NHS Grampian NHS Highland NHS Shetland NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets As Pre-Exposure Prophylaxis (PrEP) For The Prevention Of HIV Infection Within NHS Grampian, Highland, Shetland And Western Isles

Lead Author: Adapted from BASH/BHIVA/BIA/SPS Supply of emtricitabine 200mg/tenofovir disoproxil 245mg as Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV infection, Version 2 – Published June 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/PrEP/1451	**Review Date:** November 2025 **Expiry Date:** May 2026	**Date Approved by NoS:** 29th April 2024

NHS Grampian, Highland, 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NoS PGD that has been superseded	NoS/PGD/PrEP/MGPG1200, Version 2.1	
Date of change	**Summary of Changes**	**Section heading**
November 2023	Reference to NoS Appendix 1 and 2.	Authorisation
November 2023	Statement added in about nurses being registered by the NMC.	Professional registration
November 2023	Removed SPS advised training and added TURAS NoS PGD training link added. Amended safeguarding training in keeping with other PGD.	Initial Training
November 2023	NICE Competency framework statement removed.	Competency assessment
November 2023	Statement added about under 16 years and having capacity.	Criteria for inclusion
November 2023	Statement added as per NHSG.	Follow-up
November 2023	Added clinical systems utilised.	Records
January 2024	NES module training added.	Initial Training
January 2024	MSM terminology updated to GBMSM.	Throughout
January 2024	NHS Inform website added to list.	Written information and further advice to be given to individual
February 2023	Local authority statement removed.	Qualifications and professional registration

FSRH/SPS most recent changes

Change History	
Version and Date	**Change details**
Version 1.0 July 2020	New template.
Version 1.1 December 2020	Inclusion criteria amended in line with updated BHIVA/BASHH/BIA Adult HIV Testing guidelines 2020: • Either documented negative combined HIV antigen/antibody test in the last four weeks or outside of the four week window period after last risk. **Amended to:** • Either documented negative combined HIV fourth-generation antigen/antibody test in the last 45 days or outside of the 45 day window period after last risk. Inclusion criteria amended to align with BASHH/BHIVA guidance (previously reflected Impact trial criteria): A. Men (cisgender and transgender) and transgender women who: 1. Have sex with men. 2. Report condomless intercourse (excluding oral) in the previous 3 months. 3. Affirm their likelihood of having condomless intercourse (excluding oral) in the next 3 months. **Amended to:** A. Men (cisgender and transgender) and transgender women who: 1. Have sex with men. 2. Report condomless intercourse (excluding oral) in the previous 6 months. 3. Affirm their likelihood of having condomless intercourse (excluding oral).
Version 1.2 July 2021	Inclusion criteria separated into initiation and continuation to clarify specific testing requirements.
Version 2.0 June 2023	Updated template – rewording in inclusion criteria to improve clarity of testing requirements.

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 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 administer 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 Medicines supplied 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	Daniela Brawley	Signature	Daniela Brawley	Date Signed	19/03/2024
Pharmacist	Alison Jane Smith	Signature		Date Signed	11/03/2024
Nurse	Julia Penn	Signature	Julia Penn	Date Signed	14/03/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		15/04/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		29/04/2024

Version 2 – Approved for NoS from 29th April 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	June 2023
Review date	November 2025
Expiry date:	May 2026

This PGD template has been peer reviewed by the PrEP PGD 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 December 2022.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Belinda Loftus	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Chetna Parmar	Pharmacist adviser, Umbrella
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Vice President, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Specialist Nurse
Dr Rachael Jones	Consultant in HIV and Sexual Health, Chelsea and Westminster NHS Foundation Trust
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Associate Specialist
Dr Michael Brady	HIV consultant at King's College Hospital NHSEI national advisor for LGBT health
Dr Killian Quinn	Clinical Lead for Sexual Health Services King's College Hospital
Odelia Eke	Pharmacist, NHSE Specialised Commissioning
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms, Medicines Use and Safety, Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jonathan O'Sullivan	Commissioner
Luke Byron-Davies	London Sexual Health Programme
Martin Murchie	Sexual Health Adviser
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Nadia Naous	Pharmacist, Chelsea and Westminster NHS Foundation Trust
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service

Glossary

HIV	Human Immunodeficiency Virus
STI	Sexually Transmitted Infection
ART	Anti-Retroviral Therapy
eGFR	Estimated Glomerular Filtration Rate
BHIVA	British HIV Association
BASHH	British Association for Sexual Health and HIV
RCN	Royal College of Nursing
CPPE	Centre for Postgraduate Pharmacy Education
MSM	Men who have sex with men
POCT	Point of Care test
POM	Prescription only medicine
PrEP	Pre-exposure prophylaxis

Inclusivity

In line with BHIVA guidelines for PrEP this PGD recognises the importance of the PGD being inclusive and relevant to all, regardless of sexuality or gender identity or expression.

For the sake of brevity in the main text of the guidelines, phrases such as ‘gay, bisexual and other men who have sex with men (GBMSM)’ refer to cis-gender or non-binary or gender-queer men who have sex with men and ‘heterosexual men and women’ refers to cis-gender, non-binary or gender-queer men and women who have heterosexual sex.

Where sections are specifically relevant to trans people, we identify this using the terms trans people, trans men or trans women.

1. Characteristics of staff

Qualifications and professional registration	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
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 diagnosis of the conditions listed. 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 or level 2 safeguarding or the equivalent. Recommended requirement for training would be successful completion of a PrEP specific relevant module/course accredited or endorsed by BHIVA, BASHH, CPPE, RCN or a university or as advised in the RCN Sexual Health Education directory and HIV pre-exposure prophylaxis (HIV PrEP) Scotland | Turas | Learn (nhs.scot)
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete a self-declaration of competence for HIV testing and management of prevention of infection.
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	• Pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in individuals at high risk.
Criteria for inclusion	**At Initiation Of PrEP** Individuals who are eligible for PrEP according to the following national eligibility criteria: ➢ Aged 15 or over; all individuals under the age of 18 years - follow local young person's risk assessment or equivalent local process. ➢ Individual under 16 years of age may give consent for the supply of emtricitabine 200mg/tenofovir disoproxil 245mg, 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. ➢ Either documented negative combined HIV fourth-generation antigen/antibody test in the last 45 days or outside of the 45 day window period after last risk. **If combined HIV fourth-generation antigen/antibody test result in the last 45 days is not available on the day** then a non-reactive rapid blood-based HIV POCT is advisable on the day of PrEP initiation and a laboratory HIV fourth-generation antigen/antibody test **must** be sent on the day; PrEP can be supplied, assuming all other criteria are met, but the result must be reviewed as soon as possible. ➢ Willing and able to test for HIV and other STIs on a 3 monthly basis as part of PrEP care. ➢ Able to access at least 6 monthly review for safety and adherence monitoring, sexual health care and support. Plus **one or more** of the following additional criteria from A, B **or** C:

A. Men (cisgender and transgender) and transgender women who:

1. Have sex with men.
2. Report condomless intercourse (excluding oral) in the previous 6 months.
3. Affirm their likelihood of having condomless intercourse (excluding oral).

B. HIV negative partners of an HIV positive person when:

1. The HIV positive partner is not known to be virally suppressed (on ART for at least 6 months with a viral load of <200 copies/mL).
2. Condomless intercourse (excluding oral) is anticipated before the HIV positive partner has been on ART for at least 6 months and is virally suppressed.

C. HIV negative persons who are clinically assessed and considered to have current factors that may put them at increased risk of HIV acquisition.

At Continuation Of PrEP

Individuals continue to be eligible for PrEP according to the following national eligibility criteria:

- Aged 15 or over; all individuals under the age of 19 years - follow local young person's risk assessment or equivalent local process.
- A negative combined HIV fourth-generation antigen/antibody test in the past 3 months. If this is performed at the point of PrEP continuation, the PrEP can be supplied, assuming all other criteria are met, but the result must be reviewed as soon as possible.
- Willing to continue to test for HIV and STIs on a 3 monthly basis as part of PrEP care.
- Able to access at least 6 monthly review for safety and adherence monitoring, sexual health care and support.

Plus **one or more** of the following additional criteria from A, B **or** C:

A. Men (cisgender and transgender) and transgender women who:

1. Have sex with men.
2. Report condomless intercourse (excluding oral) in the previous 6 months.
3. Affirm their likelihood of having condomless intercourse (excluding oral).

	B. HIV negative partners of an HIV positive person when: 1. The HIV positive partner is not known to be virally suppressed (on ART for at least 6 months and have a viral load of <200 copies/mL). 2. Condomless intercourse (excluding oral) is anticipated before the HIV positive partner has been on ART for at least 6 months and is virally suppressed. **C. HIV negative persons who are** clinically assessed and considered to have current factors that may put them at increased risk of HIV acquisition. For information on how to assess those at increased risk of HIV see Section 5.1 of the BHIVA/BASHH PrEP guidelines: 'How to identify those at risk of HIV'.
Criteria for exclusion	• Consent not given. • Individuals under 15 years of age. • 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. • Known hypersensitivity or allergy to emtricitabine or tenofovir disoproxil or to any component of the product - See current Summary of Product Characteristics (SPC) for active ingredients and excipients. • Individuals are excluded if they: ➢ Do not meet all the national eligibility criteria and at least one of the additional eligibility criteria as detailed in the inclusion section ➢ Have an acute viral illness at enrolment or within the last month that could represent HIV seroconversion ➢ Known to be HIV positive ➢ Renal impairment where eGFR is less than 60mL/minute ➢ Known hepatitis B infection ➢ Proteinuria ++ or +++ on urinalysis ➢ Osteoporosis ➢ Known liver impairment or disease ➢ Immunocompromised individuals ➢ Individuals who are pregnant or breastfeeding ➢ Hereditary galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption ➢ Are concomitantly taking any of the following drugs: ▪ emtricitabine ▪ tenofovir (all salts) ▪ adefovir dipivoxil

	▪ lamivudine and other cytidine analogues ▪ cidofovir and other medicines that compete for active tubular secretion.
Cautions including any relevant action to be taken	• Adults with renal impairment: Individuals with eGFR 60-90mL/minute - monitor renal function more frequently in line with BHIVA / BASHH guidelines. • If proteinuria + on urinalysis at baseline, send a sample for urine protein/creatinine ratio and blood for eGFR and discuss the results with a prescriber but proceed with supply pending result. • Individuals with lower bone mineral density (BMD) (osteomalacia or osteopenia) or risk factors for bone loss should be counselled to reduce factors associated with low BMD in line with BHIVA / BASHH guidelines this includes adolescents • If treatment is interrupted, discontinued or poor adherence is reported then treat as a new episode of care under the PGD having reviewed inclusion/exclusion criteria. • Discuss with a prescriber where there is any uncertainty about conditions, medicines or side effects. • In the event of dose modifications, interruptions, overdoses and treatment discontinuations, a prescriber should be notified, and the individual managed according to the current local guidelines.
Action to be taken if the individual is excluded or declines treatment	• If an individual declines PrEP, ensure they understand why this medication has been offered and the potential consequences of not receiving it. Discuss other HIV prevention options such as condoms and Post-exposure prophylaxis access. Record reason for declining in record. • If individual tests HIV positive at enrolment manage as per local pathway. • If recent HIV seroconversion is suspected (<45 days) defer initiation until outside window period for testing and repeat HIV test(s). Refer to independent prescriber for risk/balance assessment regarding initiation prior to window period. ➢ If then tests HIV negative can proceed under PGD. ➢ If then tests positive refer to HIV services as per local pathway. • If currently showing symptoms of HIV seroconversion - refer to the appropriate independent prescriber. • If a HIV test is reactive/positive whilst taking PrEP, perform confirmatory serology with a combined antigen/ antibody test, HIV viral load and resistance testing and consider therapeutic drug monitoring (TDM). Refer to HIV service as per local pathway.

	• If eGFR less than 60mL/minute - refer to a prescriber for further investigation and consideration of PrEP supply via a prescription. • If risk to bone mineral density especially in adolescents for consideration of alternative (emtricitabine/tenofovir alafenamide). • Individuals with Hepatitis B are excluded from being treated under this PGD. • If deemed ineligible for PrEP this should be explained to the individual and rationale documented 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
Legal category	POM
Route of administration	Oral
Off label use	Best practice advice is given by BHIVA/BASHH and is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off label use in the following conditions: • Event based dosing (EBD) included in this PGD is outside the product licence but accepted and supported practice as per BASHH/BHIVA PrEP Guidelines 2018, English Impact Trial Protocol and the IPERGAY study. 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.
Dose and frequency of administration	Risk assessment and discussion between participant and practitioner will determine the regimen to be followed. **For cisgender GBMSM and transgender women, transgender men or non-binary people who *exclusively have anal sex*** **Option 1 - Daily Regimen:** Day 1: Take two tablets 2-24 hours prior to anticipated sex. Continue with one tablet per day thereafter. When discontinuing, PrEP should be continued for 48 hours after the last condomless anal sex has occurred. **Option 2 - On-demand (OD) or Event Based Dosing (EBD) Regimen:** Take two tablets 2-24 hours before sex and 1 tablet at 24 and 48 hours after the initial dose. Continue with a daily tablet on each day sex happens. When discontinuing, PrEP should be continued for 48 hours after the last condomless anal sex has occurred. **EBD should *only* be offered to people who *exclusively* have anal sex.** **EBD is not recommended for anyone reporting insertive or receptive frontal or vaginal sex as this regimen has not been evaluated in clinical trials in these groups.** **Heterosexual, cisgender men and women and transgender men and women having frontal/vaginal sex.** **Daily Regimen**: 1 tablet once daily for a minimum of 7 days prior to sex and for at least 7 days after last sex.

	This requires 7 days of dosing to be effective before sex can occur and for 7 days after last sex has occurred. If risk is likely to occur within 7 days of starting PrEP, advise to start with 2 tablets and then continue with daily dosing. **Labelling** Supplied packs will be labelled as follows or similar: Take ONE tablet ONCE a day **OR** Take TWO tablets 2-24 hours before sexual activity, THEN take ONE tablet every 24 hours, until 48 hours after last sex. Do NOT take more than 8 tablets in 7 days. **The dosing regimen that is NOT applicable should be crossed out on the label when the medication is supplied.** **Ensure the individual is counselled as to which regimen is to be followed and that they also have additional clear written information provided on the appropriate regimen.**
Duration of treatment	No maximum or minimum period. Participants may stop PrEP at any time for the following reasons: • Change in the participant's sexual behaviour meaning indications for PrEP are no longer met. • They choose to stop the medication.
Quantity to be supplied	Appropriately labelled, complete packs of 30 tablets up to a maximum of 6 packs/6-month supply. It is recommended that 3 months be supplied when initiating or re-starting PrEP. A subsequent 6-month supply can be given 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.

Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. See exclusions for interactions which exclude supply under this PGD. A detailed list of all drug interactions is available in the BNF, the product SPC or the Liverpool HIV Interactions checker.
Identification of adverse reactions	A detailed list of adverse reactions is available in BNF or the product SPC The following side effects are reported with emtricitabine/ tenofovir disoproxil: • diarrhoea, vomiting, nausea • dizziness, headache • rash • feeling weak • pain, stomach pain • difficulty sleeping, abnormal dreams • problems with digestion resulting in discomfort after meals, feeling bloated, flatulence. • Rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, 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.
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 individual's clinical record. • Report via organisation incident policy where appropriate.

Written information and further advice to be given to individual	**Medicine:** • Give manufacturer's information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine. • Ensure individual is counselled as to which regimen is to be followed and that they also have clear written information provided on the appropriate regimen and the non-applicable regimen has been crossed out on the supplied product label. • If needed, the tablet(s) can be dispersed in approximately 100mL of water, orange juice or grape juice and taken immediately. • There is no requirement for PrEP to be taken with/after food. • Advise the individual that if they vomit within 1 hour of taking a dose a single repeat dose should be taken. • Advise to note date a new medicine's container is opened and to either use or discard medicines in line with expiry information on the container. • Advise the individual that if they are concerned about any side effects they experience they should contact their clinic as soon as possible. • Advise individuals to report any new medicines to prescriber/pharmacist to check for drug interactions. **Clinical:** • Adherence and dosing information including manufacturers' product information leaflet or locally agreed alternative to support use and understanding of use. Information is available through: ➢ IWantPrEPNow/THT https://www.iwantprepnow.co.uk/ ➢ PrEPster https://prepster.info/ ➢ i-base http://i-base.info/prep and http://i-base.info/guides/prep ➢ https://www.nhsinform.scot/hiv-prep-pre-exposure-prophylaxis/ • Advise on safer sex and condom use and risk of other STIs. PrEP provision should include condom provision and behavioural support. • Advise that PrEP is not a contraceptive. • Advise on the importance of regular 3 monthly HIV/STI testing in-clinic or online. • Information should be provided to all individuals on: ➢ PrEP medication dose and schedule ➢ Lead-in time to protection ➢ Relationship of adherence to PrEP efficacy

	➢ Risks of HIV infection and antiretroviral resistance from suboptimal adherence ➢ Symptoms of HIV seroconversion that require assessment.
Follow up treatment	The following monitoring is required during ongoing treatment: **Three monthly the following must be performed:** • Assess eligibility and exclusion from PGD • A 4th generation HIV test • STI screen for chlamydia, gonorrhea and syphilis • Hepatitis C testing according to established practice supported by clinical evidence • Completion of STISS PrEP coding. **Every 3-12 months according to local protocol;** • Serum creatinine and potassium as part of renal function testing/eGFR and urinalysis. Urinary protein/creatinine ratio should be sent if raised protein on urinalysis or other risk factors. **Note:** Regular review of the prescribing and dispensing of PrEP should be undertaken in conjunction with the above three monthly monitoring.
Records	**Record:** • The consent of the individual and o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken o 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 and consent given. • 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 documented in a password controlled e-record) and kept securely for a defined period in line with local policy. 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. 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 Individual service specific systems.

4. Key references

Key references (accessed November 2022)	• 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

	• BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2018 http://bhiva.org/PrEP- guidelines.aspx • PrEP IMPACT TRIAL: https://www.prepimpacttrial.org.uk/ • Scottish Medicines Consortium report https://www.scottishmedicines.org.uk/medicines-advice/emtricitabinetenofovir-disoproxil-truvada-fullsubmission-122517/ • BHIVA/BASHH/BIA Adult HIV Testing guidelines 2020 https://www.bhiva.org/HIV-testing-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 200mg/Tenofovir Disoproxil 245mg Tablets As Pre-Exposure Prophylaxis (PrEP) For The Prevention Of HIV Infection Within NHS Grampian, Highland, 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 200mg/Tenofovir Disoproxil 245mg Tablets As Pre-Exposure Prophylaxis (PrEP) For The Prevention Of HIV Infection Within NHS Grampian, Highland, 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 200mg/Tenofovir Disoproxil 245mg Tablets As Pre-Exposure Prophylaxis (PrEP) For The Prevention Of HIV Infection Within NHS Grampian, Highland, Shetland And Western Isles, Version 2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**