Supplying generic PrEP (pre-exposure prophylaxis):
NHS England contract requirements 2020/21

Introduction

NHS England (NHSE) will reimburse only the use of generic Tenofovir Disoproxil (TD)/ Emtricitabine (FTC) which is bio-equivalent to the reference product (Truvada®) based on the following conditions:

1. Individuals supplied PrEP are assessed in local authority commissioned and approved sexual health clinics meeting the 2018 BHIVA/BASHH guidelines on the use of HIV PrEP and the standards set out in the LA service specification insert appended to either the Integrated Sexual Health Services – A suggested national service specification or the equivalent local service specification. This would include arrangements for audit; AND

2. Supply of PrEP is in line with the licence or provided off label for event-based dosing in accordance with established practice supported by clinical evidence and guidelines. These are to be reviewed regularly. Providers ensure appropriate governance is in place and followed for the prescribing or supply of PrEP. All incidents are reported in accordance with guidance from the MHRA; AND

3. All data relating to individuals supplied PrEP and the drugs they receive must be recorded accurately and in full. PrEP drugs supplied are recorded and reported to NHSE using the Drugs Patient Level Contract Monitoring (DrPLCM) (which must not be changed). Use of HIV drugs must be separately recorded for those with a) diagnosed HIV, b) those without HIV supplied *post* exposure prophylaxis (PEP), and c) those without HIV supplied (PrEP). Those receiving PrEP must also be recorded in GUMCAD in accordance with mandatory surveillance requirements; AND

4. PrEP drugs are made available in accordance with the usual arrangements for the GU service and any specific requirements set out by NHSE.

Exclusions

NHSE will not reimburse the use of PrEP drugs outside of the conditions listed above.

Other specific exclusions include:

- Reference drug (Truvada ®) or any other drug used for PrEP. These are not commissioned for this indication and will not be reimbursed.
- Claims for drugs not sourced from the NHSE approved HIV drug frameworks.
- PrEP supplied via an FP10 prescription.

Background

New prevention efforts are required to reduce the estimated 4,700 incident HIV infections occurring annually in England, of which 2,800 occur among men who have sex with men (MSM).

Tenofovir containing regimens used as HIV PrEP are highly effective at reducing HIV acquisition. The data from the PROUD trial in the UK reinforced the evidence for efficacy, though the relatively small sample prevented the results being generalised to all GU clinic attendees and left unanswered key questions about large-scale use of PrEP.

The PrEP Impact Trial was funded by NHSE and supported by local authorities to address these outstanding questions about PrEP, eligibility, uptake and duration of use of PrEP through expanding the assessment to the scale required to obtain sufficient data. The trial began enrolment in October 2017 and is due to complete enrolment in July 2020. There is a commitment to the seamless transition of access to PrEP from trial to routine access.

PrEP involves giving an HIV drug to people without HIV during periods of risk to prevent them catching HIV. The drug can be given on a daily basis or specific times around periods of risk. Identifying and engaging individuals at high risk of HIV – men who have sex with men (MSM), black Africans, and transgender men and women – is needed to maximise the potential benefits of PrEP to HIV prevention.

PrEP drug

Drug	Tenofovir Disoproxil (TD)/ Emtricitabine (FTC). Each film-coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (as maleate).
Route of administration	Oral
Regimen	Daily or event-based regimens (EBD). Daily involves taking 245 mg TD and 200mg FTC once a day. EBD will involve taking a double dose before sex and then single doses 24 and 48 hours after the initial dose.

Two prophylaxis schedules for PrEP are available for MSM and trans-women populations: daily PrEP or event-based dosing (EBD).

EBD cannot be recommended for heterosexuals and transgender men as this technology has not been assessed for effectiveness, nor for participants with active hepatitis B infection due to the risk of hepatic flares on withdrawal. Therefore, daily PrEP must be offered to these users.

Both drugs are nucleotide/side analogue HIV-1 reverse transcriptase inhibitors. The drug is UK licensed and used off label for event-based dosing in accordance with established practice supported by clinical evidence. It is bio-equivalent to the reference product (Truvada ®).

Supply of this medicine should be in line with the SmPC for Tenofovir Disoproxil (TD)/ Emtricitabine (FTC) and 2018 2018 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP).

Supply

It is recommended that 3 months be supplied when initiating or re-starting PrEP. After that longer supply may be given, in line with clinical guidelines and if arrangements are made for 3 monthly STI and HIV tests (either face-to-face or online). Quantity to supply will be defined by eligibility, expected usage and local commissioning framework.

