Patient Group Direction For The Supply Of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets By Sexual Health Nurses Working Within NHS Grampian, Highland And Tayside For Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV Infection

Lead Author: Consultant in Sexual Health & HIV, NHSG
Consultation Group: See relevant page in the PGD
Approver: NoS PGD Group
Authorisation: NHS Grampian

Signature: Daniela Brauley

NoS Identifier: NoS/PGD/PrEP/MGPG1018
Review Date: March 2021
Date Approved: March 2019

NHS Grampian, Highland and Tayside have authorised this Patient Group Direction to help patients 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 1
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2019</td>
<td>Statement added regarding the off-label use in the event based dosing regimen.</td>
<td>Name form and strength of medicine</td>
</tr>
<tr>
<td>March 2019</td>
<td>Uncommon side effects updated in-line with SmPC.</td>
<td>Identifying and managing possible adverse effects</td>
</tr>
</tbody>
</table>

NoS Identifier: NoS/PGD/PrEP/MGPG1018  
Keyword(s): PGD Patient Group Direction HIV Pre-exposure prophylaxis PrEP Emtricitabine Tenofovir Disoproxil

Policy Statement: It is the responsibility of individual nurse and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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

Document:
- Drafted: January 2019
- Completed: February 2019
- Approved: March 2019 (published – March 2019)
- Amended:
Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by:

| Medical practitioner | Name: Dr Steve Baguley  
Health Board: NHSG  
Title: Consultant in Sexual Health & HIV, NHSG  
Contact email: steve.baguley@nhs.net  
Signature |
|----------------------|--------------------------------------------------|
| Senior Representative of the professional group who will provide care under the direction (if different from below) | Name: Julia Penn  
Health Board: NHSG  
Title: Sexual Health Nurse Team Leader, NHSG  
Contact email: Julia.penn@nhs.net  
Signature |
| Lead author | Name: Dr Daniela Brawley  
Health Board: NHS Grampian  
Title: Consultant in Sexual Health & HIV, NHSG  
Contact email: dbrawley@nhs.net  
Signature |
| Pharmacist | Name: Liz Kemp  
Health Board: NHSG  
Title: Principal Pharmacist P&MD, NHSG  
Contact email: e.kemp@nhs.net  
Signature |
Patient Group Direction For Use Within NHS Grampian, Highland and Tayside

Approved for use within NoS Boards by;

<table>
<thead>
<tr>
<th>North of Scotland (NoS) PGD Group Chair</th>
<th>Signature</th>
<th>Date Signed</th>
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</thead>
<tbody>
<tr>
<td>Lesley Thomson</td>
<td></td>
<td>March 2019</td>
</tr>
</tbody>
</table>

Authorised and executively signed for use within NoS Boards by;

<table>
<thead>
<tr>
<th>NHS Grampian Chief Executive</th>
<th>Signature</th>
<th>Date Signed</th>
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<tbody>
<tr>
<td>Professor Amanda Croft</td>
<td></td>
<td>March 2019</td>
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</table>

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Dr Daniela Brawley</td>
<td>Lead Author: Consultant in Sexual Health &amp; HIV, NHSG</td>
</tr>
<tr>
<td>Liz Kemp</td>
<td>Pharmacist: Principal Pharmacist P&amp;MD, NHSG</td>
</tr>
<tr>
<td>Steve Baguley</td>
<td>Medical Practitioner: Consultant Sexual Health &amp; HIV, NHSG</td>
</tr>
<tr>
<td>Julia Penn</td>
<td>Senior Representative: Sexual Health Nurse Team Leader, NHSG</td>
</tr>
<tr>
<td>Lynn Chalmers</td>
<td>Senior Nurse Sexual Health Services, NHSH</td>
</tr>
<tr>
<td>Vicky Bridgeford</td>
<td>Specialist Pharmacist HIV, NHSG</td>
</tr>
<tr>
<td>Kirsteen Hill</td>
<td>Antimicrobial/HIV Pharmacist, NHST</td>
</tr>
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</table>
### Clinical indication to which this PGD applies

**Definition of situation/condition**

This Patient Group Direction (PGD) will authorise senior sexual health nurses to supply Emtricitabine 200mg/tenofovir disoproxil 245mg tablets to individuals for Pre Exposure Prophylaxis (PrEP) in combination with advice on safer sex practices to reduce the risk of sexually acquired HIV infection in adults at high risk.

This PGD should be used in conjunction with the recommendations in the current [British National Formulary (BNF)](https://www.gov.uk/government/collections/british-national-formulary), [British National Formulary for Children (BNFC)](https://www.gov.uk/government/collections/british-national-formulary-for-children), and the individual Summary of Product Characteristics (SmPC).

