR-HIV-1 infection, however in the UK, the new diagnosis of HIV, includes more men than women so this population could be reflected more in the MDR-HIV-1 patient population. In 2022, 3,805 people were newly diagnosed with HIV in the UK (2,409men and 1,391 women).[10]	The policy is inclusive of all individuals if they meet the inclusion criteria.

[10] New HIV diagnoses totals for men and women are based on gender identity and include trans people. The overall total includes people who identify as non-binary, in another way, and those with gender identity not reported.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation has been identified as a risk factor for HIV acquisition and therefore some communities may also have a higher rate of MDR-HIV-1 infection. The number of new HIV diagnoses among GBM was on the rise at the beginning of the decade, alongside simultaneous increases in testing rates and observed increases in incidence among GBM. The number of new HIV diagnoses among GBM in 2018 (1,908) was 30% lower than the number reported in 2009 (2,709) and 40% lower than in 2014 (3,165). [11] In 2018, using observed data, 724 men and 826 women who were reported as having acquired HIV through heterosexual sex were newly diagnosed in the UK, and 22% (333/1,550) of these had been previously diagnosed outside the UK. The number of newly diagnosed men and women who acquired HIV heterosexually peaked in 2004, and halved between 2009 and 2018, from 3,236 to 1,550. [12]	The policy is inclusive of all individuals, if they meet the inclusion criteria to use lenacapavir. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

[11] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)
[12] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	There should be no direct negative or positive impact on this group as looked after children and young people have not been identified as high-risk group for MDR-HIV-1 infection.	Children with HIV-1 infection are managed in a specialist HIV child-focused service. As outlined, the safety data for lenacapavir does not include children, therefore this policy is adult focused, but would allow post-puberty access, for children and young adults meeting the inclusion criteria. It is proposed that by use of the specialist HIV MDT to determine suitability for lenacapavir the individual health, emotional and developmental needs of the child are taken into consideration if lenacapavir was proposed as a treatment option.
Carers of patients: unpaid, family members.	Carers may be indirectly positively impacted by this policy. :Lenacapavir has the potential to improve an individual's health status if they can achieve viral suppression.	The policy recommends that the suitability of lenacapavir as an intervention is assessed by the MDT team. This includes considering the support and care mechanisms a patient would require undergoing the intervention.

[13] Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	This can also reduce the risk of the individual transmitting HIV. Individuals in whom the virus is not suppressed have increased morbidity and mortality. Lenacapavir, if it improves an individual's health status, may reduce their care needs allowing them to participate more in activities of daily living. This policy may benefit carers who support patients with MDR HIV-1 infection by reducing the assistance required to complete work, family, and personal tasks. The use of lenacapavir may require ongoing carer support to facilitate attendance of follow-up appointments. This might be offset by a reduction in emergency and unscheduled care or prolonged admissions to address the consequences of advanced immunosuppression.	A commissioning plan sets out the pathway of provision for lenacapavir which will include access at appropriately staffed centres.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	This group may be less likely to enter the patient pathway, due to access issues (e.g., not registered with a General Practitioner). The lack of a permanent base for which follow-up appointments could be co-	NHS England has produced the lenacapavir policy to increase access for anyone who may benefit from the intervention. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	ordinated may be challenging in this cohort of patients. However, the fact that lenacapavir is a 6 monthly injectable therapy may make it easier for individuals to adhere to treatment, as long as they are able to attend follow-up appointments. If identified, those who are homeless could be at risk of adverse outcomes, due to lack of access to services, incomplete follow-up as well as environmental conditions which may expose individuals to infection or potentially exacerbate underlying health issues with MDR HIV-1 infection.	Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for people living with HIV who are homeless.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	In 2018/19, 57,635 people newly arriving into or transferring between prisons were tested for HIV, an increase of 39% since 2017/18. This testing identified 665 HIV infections in 2018/19, a test positivity of 1.2%. [14] This data is not disaggregated for MDR HIV-1 infection. All patients who met the inclusion criteria would be considered for	All individuals who meet the inclusion criteria can be considered for treatment with lenacapavir. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

[14] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	treatment. This group is not identified at high risk for MDR HIV-1 infection.	
People with addictions and/or substance misuse issues	Substance misuse, particularly injectable, is a risk factor for HIV acquisition. The number of individuals with MDR-HIV1 infection related to substance misuse is not known, however other health concerns such as co-infection with hepatitis (also higher in individuals with addiction issues) can limit some available ART options. Individuals with HIV and concurrent injecting drug use are at a higher rate of mortality. This summary is supported by UKHSA data: [15] The number of people who probably acquired HIV through injecting drug use has fallen by a third since 2009 (140 to 94) and comprised 2% of all new HIV diagnoses in 2018 (94/4,453). Of these 94 individuals, 80% (75/94) were men, 85% (80/94) were aged between 25 to	All patients who meet the inclusion criteria would be considered for treatment. Commissioned providers will require all their staff to have completed their mandatory Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

[15] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	49 years, 89% (84/94) were of white ethnicity. The mortality among people diagnosed with HIV who injected drugs was much higher, at 23.61 per 1,000.	
People or families on a low income	This policy will promote access to lenacapavir regardless of economic status. Low economic status is not known to be a risk factor for MDR HIV-1 infection.	The policy will facilitate access to lenacapavir.
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This group may find it hard to understand their condition and the benefits and risks associated with different treatment options. It may also be harder for these individuals to understand and follow drug directions, in which case having a 6-monthly injectable therapy may be beneficial for this cohort.	Shared decision making is mandated within this policy, and so clinicians will need to ensure that individuals are well informed. This can be through various mediums including verbal as well as written shared decision-making tools, translated and Easy Read materials. The provision of lenacapavir involves face-to-face assessment and verbal instruction, this can assist those with poor health or literacy skills. A holistic MDT assessment of an individual should be undertaken to assess their suitability for lenacapavir.
People living in deprived areas	A national commissioning policy intends to ensure there is equal access to treatment regardless of location, it will reduce variation in practice.	The policy will enable people living with HIV to access lenacapavir where eligible.

