NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Cabotegravir injections for preventing HIV-1 in adults and young people

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of cabotegravir within its marketing authorisation as pre-exposure prophylaxis of HIV-1 infection in adults and young people.

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). The risk of transmission per exposure is low; estimates are on the order of 0.1% per contact for heterosexual transmission, but this varies considerably and increases with concurrent ulcerative sexually transmitted infections, high HIV viral load in the host, and lack of antiretroviral therapy.[1]

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 106,890 people were living with HIV in the UK in 2020, of which 97,740 lived in England.[2]

Pre-exposure prophylaxis (PrEP) is used as part of combination HIV prevention.[3] 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.[4]

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).[5] BASHH recommends the use of tenofovir disoproxil (TD) and emtricitabine (FTC) where it is known as TD-FTC or TDF-FTC. BASHH 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

Cabotegravir (Apretude, ViiV Healthcare) is administered as an intramuscular injection.

Cabotegravir does not currently have a marketing authorisation in the UK for prevention of HIV-1 infection. It has been studied in clinical trials in sexually active, female adults who are living without HIV, as well as cisgender men who have sex with men and transgender women at high risk of sexually acquired HIV. These trials compared cabotegravir intramuscular injections on top of standard care against placebo on top of standard care. An ongoing single-arm, open label clinical trial is studying cabotegravir in cisgender men or transgender men or women who have sex with men.

Intervention(s)	Cabotegravir intramuscular injections with or without oral lead-in therapy
Population(s)	People at risk of sexually acquired HIV-1 infection
Subgroups	• If evidence exists, subgroups of people at risk of sexually acquired HIV-1 infection for whom the technology might be particularly clinically effective or value for money will be considered
Comparators	Established clinical management including tenofovir disoproxil or alafenamide in combination with emtricitabine or tenofovir alone
Outcomes	The outcome measures to be considered include: • number of documented incident HIV infections • change in viral load • adverse effects of treatment • health-related quality of life • renal function • liver function • bone mineral density • incidence of resistance mutations • adherence to treatment regimen

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 and cost of biosimilar and generic products 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 NICE guidelines:** 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
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2018) NHS manual for prescribed specialist services (2018/2019) [Chapter 16 Adult specialist services for patients infected with HIV] NHS England (2013) 2013/14 NHS STANDARD CONTRACT FOR SPECIALISED HUMAN MMUNODEFICIENCY VIRUS SERVICES (ADULTS). Reference: B06/S/a NHS England (2013) 2013/14 NHS STANDARD CONTRACT FOR SPECIALISED HUMAN MMUNODEFICIENCY VIRUS SERVICES (CHILDREN). Reference: B06/S/b NHS England (2020) Reimbursement for the use of generic drugs for pre exposure prophylaxis (PrEP) for the prevention of HIV

	UK Health Security Agency (2022) Routine commissioning of HIV preexposure prophylaxis (PrEP) in England: Monitoring and evaluation framework Public Health England (2017) Sexual health, reproductive health and HIV: commissioning review Public Health England (2015) Making it Work – a guide to whole system commissioning for sexual health, reproductive health and HIV Department of Health and Social Care (2013) HIV Outpatient Clinical Care Pathway

References

1. BMJ Best Practice (2022) HIV infection: aetiology. Accessed May 2023

2. UK Health Security Agency (2021) HIV testing, new HIV diagnoses, outcomes and quality of care for people accessing HIV services: 2021 report. Accessed October 2023

3. Clinical Commissioning Policy Reimbursement for the use of generic drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV (2020). Accessed May 2023.

4. Terrence Higgins Trust (2020) PrEP (pre-exposure prophylaxis). Accessed May 2023

5. BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) (2018). Accessed May 2023