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

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): Reimbursement for the use of generic and second line drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV

2. Brief summary of the proposal in a few sentences

This Clinical Commissioning Policy statement is for the use and reimbursement of bio-equivalent generic medicines licensed for HIV pre-exposure (PrEP) medicines.

The Clinical Commissioning Policy: Reimbursement for the use of generic drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV was first published in July 2020. An EHIA was not completed at the time of the development of this policy. This is the first EHIA to be prepared for this policy.

This policy update recommends the use of tenofovir alafenamide (TAF) as a second line, bioequivalent alternative to tenofovir disoproxil (TD) in people who are intolerant to TD, or in whom TD is contraindicated. TAF offers benefits of reduced toxicity in individuals at certain risk of renal or bone impairment.

The revision of this clinical policy was undertaken by a Policy Working Group (PWG) consisting of HIV experts, a public health specialist and specialised commissioner for NHS England.

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.	In 2021, 7.4% (87,828 out of 1,180,923) of people who were HIV negative and accessing specialist sexual health services in England were defined as having PrEP need. Of those, 79.1% had their need identified during a clinical consultation and 69.6% initiated or continued PrEP. Broken down by age, the proportion who were defined as having PrEP need was: 15 – 24 year olds: 4.0% 25 – 34 year olds: 8.2% 35 – 49 year olds: 10.0% 50 – 64 year olds: 13.3% 65 years and over: 12.5% 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 HIV diagnosed individuals over the past 10 years, with males over 50 years	Second line therapy of TAF will potentially benefit the older age group since they are more likely to experience renal and bone disease, and therefore may be unable to receive the standard of care, TD.

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	increasing, whilst other at-risk groups in younger age brackets decreasing. Older individuals feature as a higher proportion presenting late with HIV, and subsequently have a higher mortality. The impact of late HIV diagnosis on mortality within one year in 2019 was particularly marked among people aged 65 and over, at 59 per 1,000, compared to 31 in 1,000 of the overall late diagnoses. One-year mortality in those diagnosed promptly was 4 per 1,000 (UKHSA 2021 report in HIV populations). 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 under the age of 12 years and who weigh less than 35 kg are not included within this policy due to the safety profile of the drug not being established in this population.	

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Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Disability is not known to be a risk factor for HIV-1 acquisition. However, long-term conditions such as kidney or bone disease, can limit the use of ART drugs. In addition, HIV infection without adequate viral suppression can lead to complex medical conditions which increase an individual's risk of mortality and can create morbidity. This policy will have a positive impact on this group because it offers another PrEP drug option for those with certain long-term conditions such as bone or kidney disease. This will help to prevent HIV infection in a greater number of individuals.	The decision to offer TAF should be holistic and patient focused and should be dependent on shared decision making with the patient. This policy outlines that TAF provision should be initiated and reviewed by a specialist multi-disciplinary team of professionals who are responsible for ongoing patient care and consider an individual's long-term health conditions, their unique circumstances and concurrent health needs.
Gender Reassignment and/or people who identify as Transgender	PHE 2019[1] data demonstrates that from 2015, 67 new HIV diagnoses have been recorded among trans[2] people: 11 diagnoses in 2018, 16 in 2017, 16 in 2016 and 24 in 2015. Six trans people diagnosed in 2018 were aged 35 to 49 years, 6 were white and 7 were diagnosed late.	All individuals who meet the inclusion criteria would be considered for TAF treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

[1] Public Health England (PHE). 2019. HIV in the UK: Towards Zero HIV transmissions by 2030 (publishing.service.gov.uk)
[2] 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, nonbinary, 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
	There may be a positive impact on this group because TAF offers an additional option for PrEP.	
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.	All individuals who meet the inclusion criteria would be considered for TAF.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Pregnancy is a key time to achieve viral suppression to reduce vertical transmission to the child. PrEP offers one option to prevent transmission to partners of people living with HIV during attempts to conceive if the HIV positive partner is not on suppressive ART. Continuation of PrEP during pregnancy or breastfeeding can reduce the risk of HIV transmission. The addition of TAF to the PrEP policy will have a positive impact on this group of people because it offers an additional option for women who are unable to tolerate TD, and for those in whom TD is contraindicated.	Pregnancy: TAF has a limited amount of data for use in pregnancy (less than 300 pregnancy outcomes). However, the summary of product characteristics (SPC) advises that TAF may be considered during pregnancy if necessary due to data for more than 1,000 exposed outcomes indicating no malformative nor feto/neonatal toxicity associated with the use of TAF. The policy suggests that individuals' suitability is assessed and discussed by a HIV specialist MDT. This could assist with the clinical challenges of considering TAF use in pregnancy for this cohort. Breastfeeding The SmPC data suggests the effects of TAF excretion into human breast milk are unknown. In animal studies it has been shown that tenofovir is excreted in milk. There is insufficient information on

