NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Emtricitabine/Tenofovir Disoproxil And Raltegravir Tablets For HIV Post Exposure Prophylaxis (HIV PEP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland And Western Isles

Lead Author: Adapted From FSRH/SPS Patient Group Direction (PGD) For The Supply Of Emtricitabine/Tenofovir Disoproxil And Raltegravir Tablets For HIV Post Exposure Prophylaxis (HIV PEP), Version 2, August 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/HIV_PEP/1579	**Review Date:** February 2027 **Expiry Date:** July 2027	**Date Approved by NoS:** 17th July 2025

NHS Grampian, Highland, Orkney, Shetland, and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History for NoS:

NoS PGD that has been adapted and/or superseded	New PGD	
Date of change	**Summary of Changes**	**Section heading**
August 2021	Version 1.0 was never published in NoS.	
August 2022	Version 1.1 was never published in NoS.	
September 2024	New PGD for NoS.	
September 2024	Reference to NoS Appendix 1 and 2.	Authorisation
September 2024	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
September 2024	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
September 2024	Statement added about gender based violence and welfare.	Cautions including any relevant action to be taken
September 2024	NICE Competency framework statement removed.	Competency assessment
September 2024	Statement added about over labelled stock.	Legal Category
September 2024	Added clinical systems utilised.	Records
September 2024	HEPMA added.	Records
November 2024	Advice added about problems if unable to swallow raltegravir tablets whole.	Advice
March 2025	Duration of treatment changed to 30 days as per HIV and SH Lead Clinicians group. .	Throughout
March 2025	Reference added for BHIVA recommendations.	References
May 2025	SPS PIL removed and PHS PIL added as Appendix 3.	Written information and further advice to be given to individual

FSRH/SPS most recent changes

Change History	
Version and Date	**Change details**
Version 1.0 August 2021	New template.
Version 1.1 August 2022	Updated to included advice on interaction between PEP and antacids/multi vitamin and mineral preparations and management of this interaction.
Version 2 August 2024	Reviewed PGD. Updated supply quantity. Removed statements relating to use in pandemic and starter packs. Amended statement related to intolerance of sugars. Removed trade names where generic product available. Updated members of SLWG for PEP and SH. Updated links and references.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by SPS/FSRH/BHIVA and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Daniela Brawley	Signature	Daniela Brawley	Date Signed	26/05/2025
Pharmacist	Jennifer cooper	Signature		Date Signed	26/05/2025
Nurse	Julia Penn	Signature	Julia Penn	Date Signed	02/06/2025

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		11/06/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		17/07/2025

Version 2 – Approved for NoS from 17th July 2025

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	August 2024
Review date	February 2027
Expiry date:	July 2027

This PGD template has been peer reviewed by the PEP for SARCs PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British HIV Association (BHIVA), British Association for Sexual Health and HIV (BASHH) in Feb 2024.

This section must remain when a PGD is adopted by an organisation.

Name	Designation
Abe Hamoodi	Health and Justice Public Health Specialist NHS England (North East)
Denise Farmer	National Pharmaceutical Adviser Health and Justice, Specialised Commissioning, NHS England
Dipti Patel	Pharmaceutical adviser, Mountain Healthcare Limited
Dr Helen Mills	Clinical Director, Saint Mary's Sexual Assault Referral Centre, Manchester
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service
Paula Wilkinson	Chief Pharmacist G4S Health Services, G4S Care and Justice
Portia Jackson	Lead Pharmacist iCaSH, Cambridgeshire Community Services
Rosie Furner (SLWG co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service
Kieran Reynolds	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Emma Campbell	Forensic Nurse Examiner, Willow Tree SARC Manager

The PGD has also been reviewed by members of the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British HIV Association (BHIVA) and the British Association for Sexual Health and HIV (BASHH) in February 2024.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community Pharmacy
Amy Moore	Principal Pharmacist, The Wolverton Centre, Kingston Hospital NHS Foundation Trust
Chetna Parmar	Pharmacist Adviser, Umbrella

Glossary

ART	Anti-Retroviral Therapy
BASHH	British Association for Sexual Health and HIV
BHIVA	British HIV Association
eGFR	Estimated Glomerular Filtration Rate
GUM	Genitourinary Medicine
HIV	Human Immunodeficiency Virus
PEP	Post Exposure Prophylaxis
RCN	Royal College of Nursing
STI	Sexually Transmitted Infection

1. Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals leading to an assessment of risk of infection of the condition listed. The registered healthcare professional authorised to operate under this PGD must have experience in the delivery of emergency or unplanned care in primary/secondary including, as relevant occupational health, sexual health medicine and/or the pre-hospital care setting, including forensic medicine. Recommended requirement for training would be successful completion of a HIV PEP specific relevant module/course accredited or endorsed by BHIVA, BASHH, RCN or a university or advised in the RCN Sexual Health Education directory. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see Appendix 1 and Appendix 2).
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	HIV Post-Exposure Prophylaxis (HIV PEP).
Criteria for inclusion	• Individuals 40kg or greater in weight, presenting within 72 hours of potential HIV exposure risk as per BASHH UK Guideline for the use of HIV Post-Exposure Prophylaxis 2021. • Aged 13 years and over. All individual under the age of 18 years - follow local young person's risk assessment or equivalent local process. • Individuals under 16 years of age may give consent for the administration of PEP, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment. • Individual able and willing to attend either a face to face or telephone follow up appointment with relevant GUM/Sexual Health/HIV clinic within 3 days of PEP being started. In exceptional circumstances where access to a clinic follow up may be delayed due to bank holiday etc, this must be within 5 days.
Criteria for exclusion	• Consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Individuals under 40kg in weight. • Individuals presenting following potential HIV exposure more than 72 hours ago. • Individuals where there is evidence that the index case has a current or past history of anti-retroviral therapy (ART) failure.

	• Known hypersensitivity or allergy to emtricitabine, tenofovir disoproxil, raltegravir or to any component of the product - See current product Summary of Product Characteristics (SPC) for active ingredients and excipients. • Individuals are excluded if they are: ○ known to be HIV positive ○ already being treated with anti-retroviral medication ○ known renal impairment where eGFR less than 50mL/minute ○ known hepatitis B infection, liver impairment or disease ○ immunocompromised ○ known pregnancy ○ breastfeeding ○ known to have rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the SPC before supplying ○ already receiving medication which interacts with anti-retroviral medication and defined as a rating of 'Red' when assessed on Interaction charts produced by the Liverpool HIV Pharmacology Group http://www.hiv-druginteractions.org - see 'Drug Interactions' section ○ currently taking antacids containing aluminium, calcium carbonate and magnesium either regularly or as required – PEP may be supplied if individual advised and willing/able not to take these products for duration of PEP course (30 days) ○ taking multivitamins/other supplements containing iron, aluminium, calcium, magnesium and zinc either regularly or otherwise – PEP may be supplied if individual advised and willing/able not to take these products for duration of PEP course (30 days).
Cautions including any relevant action to be taken	• Individuals with significant psychiatric illness: ○ Consider contact with mental health team/GP if possible ○ Advise individual of risks and also get consent to discuss with their GP/mental health team that they have been given PEP and will need to be monitored to ensure mental health does not deteriorate ○ For individuals who are not monitored, recommend that they should see their GP within next few days to discuss mental health