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	The UKHSA data demonstrates that some local authorities have a higher number of people living with HIV, and therefore those services may see a greater number of individuals with MDR HIV-1 infection. The UKHSA data also suggests that areas outside London may have a greater proportion of people who are currently undiagnosed with HIV. Overall, 84 of 317 local authorities in England had a "high-diagnosed-prevalence" (greater than 2 per 1,000 population aged 15 to 59 years) in 2018. Of these, 19 had an "extremely-high-diagnosed prevalence" (defined as greater than 5 per 1,000 population aged 15 to 59 years) including 17 London local authorities, Manchester, and Brighton and Hove. [16] Twice as many people with undiagnosed HIV infection in England lived in England outside of London. [17]	

[16] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)
[17] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
People living in remote, rural and island locations	A national commissioning policy intends to ensure there is equal access to treatment regardless of location.	A commissioning plan will determine the local arrangements, which may include specialist oversight, to improve access for people living with HIV. The low incidence of MDR HIV-1 infection (estimated to be 92 individuals) may mean that some centres have no eligible individuals. The provision of lenacapavir will be within NHS England Specialised Commissioned HIV services to ensure standards, expertise and satisfactory overall service delivery. The geographic area of the UK requires a significant number of services to allow for realistic access for people living with HIV. This allows for ongoing support and supervision of services, if the appropriate expertise is available and remote technology can facilitate this. People living in remote, rural and island locations may find a long-acting injectable treatment beneficial to them.
Refugees, asylum seekers or those experiencing modern slavery	In 2018, almost half (47%, 698/1,475) of men and women diagnosed with HIV in the UK who acquired HIV heterosexually were born in a country	The Clinical Commissioning policy for lenacapavir intends to increase access for anyone who may benefit from the intervention. Commissioned providers should work with the individual and other relevant agencies (e.g., GP, Local Authority, charities) to mitigate risk for

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	of high HIV prevalence[18] and 31% (452) were born in the UK. Nearly one quarter (23%) 445/1,908) of new HIV diagnoses in GBM in 2018 were known to have been previously diagnosed outside the UK. [19] Individuals who are refugees, asylum seekers or those experiencing modern slavery could be more vulnerable to sexual violence and exploitation which may increase their risk of HIV acquisition. This group may be less likely to enter the pathway, due to access issues (e.g. not registered with a General Practitioner). The lack of a permanent base for which HIV care and follow-up and/or review appointments could be co-ordinated may be challenging in this cohort of people living with HIV. If identified, those who are refugees, asylum seekers or those experiencing	refugees, asylum seekers and those experiencing modern slavery. Commissioned providers will require all their staff to have completed their mandatory Safeguarding and Equality, Diversity & Inclusion training to ensure they are fully compliant with all relevant legislation.

[18] Proportions presented where data on country of birth are known. Data completeness for country of birth among new diagnoses was 85% in 2018 and 96% in 2009

[19] Public Health England (UKHSA). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)

Groups who face health inequalities[13]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	modern slavery could be at significant risk of adverse outcomes due to lack of access to services, incomplete follow-up as well as environmental conditions which may exposure individuals to be more vulnerable due to their MDR-HIV-1 status. In addition, refugees, asylum seekers and those experiencing modern slavery may face difficulties in accessing primary care if they have no recourse to public funds, are unable to prioritise their health needs or have poorer literacy and health literacy. This may be compounded by language and other cultural barriers and exacerbated by any additional vulnerabilities including safeguarding issues.	
Other groups experiencing health inequalities (please describe)	Not applicable.	Not applicable.

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes X	No	Do Not Know

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	Stakeholder testing	Stakeholder testing for this policy took place for 28 days in July/August 2024	18/07/24-15/08/24
2	Public consultation		Not required
3			

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An external review of available clinical evidence was undertaken to inform this policy.	
Consultation and involvement findings	Planned	
Research	No pending research is known.	Not applicable
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A Policy Working Group was assembled which includes HIV specialists, specialist pharmacists, a public health specialist	

Evidence Type	Key sources of available evidence	Key gaps in evidence
	and patient and public voice representatives.	

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?	X	X	
The proposal may support?			X
Uncertain whether the proposal will support?			

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposal will support?	X	X
The proposal may support?		
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research, or additional evidence. Please list your top 3 in order of priority or state N/A

	Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1	Consensus on the eligibility criteria within the wider specialist HIV community	Stakeholder testing

2	Consensus on the patient pathway within the wider specialist HIV community	Stakeholder testing
3		

10. Summary assessment of this EHIA findings

This Policy is not considered to unfairly discriminate those with a protected characteristic. The Policy 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 commissioned policy will reduce variation in clinical practice promoting an equity of care for those in which this intervention is indicated.

11. Contact details re this EHIA

Team/Unit name:	Specialised Commissioning
Division name:	Blood and Infections Programme of Care
Directorate name:	System Development Group
Date EHIA agreed:	
Date EHIA published if appropriate:	