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		the effects of emtricitabine and tenofovir in newborns/infants. Therefore, emtricitabine and tenofovir alafenamide should not be used during breast-feeding. If a woman becomes pregnant while on PrEP, a discussion of the potential risks and benefits is advised, with recommendation to continue PrEP throughout pregnancy or breastfeeding for those with ongoing risk for HIV (BHIVA PrEP guidelines, 2018).
Race and ethnicity[3]	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 years. Race and ethnicity data is important to capture as some groups experience health inequities in access to care and support for HIV.	All individuals who meet the inclusion criteria would be considered for TAF treatment. The policy is therefore not considered to have an adverse impact on this protected characteristic group.

[3] 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.

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	There is a potential positive impact on groups where a higher rate of new diagnosis is seen because there would be an additional option for PrEP that will support the reduction in the number of HIV transmissions. These summary statements are supported by UKHSA data: The number of all new HIV diagnoses decreased by 33% in England (from 3,950 in 2019 to 2,630 in 2020). These declines in diagnoses were less apparent among gay and bisexual men who were living outside London, those of Black, Asian, Mixed or Other ethnicity ethnic groups, and those born abroad. In 2020, the number of HIV diagnoses first made in England among heterosexual people decreased by 23% (from 1,310 in 2019 to 1,010 in 2020, adjusted for missing information). The decline was 40% among White heterosexuals (from 470 in 2019 to 280 in 2020) and Black Caribbean heterosexuals (from 50 to 30) but less pronounced among Black Africans (25%,	

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	400 to 300) and among Asians (17%, 60 to 50). The decline in HIV diagnoses first made in England among heterosexual men and women is likely to have been impacted by reduced access to HIV testing in 2020 and rather than longer term decreased transmission. In 2020, a higher proportion of people diagnosed late with HIV were Black African (54%) and Black Caribbean/Black Other (43%) individuals than White (39%) or Asian/Other (34%). The proportion of heterosexual men who were diagnosed late (first diagnosed in England and after correction for recent seroconversion) was high, with 55% (170 out of 310), compared with 50% (170 out of 340) among heterosexual women. The overall rate of late diagnoses for all heterosexuals was 53%. Rates were higher among Black African heterosexuals (59%), compared with White heterosexuals (51%).	
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 since people with different religions/faiths or beliefs have not been identified as high risk groups.

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Sex: men; women	Sex is not determined to be a risk factor for HIV infection, however in the UK, a new diagnosis of HIV is seen in more men than women so this population could be reflected more in the patient population. In 2020, 2,630 people were newly diagnosed with HIV in England (1,860 men and 770 women).	Not applicable since sex has not been determined to be a risk factor for HIV infection.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Sexual orientation has been identified as a risk factor for HIV acquisition. This policy provides an additional option for PrEP that will support the reduction of HIV transmissions. Gay and bisexual men comprised 45% of all diagnoses first diagnosed in England in 2020; heterosexual women, 26%; heterosexual men, 24%; and people who inject drugs (PWID), 3% (adjusted for missing information). HIV incidence among gay and bisexual men in England declined by 91%, from an estimated peak of 2,730 (95% CrI	All individuals who meet the inclusion criteria would be considered for TAF treatment.

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	2,560 to 2,900) in 2011, to 400 (95% CrI 240 to 800) in 2019 to an estimated 250 (95% CrI 110 to 710) in 2020, equivalent to less than 1 per 1,000 gay and bisexual men in England. However, more conservative sensitivity analyses suggest up to 590 (95% CrI 200 to 2,050) new infections in gay and bisexual men in England in 2020 may have occurred, if we assume the extreme scenario that the lockdowns did not reduce new infections but did reduce the number of people testing and being diagnosed. The intervention will potentially have a positive impact for individuals in this category because it offers an additional treatment option.	