	○ Highlight to the referral team that the individual has a pre-existing mental health condition • Any gender based violence, child protection and welfare issues or adult protection concerns should be referred through the appropriate channels • Individual already receiving medication which interacts with anti-retroviral medication defined as an 'Amber' rating when assessed on Interaction charts produced by the Liverpool HIV Pharmacology Group http://www.hiv-druginteractions.org or where an interaction check is not available via this resource. See 'Drug Interactions' section • Discuss with an Independent Prescriber regarding conditions/medicines/side effects of which the health care professional is unsure.
Action to be taken if the individual is excluded or declines treatment	• If declined, ensure individual is aware of the reasons this medication has been offered and the potential consequences of not receiving it. Record reason for declining in record. • Weight under 40kg does not preclude the use of HIV PEP but the individual should be referred to a prescriber for consideration of suitability/an alternative regime. • PEP is generally not recommended beyond 72 hours post-exposure. Any decision on initiation of PEP more than 72 hours after the exposure should be left to the discretion of clinicians in discussion with the exposure recipient, in full knowledge of the lack of evidence of efficacy after this time point. In this circumstance PEP would need to be prescribed – it cannot be supplied under this PGD. • If eGFR known to be less than 50mL/minute - refer to a prescriber for further investigation and consideration of PEP. • Known hepatitis B does not preclude the use of HIV PEP but the individual should be referred to a prescriber. • Pregnancy does not preclude the use of HIV PEP but the individual should be referred to a prescriber. • Breast feeding does not preclude the use of HIV PEP but the individual should be referred to a prescriber. • If excluded, explain the reasons for exclusion to the individual and document in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength and formulation of drug	Emtricitabine 200mg/tenofovir disoproxil 245mg tablet	Raltegravir 600mg tablet (e.g. Isentress®)
Legal category	POM	POM
	In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.	In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Route of administration	Oral	Oral
Dose and frequency of administration	One tablet once daily	Two x 600mg tablets (1200mg) once daily
Duration of treatment	30 days.	
Quantity to be supplied (Note both emtricitabine/tenofovir disoproxil and raltegravir tablets must be supplied)	Appropriately labelled pack of 30 x emtricitabine 200mg/tenofovir disoproxil 245mg tablets	Appropriately labelled pack of 60 x raltegravir 600mg tablets
Identification of adverse reactions	A detailed list of adverse reactions is available in BNF or the product SPC. The following side effects are reported as common with emtricitabine/tenofovir disoproxil: • diarrhoea, vomiting, nausea • dizziness, headache • feeling weak • pain, stomach pain • difficulty sleeping, abnormal dreams	A detailed list of adverse reactions is available in BNF or the product SPC. The following side effects are reported as common with raltegravir: • decreased appetite • abnormal dreams, insomnia, nightmare • abnormal behaviour • depression • dizziness, headache • psychomotor hyperactivity • vertigo

	• problems with digestion resulting in discomfort after meals, feeling bloated, flatulence • rashes (including red spots/ blotches sometimes with blistering and swelling of the skin) which may be allergic • itching, changes in skin colour including darkening of the skin in patches • other allergic reactions, such as wheezing, swelling or feeling light-headed • swelling of the face, lips, tongue or throat.	• abdominal distention, abdominal pain, diarrhoea, flatulence, nausea, vomiting, dyspepsia • rash • asthenia • fatigue • pyrexia.
Drug interactions	All concurrent medications should be reviewed for interactions. Interactions which mean the named medicines **must not be supplied under this PGD** are defined as 'Red' rating when assessed on the interaction charts produced by the Liverpool HIV Pharmacology Group http://www.hiv-druginteractions.org. Refer individual to a prescriber. Where an interaction is defined as 'Amber' rating when assessed on the interaction charts produced by the Liverpool HIV Pharmacology Group http://www.hiv-druginteractions.org discuss with a relevant prescriber or pharmacist to confirm suitability of supply. Refer individual to a prescriber where supply not suitable within parameters of this PGD. **Note:** The following are exclusions to supply under this PGD due to risk of compromisation of raltegravir absorption: • Antacids containing aluminium, calcium carbonate and magnesium. • Multivitamins/other supplements containing iron, aluminium, calcium, magnesium and zinc. Discuss with a relevant prescriber or pharmacist to confirm suitability of supply in all cases where an interaction is not available on the interaction charts produced by the Liverpool HIV Pharmacology Group http://www.hiv-druginteractions.org.	

	Refer individual to a prescriber where supply not suitable within parameters of this PGD.
Off label use	Best practice advice is given by BHIVA/BASHH and the Faculty of Forensic and Legal Medicine (FFLM) is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). **Off label use included within this PGD:** • The named medicines within the PGD do not include PEP within their licenced indications – guidance supports their use. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	• Individual should be advised that total course length is 30 days. • Advise that a patient information leaflet (PIL) is provided with the original pack. **Note:** The regime being taken may not reflect that detailed in the PIL (see Appendix 3). Please print and give to the patient.

