NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Lenacapavir for preventing HIV-1 in people aged 16 years or older ID6495

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of lenacapavir within its marketing authorisation for preventing HIV-1 in people aged 16 years or older.

Background

Human Immunodeficiency Virus (HIV) is a virus that attacks the immune system by destroying CD4 positive T cells, a type of white blood cell that is vital for fighting infections. The destruction of these cells leaves people living with HIV unable to fight off infections and some other conditions. It can result in complications from advanced HIV, also known as acquired immune deficiency syndrome (AIDS).

HIV is transmitted through the body fluids of a person, usually with a detectable level of the virus (including semen, vaginal and anal fluids, blood and breast milk). The most common way of getting HIV for people treated in the NHS is sexual intercourse without a condom or other proven HIV prevention interventions (such as oral-based pre-exposure prophylaxis).

There are two main types of HIV. Most cases within the UK are from the HIV-1 type and it is considered more transmissible than HIV-2. An estimated 100,063 people were living with HIV and seeking care in England in 2023.[1]

Pre-exposure prophylaxis (PrEP) is used as part of combination HIV prevention.[2] HIV prevention includes a mix of behavioural, biomedical (oral PrEP) and structural interventions (barrier-method contraception). PrEP is the use of treatments to prevent infection in people who have not yet been exposed. Taking PrEP before HIV exposure can prevent HIV from getting into the body and replicating.[3]

NICE guideline 221, on reducing sexually transmitted infections recommends that PrEP is offered to people at higher risk of HIV using the criteria in the British HIV Association / British Association for Sexual Health and HIV (BHIVA/BASHH) guidelines. Normally treatment involves taking tablets every day (daily PrEP) but in some cases, it may mean taking tablets at before sexual exposure (event-based or on-demand PrEP).[4] BHIVA/BASHH recommends the use of tenofovir disoproxil (TD) and emtricitabine (FTC) where it is known as TD-FTC or TDF-FTC. It also recommends that TD alone can also be offered to heterosexual men and women where FTC is contraindicated, but not to men who have sex with men. The NHS England commissioning policy on PrEP for the prevention of HIV recommends alafenamide (TAF) in combination with FTC as a second line option where TD-FTC is contraindicated.

The technology

Lenacapavir (Sunlenca, Gilead) does not currently have a marketing authorisation for preventing HIV in people aged 16 years or older. It has been studied in two phase 3

clinical trials compared to oral PreP. One trial included cisgender men, transgender men, transgender women, and gender non-binary individuals who have sex with partners assigned male at birth and the other included cisgender women.

Lenacapavir has a marketing authorisation 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, for oral loading prior to administration of long-acting lenacapavir injection.

Intervention(s)	Lenacapavir by subcutaneous injections with oral lead-in therapy
Population(s)	People aged 16 years or older at risk of sexually acquired HIV-1 infection
Comparators	Established clinical management including • tenofovir disoproxil or alafenamide in combination with emtricitabine or tenofovir alone • cabotegravir (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • number of documented incident HIV infections • change in viral load • renal function • liver function • bone mineral density • incidence of resistance mutations • adherence to treatment regimen • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Cabotegravir with rilpivirine for treating HIV-1 (2022) NICE technology appraisal guidance 757 **Related technology appraisals in development:** Cabotegravir injections for preventing HIV-1 in adults and young people. NICE technology appraisal guidance [ID6255] Publication date to be confirmed. Cabotegravir with ribavirin for the oral treatment of HIV-1. NICE technology appraisal guidance [ID3731] Publication date to be confirmed. **Related NICE guidelines:** Reducing sexually transmitted infections (2022) NICE guideline 221 HIV testing: increasing uptake among people who may have undiagnosed HIV (2016) NICE guideline 60 **Related quality standards:** HIV testing: encouraging uptake (2017) NICE quality standard 157

Questions for consultation

Where do you consider lenacapavir will fit into the existing care pathway for preventing HIV-1 in people aged 16 years or older? And in which population do you expect lenacapavir to be used?

Please select from the following, will lenacapavir be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would lenacapavir be a candidate for managed access?

Do you consider that the use of lenacapavir can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which lenacapavir will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. UK Health Security Agency (2024) HIV testing, new HIV diagnoses, outcomes and quality of care for people accessing HIV services: 2024 report. Accessed February 2025

2. Clinical Commissioning Policy Reimbursement for the use of generic drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV (2020). Accessed February 2025

3. Terrence Higgins Trust (2020) PrEP (pre-exposure prophylaxis). Accessed February 2025

4. BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) (2018). Accessed February 2025