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[4]	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 is no identified direct negative or positive impact on this group as looked after children and young people have not been identified as a high-risk group for HIV-1 infection.	Not applicable
Carers of patients: unpaid, family members.	There is no identified potential negative or positive impact on carers of patients by this policy update policy.	Not applicable.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	This group may be less likely to access PrEP, due to lack of access to services (e.g. not registered with a General Practitioner). Environmental conditions may expose individuals to infection or potentially exacerbate underlying health issues. The lack of a permanent base for which follow-up appointments could be co-ordinated may be challenging in this cohort of patients.	The TAF policy will increase access for anyone who may benefit from the intervention. It should be noted that only the PrEP medicines are commissioned by NHS E/I. The service is commissioned by Local Authority. It is recommended that service providers work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for homeless patients.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	In 2018/19, 57,635 people newly arriving at or transferring between prisons were tested for HIV, an increase of 39% since 2017/18. This testing identified 665 HIV	It should be noted that only the PrEP medicines are commissioned by NHS E/I. The service is commissioned by Local Authority. It is recommended that service providers work with the

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

Groups who face health inequalities[4]	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
	infections in 2018/19, a test positivity of 1.2%.	health and justice system to mitigate the risk for people involved in the criminal justice system.
People with addictions and/or substance misuse issues	Drug use, particularly injection is a risk factor for HIV acquisition. Also, other health concerns may limit some available antiretroviral therapy options. Individuals with HIV and concurrent injecting drug use are at a higher risk of mortality. This policy will have a potential positive impact on this group because it offers an additional option for PrEP.	It should be noted that only the PrEP medicines are commissioned by NHS E/I. The service is commissioned by Local Authority. It is recommended that service providers work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate the risk for people with addictions and/or substance misuse issues.
People or families on a low income	This policy will promote access to PrEP regardless of economic status.	All patients who meet the inclusion criteria would be considered for treatment.
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 the benefits and risks associated with different treatment options. It may also be harder for these individuals to understand and follow the directions for administration of the medicines.	Shared decision making is mandated within this policy and so clinicians will need to ensure that patients 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 TD or TAF involves face-to-face assessment and verbal instruction, this can assist those with poor health or literacy skills.
People living in deprived areas	A national commissioning policy attempts to ensure there is equal access to	All individuals who meet the inclusion criteria would be considered for TAF treatment.

Groups who face health inequalities[4]	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 regardless of location, and will reduce variation in practice. Overall, 80 local authorities in England had a “high-diagnosed-prevalence” (greater than 2 per 1,000 population aged 15 to 59 years) in 2020. Of these, 19 had an “extremely-high-diagnosed prevalence” (defined as greater than 5 per 1,000 population aged 15 to 59 years) including 16 London local authorities, Manchester, Salford and Brighton and Hove.	
People living in remote, rural and island locations	This national commissioning policy attempts to reduce variation in practice by promoting equal access to treatment regardless of location. Since the medicines in this policy are oral formulations, they may not require frequent clinic visits. As such, this policy will have a positive impact this group.	This will benefit those who live in remote, rural and island locations.
Refugees, asylum seekers or those experiencing modern slavery	Individuals who are refugees, asylum seekers or those experiencing modern slavery could be more vulnerable to sexual violence and exploitation which	This policy intends to increase PrEP access for anyone who may benefit from the intervention. Commissioned providers should work with the patient and other relevant agencies (e.g., GP, Local

Groups who face health inequalities[4]	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
	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 sexual health care and follow-up and/or review appointments could be co-ordinated may be challenging in this cohort of patients.	Authority, charities) to mitigate risk for refugees, asylum seekers and those experiencing modern slavery.
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	No X	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	Policy working group consisting of HIV clinicians, pharmacists, commissioners, patient group representatives	Policy working group meetings and drafts circulated for comments and amendments.	Q3 – Q4 2021

2	Stakeholder testing	Two week stakeholder testing period, responses summarized separately in engagement report.	12 - 26 May 2021
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	The evidence base consisted of a single phase 3 non-inferiority study in individuals with a normal renal function.	A paucity in evidence was considered and acknowledged by Clinical Panel.
Consultation and involvement findings	Not applicable.	Not applicable
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, a public health specialist and patient and public voice representatives.	Not applicable

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	There is a gap in evidence for event-based PrEP dosing which means this policy is only for daily dosing.	Further research in the area of event-based dosing would be beneficial.
2		
3		

10. Summary assessment of this EHIA findings

This policy update provides an additional treatment option for certain individuals who are unable to receive current PrEP therapy, and therefore will make a contribution to advancing equality of opportunity. It does not unfairly discriminate those with a protected characteristic.

It is worth noting that the population has been relatively static and is likely to remain the same or decrease over the next 5 years, however, the COVID pandemic is also likely to have had an impact on the population.

11. Contact details re this EHIA

Team/Unit name:	Specialised Commissioning
Division name:	Blood and Infection programme of care
Directorate name:	Finance

Date EHIA agreed:	
Date EHIA published if appropriate:	