	• Explain mode of action, side effects, and benefits of the medicine. • PEP should be commenced as soon as possible after exposure, allowing for careful risk assessment, ideally within 24 hours. • Ensure individual is counselled as to dosage regimen. • Advise individual not to miss any doses of the tablets; this may increase the chance that the treatment doesn't work. • Advise if individual is concerned about any side effects they experience they should contact their clinic as soon as possible. • Advise individuals to contact their clinic for urgent review to exclude an HIV seroconversion if they experience a skin rash or flu-like illness during, or after completing their course of PEP. • Advise individuals that PEP medicines may interact with other medicines, including medicines purchased over-the-counter and some supplements and herbal remedies. These include: o Calcium, iron, magnesium, aluminium and zinc which can be found in indigestion remedies, vitamins and mineral tablets. These can prevent raltegravir from being absorbed so should not be taken. **Advise individual that these must not be taken for the duration of the PEP course (30 days).** • Advise individuals to seek advice on any new medicines commenced whilst taking PEP (including over the counter medicines) from a prescriber/pharmacist to check for interactions. • Advise that PEP is not a contraceptive. • Advise on use of condoms until result of final HIV test known (minimum of 73 days/10.5 weeks after exposure assuming full 30 PEP course is completed). **Emtricitabine/tenofovir disoproxil tablets only** • If needed, the tablets can be dispersed in approximately 100mL of water, orange juice or grape juice and taken immediately. • It is preferable that these tablets are taken with food. • If a dose is missed within 12 hours of the time it is usually taken, the dose should be taken as soon as possible and the normal dosing schedule should be resumed. If a dose is missed by more than 12 hours and it is almost time for the next dose, the missed dose should not be taken and the usual dosing schedule should be resumed.

	• If vomiting occurs within 1 hour of taking the tablet, another tablet should be taken. If vomiting occurs more than 1 hour after taking the tablet a second dose should not be taken. **Raltegravir tablets only** • Tablets can be administered with or without food. The tablets **should not** be chewed, crushed or split due to anticipated changes in the pharmacokinetic profile. • Refer to HIV specialist pharmacist input if unable to swallow raltegravir tablets whole.
Follow up treatment	• Individuals must be referred to a relevant HIV, GUM, Sexual Health or infectious disease departments for regular clinical follow-up during the period of PEP, to monitor possible toxicity and adherence to the anti-retroviral regimen. • Individuals exposed to HIV should have follow-up counselling, post-exposure testing and medical evaluation whether or not they have received PEP under this PGD. • Final HIV testing is recommended at a minimum of 45 days after the PEP course is completed. If the 30 day course is completed, this is a minimum of 73 days (10.5 weeks) after exposure. For sexual exposures this can be performed at 12 weeks to align with syphilis testing – advise individual on appropriate appointment schedule/s. • Advise that it may take 14 days for a chlamydia test to show a positive result after infection and 3 months for hepatitis B, C or syphilis tests to show positive results – advise individual on appropriate testing appointment schedule/s. • Individuals should be advised of signs of infection with any STI and if symptoms of infection develop they should seek medical advice. • **Follow up appointments with the individual should be arranged in line with local care pathway.**
Records	**Record:** • The consent of the individual and/or o If individual is under 16 years of age document capacity using Fraser guidelines o If individual is under 13 years of age and not competent, record action taken o If individual is under 16 years and not competent, record action taken

	○ If individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where available/appropriate • Relevant past and present medical history • Relevant medication history (to include over the counter, herbal medications, supplements and recreational drug use) • Examination or microbiology finding/s where relevant • Any known allergies • Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including, dosing regimen, side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD). Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed January 2024)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • BASHH UK Guideline for the use of HIV Post-Exposure Prophylaxis 2023 BASHH PEPSE guidelines • BASHH UK Standards for the Management of Sexual Health in UK Prisons 2023 3079_prison_standards_bashh_1_final.pdf • BHIVA UK Guidelines for the use of HIV Post-Exposure Prophylaxis BASHH PEPSE guidelines

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Emtricitabine/Tenofovir Disoproxil And Raltegravir Tablets For HIV Post Exposure Prophylaxis (HIV PEP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland And Western Isles, Version 2

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Emtricitabine/Tenofovir Disoproxil And Raltegravir Tablets For HIV Post Exposure Prophylaxis (HIV PEP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland And Western Isles, Version 2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Emtricitabine/Tenofovir Disoproxil And Raltegravir Tablets For HIV Post Exposure Prophylaxis (HIV PEP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland And Western Isles, Version 2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

HIV POST EXPOSURE PROPHYLAXIS (PEP)

INFORMATION FOR PATIENTS - 30 DAY PACK

READ THE INFORMATION IN THIS LEAFLET CAREFULLY BEFORE TAKING ANY MEDICATION IN THIS PACK. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT ANYTHING PLEASE ASK THE PRESCRIBER.

