**January 2022**

**Routine Commissioning for Post-Exposure Prophylaxis (PEP/PEPSE) standard 30-day Packs**

**Frequently Asked Questions**

1. **What are the reasons for changing to a 30-day standard PEP pack?**

There are 3 reasons for making this change:

1. There is evidence PEP course completion rates are lower when using starter packs as the individual needs to be motivated to reattend to collect the rest of the medication. We therefore recommend provision of the full 30-day course at the first attendance, even if some subsequently stop PEP after repeat risk assessment.
2. The procurement process of 30-day packs is more streamlined and cost-efficient so will result in cost savings for the NHS.
3. The manufacturer of raltegravir 600mg tablets does not support the product being put into starter packs due to a lack of stability data once they are removed from their original packaging.

**2. Where can we find the new guidelines?**

The new guideline is available here:

 <https://www.bashhguidelines.org/media/1289/pep-2021.pdf>

<https://www.bhiva.org/file/6183b6aa93a4e/PEP-guidelines.pdf>

1. **Can we still provide a starter pack for those people attending certain services, i.e. A&E, OH, SARC’s?**

For the reasons outlined above there is no reasonable justification for any service to provide starter packs. A 30-day pack should be provided to all individuals who require PEP. If at the time of follow-up, the decision is made to discontinue PEP then the remaining drugs can be returned to any pharmacy.

**4. Do we still need to refer patients for specialist follow-up if they initiated on a 30-day pack in a non-specialist service?**

All patients receiving PEP need to have early follow-up to review their baseline blood results, revisit the risk assessment with any new information that has come to light about the index case, and to review adherence to the PEP drugs and any side-effects. The service providing this early follow-up will vary depending on whether

this is a sexual exposure or an occupational exposure and the local PEP pathway. If the 30-day pack has been provided at the outset, then the early follow-up can take place by phone or face to face.

**5. What is the national expectation about when the change to order and supply of the new standard 30-day PEP pack (once daily dosing) comes into effect?**

The new contract for the standard PEP pack will commence on **1st February 2022**. However, due to current service pressures, we recognise that it might take time to train staff and implement the new packs. Also, it will take a number of weeks for the new supplier to have the packs ready for supply.

The table below sets out the expected dates for transitioning to this new arrangement for routine commissioning of the 30-day PEP packs.

|  |  |
| --- | --- |
| **Service** | **Transition Date** |
| Level 3 Sexual Health Services | End of March 2022 |
| Occupational Health | April 2022 |
| Sexual Assault and Referral Centres | April 2022 |
| Accident and Emergencies | July 2022 |

**6. How does our service access the current packs whilst transitioning to the new 30-day packs?**

Services should continue to buy the packs from the current supplier but note that these will not be ‘free’ at point of purchase

**7. Will there be sufficient packs until the service transitions?**

Services should liaise with the current supplier to order and stock sufficient packs until you transition.

**8. What will happen to packs that are not used by the transition deadline?**

Trusts and clinics should plan to use up all existing stock to avoid wastage.

**9. How can services access the new PEP packs?**

Services can access the new PEP packs from the **1st March 2022**, if you normally order medicines from an NHS hospital pharmacy, then continue to do so and ask them to set up the new order system with Mawdsleys.

Non-NHS services can access PEP packs by placing orders directly with Mawdsleys Clinical Services in place of their current supplier.

NHS Hospital Pharmacies and non-NHS services will need to set up an account up by contacting customer services on:

e-mail: overlabellingcustomerservices@mawdsleys.co.uk

Telephone: 01302 553010

Services will be issued with further easy to follow guidance on how to order.

**10. What will be included in the PEP pack?**

The sealed bag will contain a 30-day pack of co-formulated emtricitabine 200 mg/ tenofovir disoproxil 245 mg, a 30-day pack of raltegravir 600mg tablets and a patient information leaflet explaining how to take PEP.

<https://hivpa.org/wp-content/uploads/2021/04/HIVPA-PEP-PIL-April-2021-generic-TDF-FTC-RAL-OD-Final.pdf>

**11. Will services be reimbursed for non- standard packs during the transition?**

Yes, services will continue to be reimbursed for PEP packs until the transition date outlined above.

**12. How will services get reimbursed after the transition date?**

The same process for reimbursement will apply as per the current PEP packs. Services will need to submit and invoice to NHSEI for reimbursement.

**13. Is there a minimum/maximum order quantity?**

**Minimum/maximum orders**

Mawdsleys do not apply a delivery cost for orders of 30 packs or more. Therefore, a minimum order volume (MOV) of 30 packs is requested unless this amount seems excessive and is likely to go out of date before being used.

If only a small number of packs are needed, the minimum order volume is 10 packs.

**14. Is there a national PGD like PrEP, if so, where can I access this?**

Yes, the PGD can be found here:

[**https://www.sps.nhs.uk/articles/supply-of-emtricitabine-tenofovir-disoproxil-and-raltegravir-tablets-for-hiv-post-exposure-prophylaxis-hiv-pep-pgd-template/**](https://www.sps.nhs.uk/articles/supply-of-emtricitabine-tenofovir-disoproxil-and-raltegravir-tablets-for-hiv-post-exposure-prophylaxis-hiv-pep-pgd-template/)

 **15. Our service usually submits data via the DrPLM for reimbursement, do we need to continue now that the packs are being provided free of charge?**

Data will need to be provided either through DrPLM or GUMCAD. Further details on this requirement will be provided in the next few weeks.