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25th November 2019

Circular 044/19

HIV Pre-Exposure Prophylaxis (PrEP) - Frequently Asked Questions

Dear Pharmacist,

I refer to previous communication in relation to HIV Pre-Exposure Prophylaxis (PrEP) - Circular 41/19.

Please find enclosed some FAQs that have been developed to assist you. Pharmacies can contact Pharmacy Function directly where there is a query in relation to PrEP (Tel: 01-8647100) or email pharmacy.response@hse.ie.

Yours faithfully,

Shaun Flanagan

Primary Care Reimbursement & Eligibility



Frequently Asked Questions HIV Pre-Exposure Prophylaxis (PrEP)

1. What is HIV PrEP?

HIV Pre-Exposure Prophylaxis (PrEP) is the pre-emptive use of oral antiretroviral therapy (ART) in HIV negative people to reduce the risk of HIV infection. HIV PrEP consists of a fixed dose combination of oral emtricitabine/ tenofovir disoproxil 200mg/245mg film-coated tablets. The HSE has approved reimbursement under GMS and DPS with effect from the 4th November 2019.

2. Can all prescribers (hospital and GPs) prescribe PrEP?

No - clinical services can apply to the HSE Sexual Health and Crisis Pregnancy Programme (SHCPP) for approval as a PrEP service.

Currently, there are 8 public services and 6 private services authorised to prescribe free PrEP. An updated list of approved services can be found at: https://www.sexualwellbeing.ie/sexual-health/prep/where-to-get-prep/

Once a clinical service is approved, individual prescribers in this clinic can apply to register with PCRS for a Security Certificate. This process requires authorisation from the clinical lead prescriber and the Chief Pharmacist in the Pharmacy Function Unit at PCRS. Once approved, the prescriber will have access to the Special Drug Request (SDR) system to apply for reimbursement of PrEP for their patient.

3. Who is eligible for PrEP?

A person must meet clinical eligibility criteria and who are deemed to be at substantial risk of acquiring HIV. Persons should be reviewed on a regular basis in line with national guidelines and standards.

An approved prescriber must make an online application through the Special Drug Request (SDR) reimbursement application system for an eligible person to be approved for PrEP.

4. How much does the patient pay for PrEP?

PrEP is free of charge for all HSE clinically approved persons regardless of whether they have GMS/DPS eligibility. **This product is exempt from prescription charges for approved persons.**

5. Are applications reviewed by the PCRS on the new online reimbursement application system?

While visible to PCRS, applications are automatically approved and will not be reviewed unless valid eligibility under schemes cannot be established / finalised. In such circumstances, where a person

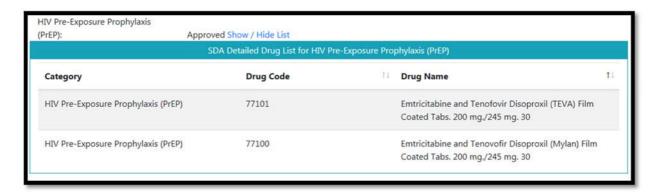
has been identified by the approved prescriber as clinically approved for access to the product free of charge, exceptional arrangements will be made by Pharmacy Function in PCRS to ensure reimbursement can be made at a person specific level to the dispensing pharmacy.

6. How will the pharmacy know if a patient has specific PrEP approval?

On the 'Secure Scheme Checker' on the Pharmacy Application Suite under 'Patient Specific Arrangements', the community pharmacy will be able to see the approval for HIV Pre-Exposure Prophylaxis (PrEP) and the drop down list to show the approved medicine (Emtricitabine/Tenofovir) and the administrative code.

Brand	Administration Code
Mylan	77100
Teva	77101

In order to be able to view this on the secure scheme checker, the person currently MUST have a valid community identifier. They will need a Drugs Payment Scheme (DPS) card or General Medical Services (GMS) card to access free PrEP from the HSE or be registered with PCRS under exceptional circumstances.



HSE is considering visibility for persons with PPSNs who cannot continue to full DPS eligibility due to their status in this country. (Usually students from Non-EU countries). In the interim, pharmacies can contact **Pharmacy Function (Phone: 01-8647100)** who will confirm the patients' approved status.

As always, Pharmacies can contact Pharmacy Function directly where there is an issue or email pharmacy.response@hse.ie.

7. Person only has a PPSN and no valid Community Drug Scheme?

Pharmacists can assist in registering persons for Express DPS but the person must complete the eligibility process for their 'Patient Specific' approval information to become seamlessly visible on the secure checker. Or the person can apply directly for a DPS card to www.mydps.ie. There may be exceptional circumstances in some cases and our processes remain under consideration in this regard as outlined in Question 6.

8. If the person is clinically approved but has no valid community drug scheme, will the pharmacy be paid?

Reimbursement claims submitted for persons who are not HSE approved will not be paid.

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However, those who have HSE clinical approval will be paid. Once the person has a valid DPS card or exceptional circumstances apply which are registered with PCRS and clinically approved, the pharmacy will be reimbursed from the date of HSE clinical approval.

9. What brands of emtricitabine/tenofovir are covered under the HSE PrEP scheme?

Teva brand and Mylan brand are the only two brands reimbursable under the HSE PrEP scheme at the agreed prices sent in Circular 41/19.

10. Is it necessary for dispensing of PrEP for a patient to present to a specific pharmacy?

No - all pharmacies are eligible to dispense PrEP. PrEP is patient specific rather than pharmacy specific.

11. What are the reimbursement arrangements for pharmacists?

The pharmacist will order the drug from the wholesaler as normal and will be reimbursed the ingredient cost plus the standard dispensing fee.

GMS approved patients do not require a GMS prescription from their GP. The patient must sign the Unified Claim Form (UCF) to confirm that they have received the service.

The top copy of the UCF is submitted with either the GMS or DPS claims bundle as supporting paper documentation using form number format. These claims are submitted in the normal manner.

12. How long does approval last for PrEP?

The approval period for PrEP dispensing will be for <u>six months from the date of application</u>. The prescriber has the opportunity to renew the application for a further six months if required. Most prescriptions will be for three months duration as monitoring within the clinical service is required.

13. Where can I access more information on HIV Pre-Exposure Prophylaxis?

Further information on the PrEP programme can be found on https://www.sexualwellbeing.ie/sexual-health/prep/.