Level 3 GU services with a pharmacy service will provide access via prescribing. Where a service does not have access to a pharmacy, registered healthcare professionals listed in the legislation may supply PrEP using a Patient Group Direction (PGD). A PGD is a written instruction which allows the administration or supply of a named medicine to an identified group of patients by certain registered healthcare professionals without the need for a prescription.

A national PGD template will be available to support the supply of PrEP by appropriate registered healthcare professionals in commissioned services in England. Provider organisations will need to clinically sign the PGD (doctor and pharmacist) and authorise its use via their own internal PGD governance procedures.

In all cases, a copy of the locally approved PGD, protocol, prescribers, delegation arrangements etc should be made available and be supported with the appropriate training.

In 2020/21, NHSE framework agreements for the supply of PrEP include the requirement for all PrEP to be 'over labelled' prior to despatch and delivery to clinic, ready for supply where PGDs are used. Specific guidance will be provided to clinics to advise them on how to access the medicine from the drug supplier contracted by NHSE for the supply of PrEP.

This arrangement may be subject to change in the future.

Safety and adverse events reporting

Information on serious suspected adverse drug reactions, including effects that are well recognised, will be reported through the 'Yellow card' system (https://yellowcard.mhra.gov.uk/).

Patient safety incidents that could have or did harm participants should also be reported through local incident reporting systems in line with routine clinical practice. Any safety events raised via the 'Yellow Card' system will also be documented by

services and a copy of the yellow card form (whether completed online or by paper) should be retained in all instances.

Local Authority Commissioned and Approved Sexual Health Services for the delivery of PrEP

There are around 200 Genitourinary Medicine (GUM) clinics in England which could potentially deliver PrEP, subject to local authority commissioner approval and provider intent. The aim is to establish a wide geographical spread of access.

Requirements have been set out in the national service specification, insert appended to either the Integrated Sexual Health Services – A suggested national service specification or the equivalent local service specification.

Users of PrEP with complex needs

Prescribing PrEP to individuals with active hepatitis B virus must be in line with the SmPC for Tenofovir Disoproxil (TD)/ Emtricitabine (FTC) and 2018 2018 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP).

There may be a small number of individuals unable to tolerate Tenofovir Disoproxil (TD)/ Emtricitabine (FTC) for other clinical reasons. NHSE commissions only TD/FTC for PrEP – no other medicines are commissioned. Proposals to develop clinical commissioning policies within the direct commissioning responsibility of NHS England should be sent to the Clinical Policy Team england.ncpt@nhs.net. Clinicians should support individuals in terms of options for HIV prevention.

Data Recording, handling and Information governance

Exceptionally and until March 2021, reimbursement for PrEP drugs will be made direct by NHS England to the manufacturers. However, return of data on PrEP drug usage remains mandatory in 20/21 in order that NHS England can ensure continuous and adequate supply of PrEP to meet clinic need. Failure to do so may result in a clinic being unable to secure supplies of PrEP needed to treat eligible service users.

Data relating to drug usage must be reported using the NHS England drugs patient level contract monitoring (DrPLCM) standard specification. Technical details and user guidance can be found here:

https://www.england.nhs.uk/publication/drugs-patient-level-contract-monitoring-drplcm-user-guidance-2/

Completion of the NHS NUMBER field in the data set is not expected. Population of the LOCAL PATIENT IDENTIFIER (EXTENDED) field with the GUMCAD patient identifier is however mandatory.

The following SNOMED CT code: 9103611000001103 (which is at the dm+d VMP level of taxonomy) relates to the official name 'Emtricitabine 200mg / Tenofovir 245mg tablets' and should be used to complete the 'HIGH COST TARIFF EXCLUDED DRUG

CODE (SNOMED CT DM+D)' field within the drugs patient level contract monitoring (DrPLCM) data submission so that correct drug usage can be monitored.

In addition to the SNOMED code, it is a further requirement that the data relating to drug usage must identify the medicine for the use in **'PREVENTION'** in the '**CONTRACT MONITORING ADDITIONAL DETAIL (FIRST)'** data element column within the contract monitoring datasets.

Data on users must be reported via GUMCAD and in accordance with local authority commissioner requirements.

Contact details
Queries relating to PrEP drug supply should be directed to mary-jo.pryor@nhs.net

Date produced: 30th June 2020
Date for review: 29th January 2021