

Clinical Commissioning Policy Reimbursement for the use of generic drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV

Commissioning Position

NHS England will routinely reimburse the drug costs associated with Pre Exposure Prophylaxis (PrEP) for the prevention of HIV as outlined in this document. This policy is for the use and reimbursement of bio-equivalent generic medicines licenced for PrEP. An exclusion to this policy is reimbursement for the use of the 'reference' antiretroviral medicine licenced for PrEP (Truvada ®).

The individuals eligible for the treatment will be those clinically assessed in local authority commissioned and approved sexual health services in line with the clinical guidance of <https://www.bhiva.org/PrEP-guidelines>

Information about PrEP

PrEP refers to the use of antiretroviral drugs called tenofovir disoproxil¹ (TD) and emtricitabine (FTC) used in combination known as TD-FTC or TDF-FTC. PrEP is prescribed for people who do not have HIV but who are at risk of contracting the virus. Prescribers and service users select one of two dosing regimens - daily or event based / on demand – depending on the risk factors experienced by the service user and as part of a comprehensive HIV prevention and clinical assessment.

PrEP is used as part of combination HIV prevention. In trials studying effectiveness of PrEP, the drug was given in addition to a comprehensive package of prevention services including HIV testing, risk-reduction counselling, condoms and sexually transmitted infection management. Of relevance in assessing the impact of PrEP are issues relating to uptake, adherence, sexual behaviour, drug resistance and cost-effectiveness.

The condition

Human Immunodeficiency Virus (HIV) is a virus that damages a type of white blood cell in the immune system called a CD4 cell. Damaging CD4 cells weakens the body's ability to fight off infection and disease, leaving people with HIV vulnerable to infection. In most cases if not treated this leads to acquired immunodeficiency syndrome (AIDS), which is the name given to several life-threatening illnesses that can develop when the immune system has become severely damaged by the HIV virus.

HIV is transmitted through the body fluids of a person with a detectable level of the virus (including semen, vaginal and anal fluids, blood and breast milk). Most people have flu-like illness several weeks after infection. After this, HIV may not cause any symptoms for several years, but it will still damage the immune system.

¹ There are different tenofovir disoproxil salts in the different generics included. TD-FTC is an inclusive term. Those with fumerate are referred to as TDF-FTC and are also included in this policy.

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According to Public Health England's ['HIV in the UK' published in 2019](#), by the end of 2018 there were

- 103,800 people living with HIV, of whom
- 93% were diagnosed, of whom
- 97% were receiving HIV treatment, of whom
- 97% were virally suppressed.
- An estimated 13,100-15,600 people were living with transmittable levels of HIV
- 4,453 new HIV diagnoses were made in 2018
- An estimated 13,000 taking PrEP through publicly funded programmes or research, and a further 6,500 self-purchasing PrEP

In 2019, the Secretary of State for Health and Social Care set the goal for England to become one of the first countries to reach HIV elimination by 2030.

Current treatments

Combination HIV prevention uses a mix of biomedical, behavioural and structural interventions to meet the needs of particular individuals and communities in efforts to reduce new infections. This includes sexual health and HIV screening, testing, partner notification, condoms, access to HIV and STI treatments. Use of antiretroviral drugs commonly used to treat those with diagnosed HIV play a key role in preventing HIV transmission in three ways:

- ['Treatment as prevention'](#) This is when people with diagnosed HIV who are on effective treatment for 6 months or more and have an undetectable viral load, cannot pass on the virus during sex. In addition, for the majority of people with HIV on effective treatment, they will experience near normal life expectancy and will not develop AIDS-related illness.
- Post exposure prophylaxis (PEP): This is when antiretroviral drugs are used for 1 month after possible exposure to HIV to prevent HIV infection occurring.
- Pre Exposure Prophylaxis (PrEP): This is when antiretrovirals are used before exposure to HIV as directed by qualified members of the sexual health team following a clinical assessment.