You must tell the prescriber if you:

- Have diabetes
- Have a history of anaemia
- Have kidney disease
- Have liver disease
- Have any history of pancreatitis
- Are pregnant or breastfeeding
- Have allergies to any medication
- Are taking any other medication for example:

Prescribed medication from GP or hospital	Including inhalers and nasal sprays
Over the counter medication from pharmacy, supermarket or health food shops	E.g. vitamins, indigestion remedies and herbal supplements
Medication and supplements bought online	E.g. gym supplements
Recreational drugs	E.g. cannabis or cocaine

What is post exposure prophylaxis (PEP)?

PEP is a course of medicines taken to reduce the risk of a person becoming infected with HIV after they may have come into contact with the virus.

What is HIV?

HIV stands for Human Immunodeficiency Virus. It is a virus which attacks the body's immune system.

Is PEP effective?

- It is important to remember that in most circumstances the risk of actually catching HIV from either a single needle stick injury or sexual act is small.
- Taking the 30 day course of anti-HIV medication should make that risk even smaller.
- PEP should be started as soon as possible after risk of contact with the virus and always within 72 hours of contact.
- All the tablets should be taken as prescribed at regular intervals

How will I know PEP has worked?

You will have follow up appointments during your treatment and HIV tests after treatment. These appointments are important as PEP does not reduce risk of transmission to zero. Please make sure you know where to attend for follow up.

How do I take the medication?

This pack contains a ***30*** day supply of two anti-HIV medications which need to be taken together as prescribed. It is important that you complete the course as prescribed and also attend for follow up appointments. Please contact your follow up clinic if you have any issues taking this medication.

Tenofovir disoproxil 245mg/Emtricitabine 200mg Tablets x **30**

Raltegravir 600mg Tablets x **60**

Tenofovir disoproxil 245mg/Emtricitabine 200mg	Take ONE tablet immediately then ONCE daily at same time each day	Take with food or light snack if possible	Most common side effects include diarrhoea, vomiting, nausea, dizziness, headache, rash, weakness, difficulty sleeping, abnormal dreams stomach discomfort, bloating and flatulence
Raltegravir 600mg Tablets	Take TWO tablets immediately then take TWO tablets ONCE daily at same time each day	Swallow whole do not crush or chew. Can be taken with or without food	Most common side effects include Decreased appetite, trouble sleeping, dizziness, headache, bloating, diarrhoea, nausea, vomiting, rash, weakness, fever and change in mood.

- If you have a rash or any sign of allergy seek medical advice
- Further information on side effects can be found in the medication packaging but most side effects during PEP should be mild and improve as the course continues. However if you feel you are experiencing severe side effects please contact your follow up clinic.

What do I do if I forget to take a tablet or I am sick?

It is important to try not to miss any doses as taking these medications regularly will improve the chance of them working. If you do miss a dose take it as soon as you remember then continue with normal dose times. If it is nearly time for the next dose when you remember then don't take the forgotten dose and continue as usual, do not take double doses to make up for a missed dose.

If it is more than 48 hours since you have last taken a dose then please contact your follow up clinic to discuss. Depending on the reason for missing doses then PEP medicines may need to be changed or stopped.

If you vomit within 2 hours of taking your medication then take the dose again.

Can I take other medicines?

The health professional reviewing you for PEP will check that there are no problems with other medicines or supplements you are taking and the medicines in this pack.

Calcium, iron, zinc, magnesium and aluminium which can be found in indigestion remedies, some medicines, vitamins and mineral tablets can stop you from absorbing raltegravir properly. Ideally these should not be taken while you are taking post exposure prophylaxis treatment. If they cannot be stopped then please check with a pharmacist about timing of doses.

Always check with a doctor, pharmacist or nurse before starting any new medicines during the treatment.

What else do I need to know?

- Make sure you know how your follow up will be arranged for you.
- Do not donate bloods and use condoms with all sexual partners while you are being treated and until you have your results of your final HIV test.

Adapted from HIVPA/BHIVA/BASHH PEP leaflet
and NHS Board leaflets for NHS Scotland
Drafted by: Scottish HIV Pharmacists Group
Approved by: HIV and SH Lead Clinicians
Reviewed by Scottish HIV Pharmacist Group Date: 12/2024
Next Review Date: 12/2027