**Inclusion criteria**

The participant population for this PGD will be individuals attending Sexual Health Service clinics who are eligible for PrEP according to the following Scottish national eligibility criteria:

**Universal criteria:**
- Aged 16 or over
- Tested HIV negative
- Able to attend the clinic for regular 3 monthly review including for monitoring, sexual health care and support, and to collect prescriptions
- Willing to stop NHS-funded PrEP if the eligibility criteria no longer apply
- Resident in Scotland.

Plus one or more of the following **eligibility criteria:**
- Current sexual partners, irrespective of gender, of people who are HIV positive and with a detectable viral load.
- Men who have Sex with other Men (MSM)* and transgender women with a documented bacterial rectal STI in the last 12 months.
- MSM* and transgender women reporting condomless penetrative anal sex with two or more partners in the last 12 months and likely to do so again in the next three months.
- Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.

*The term MSM used here includes transgender men who have male sexual partners.
Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.

| Exclusion criteria | Participants are excluded if they:
|---|---|
|  | • Do not meet all of the universal criteria and at least one of the eligibility criteria
|  | • Have an acute viral illness at enrolment or within the last month that could represent seroconversion
|  | • Have had a sexual risk in last 72 hours which makes them eligible for HIV Post exposure prophylaxis
|  | • Test HIV positive at enrolment
|  | • Are below the age of 16 years or over the age of 65 years.
|  | • Have an eGFR <60mL/minute - this will be evident from the individuals last U&E blood result
|  | • Have a history of osteoporosis, reduced bone density, liver disease or hypertension
|  | • Are allergic/hypersensitive or have any contraindication to emtricitabine, tenofovir or tenofovir disoproxil fumarate
|  | • Have Hepatitis B or C infection
|  | • Are concomitantly taking any of the following medicines:
|  |   o Emtricitabine
|  |   o Tenofovir (all salts)
|  |   o Adefovir dipivoxil
|  |   o Lamivudine and other cytidine analogues
|  |   o Didanosine
|  |   o Cidofovir and other medicines that compete for active tubular secretion
|  |   o Medicines that reduce renal function.*
|  | • Have no valid consent.

*Consult the latest edition of the BNF for further information.

Discuss with a Consultant in Sexual Health/Genitourinary Medicine (GUM) if any of the exclusion criteria are present.

| Precautions and special warnings | Adults with renal impairment: PrEP should only be used in these individuals if eGFR is between 60 and 90mL/minute.
|---|---|
|  | Follow local protocols and guidelines for assessment, monitoring, prescribing and recording of PrEP.
|  | Discuss with the Consultant in Sexual Health/GUM regarding conditions/medicines/side effects, etc of which the nurse is unsure.
In the event of dose modifications, interruptions, overdoses and treatment discontinuations the Consultant in Sexual Health/GUM should be notified and the individual closely observed and managed according to the current local guidelines.

**Action if excluded from treatment**

If an individual does not meet the eligibility criteria but wishes to take PrEP refer to a general GUM appointment to discuss self-sourcing of generic PrEP.

If tests HIV positive at enrolment manage as per local pathway.

If recent HIV seroconversion is suspected (<1 month) – Rapid HIV test and refer to a doctor for discussion of risks and benefits of starting PrEP in window period.

If an HIV test is reactive/positive whilst taking PrEP, take confirmatory serology, resistance test and sample for Therapeutic Drug Monitoring (TDM); refer to local HIV service for follow-up care.

Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.

**Action if treatment is declined**

Inform/refer to the relevant medical practitioner if individual declines treatment.

Document refusal, advice given and, if possible the reason for refusal in appropriate clinical records.

**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th>Name form and strength of medicine</th>
<th>Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets</th>
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<tr>
<td><strong>N.B.</strong> The dose used in the Event Based Dosing Regime within this PGD is off-license and constitutes an off-label use of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets. However the use of this dosing regimen is supported by evidence and recommended by BHIVA/BASHH Guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2018. The individual should be informed prior to the supply that this use is off-label.</td>
<td></td>
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</table>

**Legal status**

Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets are a Prescription-only Medicine (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.

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<th>Dosage/Maximum total dose</th>
<th>Risk assessment and discussion between individual and practitioner will denote the following;</th>
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<tbody>
<tr>
<td>Daily Regimen:</td>
<td>1 tablet once daily for a minimum of 7 days prior to sex and for 7 days after last sex for cisgender* and transgender heterosexual men and women and at least 2 days after last sex for MSM.</td>
</tr>
</tbody>
</table>
| This option is suitable for: | • Cis and transgender heterosexual men  
• Cis and transgender gay, bisexual and other MSM  
• Cis and transgender women. |
| Event Based Dosing Regimen (EBD): | 2 tablets 2-24 hours before sex and 1 tablet at 24 and 48 hours after the initial dose, with at least 2 doses of drug being administered after the last sex has occurred. |
| This option is suitable for: | • Men (cis and/or bisexual) who have sex with men whose principal HIV risk is through condomless insertive and/or receptive anal sex.  

N.B. EBD is not recommended for heterosexual and transgender men or women. |
| • Take tablets with or just after food  
• If needed, the tablet(s) can be dispersed in approximately 100mL of water, orange juice or grape juice and taken immediately. |
| Maximum daily dose: | EBD: 2 tablets in 24 hours on day 1 and 1 tablet in 24 hours thereafter. |
| Daily Regimen: | 1 tablet in 24 hours. |

*cis/cisgender is referring to people whose sense of personal identity and gender corresponds with their birth sex.
| Frequency of dose/Duration of treatment | **Daily Regimen**: 1 tablet once daily for a minimum of 7 days prior to sex and for at least 7 days after last sex for cisgender and transgender heterosexual men and women and 2 days after last sex for MSM.

For MSM, if risk is likely to occur within 7 days of starting, start with 2 tablets 2-24 hours before sex as per event based dosing regimen (EBD).

**Event Based Dosing Regimen**: 2 tablets 2-24 hours before sex and then 1 tablet at 24 and 48 hours after the initial dose, with at least 2 doses being administered after the last sex has occurred.

Individuals can stop/start PrEP at any time for the following reasons, however should make sure they continue the medicine for 2-7 days after last sex as per advice:

- Change in the individual’s sexual behavior meaning indications for PrEP are no longer met
- They choose to stop drug.

If re-starting PrEP, an HIV test must be performed on the day prior to re-starting PrEP. Adherence and appropriate regimen needs to be re-iterated at the point of re-starting PrEP. If any unprotected anal intercourse has occurred within the last 4 weeks then a 4th generation/serology HIV test must be performed at least 4 weeks after their risk. |

| Maximum or minimum treatment period | N/A |

| Route/Method of administration | Oral administration. |

| Quantity to be administered | Quantity to supply is based on planned/actual individual use and medication expiry. This is to be decided between the dispensing practitioner and the individual, but can be one of the following options depending upon eligibility according to local protocols:

- 1 x 30 tablets
- 2 x 30 tablets
- 3 x 30 tablets

The quantity, drug manufacturer and dosing schedule (daily or EBD) should be prescribed on the National Sexual Health System (NaSH) where available. |
### Storage requirements
Store in the original package in order to protect from moisture. Keep the container tightly closed.

### Follow-up (if applicable)
Must attend clinic every 3 months for HIV testing, sexual health screen and renal monitoring as per local protocol.

Advising individual to attend sooner if any symptoms of HIV seroconversion.

### Advice (Verbal)
Advising individual what to expect and what to do for minor and major reactions. Advising the individual that should they notice any of the side effects, including those listed below to contact the clinic as soon as possible.

If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24.

Confirm the date needed for repeat HIV test if within 1 month window from unprotected anal sex if starting/re-starting PrEP.

Advise in regard to safer sex and condom use and risk of other Sexually Transmitted Infections (STI’s).

Individually should report any new medicines prescribed to the prescriber/pharmacist to check for interactions with this medicine.

### Advice (Written)
The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Adherence and dosing information including ‘PrEP in Scotland’ patient leaflet or an alternative to support use and understanding of use.

### Identifying and managing possible adverse reactions
**N.B.** The following list may not represent all reported side effects of this medicine.

**Very common side effects** (may affect more than 1 in 10 people):
- Diarrhoea, vomiting, nausea
- Dizziness, headache
- Rash
- Feeling weak.
**Common side effects** (may affect up to 1 in 10 people):
- 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.

Laboratory tests may also show:
- Low white blood cell count
- Increased triglycerides, bile or glucose
- Liver and pancreas problems.

**Uncommon side effects** (may affect up to 1 in 100 people):
- Pancreatitis
- Swelling of the face, lips, tongue or throat
- Anaemia
- Hepatic steatosis or hepatitis
- Osteomalacia
- Myopathy.

Laboratory tests may also show:
- Hypokalaemia
- Elevated creatinine
- Proteinuria.

This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.

**BNF:**
[https://www.bnf.org](https://www.bnf.org)

**SmPC/PIL/Risk Minimisation Material:**
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)
[https://www.medicines.org.uk/emc/rmm-directory](https://www.medicines.org.uk/emc/rmm-directory)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report any severe reactions or reactions to any medicines using the Yellow Card System. [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)
### Monitoring

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, gonorrhoea 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.

_N.B._ Regular review of the prescribing and dispensing of PrEP should be undertaken in conjunction with the above three monthly monitoring.

### Facilities and supplies required

The following should be available at sites where the medicine is to be supplied:
- Appropriate storage facilities
- An acceptable level of privacy to respect individual’s right to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via the telephone)
- Clean and tidy work areas, including access to hand washing facilities
- Copy of the current PGD for the medicine specified in the PGD.

### Characteristics of staff authorised to supply medicine(s) under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered nurses as recognised by the Nursing and Midwifery Council (NMC).</th>
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<tbody>
<tr>
<td>Specialist competencies</td>
<td>Approved by the organisation as:</td>
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<td></td>
<td>Competent to assess the individuals capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent</td>
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<td></td>
<td>Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual</td>
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<tr>
<td></td>
<td>Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD.</td>
</tr>
</tbody>
</table>
**Ongoing training and competency**

<table>
<thead>
<tr>
<th>All professionals working under this PGD must:</th>
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<tbody>
<tr>
<td>• Have undertaken PGD training as required/set out by each individual Health Board</td>
</tr>
<tr>
<td>• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct</td>
</tr>
<tr>
<td>• Have knowledge and familiarity of the following;</td>
</tr>
<tr>
<td>○ <strong>SmPC</strong> for the medicine(s) to be supplied in accordance with this PGD</td>
</tr>
<tr>
<td>○ Relevant local protocol relating to PrEP and the monitoring of individuals taking the medicine. Nurses must also be aware of any/all changes to local PrEP protocols and action these in a timely manner.</td>
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</tbody>
</table>

**Responsibilities of professional manager(s)**

<table>
<thead>
<tr>
<th>Professional manager(s) will be responsible for;</th>
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<tbody>
<tr>
<td>Ensuring that the current PGD is available to all staff providing care under this direction.</td>
</tr>
<tr>
<td>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</td>
</tr>
<tr>
<td>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</td>
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</tbody>
</table>

**Documentation**

<table>
<thead>
<tr>
<th>Authorisation of supply</th>
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</thead>
<tbody>
<tr>
<td>Senior nurses working in Sexual Health Clinics within NHS Grampian, Highland and Tayside can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant.</td>
</tr>
<tr>
<td>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (<strong>Appendix 1</strong>).</td>
</tr>
<tr>
<td>A Certificate of Authorisation (<strong>Appendix 2</strong>) 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.</td>
</tr>
</tbody>
</table>
Record of supply

An electronic or paper record for recording the screening of individuals and the subsequent supply of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of supply
- Individuals name and CHI
- Exclusion criteria, record why the medicine was not supplied
- Record that valid consent to treatment under this PGD was obtained
- The name, dose, form, route of the medicine(s) supplied
- Advice given, including advice given if excluded or declined treatment under this PGD
- Signature and name in capital letters of the healthcare professional who supplied the medicine(s)
- STISS Coded appropriately on NaSH
- Record of any adverse effects (advise individuals GP/relevant medical practitioner).

Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

- Consent forms
- NaSH – Sexual Health Electronic Patient Record
- Individual’s GP records if appropriate
- Secondary Care Medical Notes
- Individual service specific systems.

Audit

All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.

References

Electronic Medicines Compendium http://www.medicines.org.uk Emtricitabine/Tenofovir disoproxil 200 mg/245 mg Film-Coated Tablets (Lupin Healthcare Brand) – Date of revision of text 18/01/18, accessed 05/02/19.

British National https://www.bnf.org accessed 05/02/19.


<table>
<thead>
<tr>
<th>SMC Advice: Emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No. (1225/17)</th>
</tr>
</thead>
</table>


PROUD Study Results, Key Messages, Questions and Answers [http://www.proud.mrc.ac.uk/study_results](http://www.proud.mrc.ac.uk/study_results)
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 By Sexual Health Nurses Working Within NHS Grampian, Highland And Tayside For Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV Infection

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  

____________________________________
## 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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.

### Patient Group Direction For The Supply Of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets By Sexual Health Nurses Working Within NHS Grampian, Highland And Tayside For Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV Infection

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
<th>Signature</th>
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