There is currently no vaccination or cure for HIV.

Marketing Authorisations

NHS England will confirm which approved products are available for use via the HIV drugs framework. Products currently known to have a marketing authorisation are:

Emtricitabine/Tenofovir disoproxil Dr. Reddy's 200 mg/245 mg Film-Coated Tablets (Dr Reddy's)

Emtricitabine/Tenofovir disoproxil Lupin 200 mg/245 mg Film-coated Tablets (Lupin)

Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets (Mylan)

Emtricitabine/Tenofovir disoproxil Teva 200 mg/245 mg film coated tablets (Teva)

Emtricitabine/Tenofovir disoproxil Zentiva 200 mg/245 mg film coated tablets (Zentiva)

Evidence of Effectiveness

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NHS England has previously considered the evidence base for PrEP. In 2016, NICE published an Evidence Summary [ESNM78] on the clinical effectiveness, safety, patient factors and resource implication of PrEP ([link](#)). This summary included review of four randomised trials of Truvada (emtricitabine/tenofovir disoproxil 200 mg/245 mg) for pre-exposure prophylaxis (PrEP) of HIV in either HIV-negative men or transgender women who have sex with men, or HIV-negative individuals in a heterosexual partnership with a person already infected with HIV. The conclusion of the summary was that PrEP “reduced the relative risk of acquiring HIV infection by between 44% and 86% compared with placebo or no prophylaxis, which is equivalent to approximate numbers needed to treat of between 13 and 68 per year”.

In 2017, NHS England announced funding for the 3-year [PrEP Impact implementation trial](#) to address outstanding questions including the need for, uptake of and duration of PrEP. By April 2020, over 21,000 individuals were enrolled on the trial with recruitment of up to 26,000 individuals by July 2020. Routine commissioning of PrEP services by local authorities is expected to commence during 2020. NHS England has committed to reimburse agreed PrEP drug costs.

Safety

The marketing authorisations for each relevant drug product covers side effects, contra-indications, drug interactions.

Implementation

Criteria

PrEP use will be reimbursed where all the following applies

- Local authority confirms it has commissioned a provider to offer PrEP services
- Decisions to offer PrEP are made by appropriately qualified members of the sexual health service following a clinical assessment and that ongoing monitoring is in accordance with the BASHH/BHIVA guidelines (2018)
- Generic TD-FTC is prescribed / supplied and approved in accordance with the appropriate provider arrangements for clinical governance. Drugs supplied must be from NHS England and Improvement’s approved drug supply framework.
- Data submission is in accordance with contract terms set out by both local authorities and NHS England.

Effective from

July 2020

In April 2020, government announced funding for local authorities to support routine commissioning of PrEP services during 2020/21. NHS England and NHS Improvement had already committed to reimburse PrEP drug costs within routinely commissioned local authority PrEP services from the end of the trial.

Requirements and recommendations for data collection

Mandatory data collection will be via the existing epidemiological surveillance system operated by Public Health England to monitor population level sexually transmitted infections (STIs) and HIV: [GUMCAD STI Surveillance System](#). Additional contractual data collection requirements to secure sufficient supply and support reimbursement will be set out in the local authority’s service specification and the NHS England contract reporting requirements.

Mechanism for funding

NHS England will reimburse the use of generic PrEP (TD-FTC) for eligible individuals as per the 2018 BHIVA recommendations within approved local authority commissioned PrEP services.

Excluded from this policy is reimbursement for the use of the 'reference' antiretroviral medicine licenced for PrEP (Truvada ®) or any other drug used as PrEP. Any service costs associated with PrEP are also excluded as these are commissioned by local authorities. Reimbursement for drugs sourced outside of NHS England and Improvement drug framework or issued via FP10s is also excluded from this policy.

Policy review date

This policy will be reviewed if required.

Links to other Policies

Policies relating to the treatment of HIV and 'treatment as prevention' can be found [here](#).

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities