| Patient Group Direction for the supply of : Emtricitabine 200mg &Tenofovir Disoproxil 245mg | |
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| **Title of patient group direction** | **PrEP- PGD Emtricitabine 200mg &Tenofovir Disoproxil 245mg** |
| **Approved at** | NMP/PGD Group |
| **PGD approved / valid from** | September 2020 |
| **Review date** | April 2023 |
| **Expiry date** | September 2023 |
| **Clinical area(s) where PGD applies** | York Sexual Health and North Yorkshire Sexual Health services |
| **Identified Lead for monitoring / review and contact details** | Alison Chorlton, Lead Sexual Health Nurse |
| | |
| **CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)** | |
| **New Document** | No |
| **Reviewed Document** | Adapted document |
| **If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation** | PEPSE PGD document amended in preparation for the use of PrEP commissioning with raltegravir removed and regime changes to reflect PrEP use |
| **List of persons involved in the consultation process.** (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed). | Rebecca Bussy<br>Alison Chorlton, Lead Nurse Sexual health<br>Dr Ian Fairley, Consultant |

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| **Condition** | For the prevention of HIV acquisition where there may be transmission of HIV via sexual contact. |
| **Inclusion criteria** | • Patients aged 18 to 65 years who are at risk of acquiring HIV in the future and have a negative Point of Care Testing (POCT) HIV test on the day, or a negative combined HIV antigen/antibody test within the past 4 weeks.<br>• Patients who present and meet BHIVA/BASHH current guidelines on the use of HIV pre-exposure prophylaxis (PrEP)<br>• Men who have Sex with Men (MSM) and risk equivalent transwomen and transmen having condomless anal sex in the previous 6 months and ongoing condomless anal sex.<br>• Anyone having condomless sex with partners who are HIV positive, unless the partner has been on Anti-retroviral therapy(ART) for at least 6 months and their plasma viral load is <200 copies/mL.<br><br>**The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV www.bashh.org.uk** |
| **Exclusion criteria** | • Patients who do not meet the eligibility criteria as specified in the current BHIVA/BASHH guidelines on the use of PrEP<br>• Patients under the age of 18 or over 65 years.<br>• Pregnant.<br>• Patients who are breastfeeding.<br>• Patients who refuse treatment under PGD.<br>• Allergy or hypersensitivity to tenofovir, emtricitabine and/or excipients of these products.<br>• Where patient is known to be HIV positive.<br>• Reactive result on HIV POCT. |

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| | • Known blood disorders and liver disease.<br>• Acute or chronic hepatitis B & C disease.<br>• Immunocompromised individuals<br>• Diabetes.<br>• Known high cholesterol.<br>• Kidney disease or receiving haemodialysis.<br>• Proteinuria on urinalysis > trace<br>• Known eGFR < 60ml/min/1.73m$^2$<br>• History of depression or psychiatric illness, resulting in hospitalisation.<br>• Suicidal thoughts<br>• Risk factors for reduced bone mineral density including demonstrated osteoporosis/osteomalacia/osteopenia<br>• History of myopathy and rhabdomyolysis.<br>• Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.<br>• Taking adefovir, atazanavir cidofovir, darunavir, didanosine, fosamprenavir, lopinavir, rifampicin, telaprevir, gemfibrozil, orlistat, or aluminium and magnesium containing antacids.<br>• Interacting medicines – see current British National Formulary for interactions in Appendix 1 under, emtricitabine and tenofovir |
| **Action if excluded** | • Refer to medical practitioner that clinical session<br><br>• As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. |
| **Action for patients not wishing to receive care under the PGD** | Refer to medical practitioner/prescriber that clinical session or when next available in clinic. As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner first. |

| DESCRIPTION OF TREATMENT | | | |
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| **Name of Medicine** | Emtricitabine plus tenofovir disoproxil | | |
| **Legal Classification** | Prescription only medicine (POM) | | |
| **Licensing information** | Licensed | | |
| | **Is the medicine licensed for the intended use?** | **YES** | |
| | **Does it have a black triangle status?** | | **NO** |
| | **Does it have a Risk Minimisation Measures (RMM) recommendation** | | **NO** |
| **Form** | Tablet | | |
| **Strength** | Emtricitabine 200mg plus tenofovir disoproxil 245mg | | |
| **Dose** | See below for dosing schedules | | |
| **Frequency** | Emtricitabine 200mg plus tenofovir disoproxil 245mg<br>**Daily PrEP:**<br>Women and transmen who want protection from vaginal or front hole sex, need to take daily PrEP One tablet daily. It also takes about a week to reach protective drug levels. This is because PrEP is absorbed differently in vaginal tissue compared to rectal tissue.<br>Treatment should continue for at least 7 days after last sex.<br><br>**On-demand PrEP**<br>On-demand dosing is very effective for anal sex. This involves taking two tablets 2 to 24 hours before sex as a double dose (single) tablet at 24 hours and 48 at hours after the initial dose and continue daily until 48 hours after the last condomless sex has occured.<br>A loading dose of two tablets taken 2–24 hours before sex, followed by a third (single) tablet 24 hours and a fourth (single) tablet 48 hours after the | | |

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| | initial dose. Where potential exposure is sustained over more than a 24-hour period, one tablet per day should be taken until the last sexual intercourse **and for 48 hours afterwards** Not more than 8 tablets to be taken in 7 days<br>On demand dosing is not recommended for heterosexual men and women |
| **Route** | Oral |
| **Total Treatment Quantity** | **At initial visit:**<br>Daily PrEP:<br>Emtricitabine 200mg plus tenofovir disoproxil 245mg supply 90 tablets<br>Total supply for 3 month course is 90 tablets<br><br>On demand PrEP(also known as event based)<br>Emtricitabine 200mg plus tenofovir disoproxil 245mg supply 30-60 tablets<br>Total supply for 3 month course is 30-60 tablets<br><br>**At follow up visit every 3 months:**<br>Daily PrEP:<br>Emtricitabine 200mg plus tenofovir 245mg supply 90 tablets<br>Total supply for 3 month course is 90 tablets<br><br>On demand PrEP(also known as event based)<br>Emtricitabine 200mg plus tenofovir disoproxil 245mg supply 30-60 tablets if required<br>Total supply for 3 month course is 30-60 tablets if required |
| **Interactions with other medicines**<br>(This must include all potentially serious interactions listed in the BNF) | An accurate medication history should be obtained including OTC , vitamins/minerals and herbal products<br>See Appendix 1 in British National Formulary under emtrictibine, and tenofovir.<br>• Check Liverpool Drug Interaction website: www.hiv-druginteractions.org<br><br>There is the potential for numerous drug interactions with these medicines, if in doubt then contact Medicines Information on ext: 5960 |

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| **Adverse Reactions**<br>(This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information) | **Common or Serious adverse reactions:**<br><br>• Nausea and vomiting, diarrhoea, stomach pain<br>• Dizziness, headache<br>• Muscle breakdown, pain or weakness<br>• Allergy, rash, itching.<br>• Swelling of face, lips or tongue<br>• Fatigue, insomnia, abnormal dreams, fever<br>• Depression including suicidal ideation and behaviour.<br>• Liver inflammation and jaundice.<br>• Kidney failure or impairment, elevated creatinine.<br>• Abdominal pain and pancreatitis<br>• Lactic acidosis<br>• Risk of reduced bone mineral density after 48/52 of use<br>This list is not exhaustive. Refer to current BNF and SmPC for details of all potential adverse reactions | **Treatment of adverse reactions:**<br><br>Seek urgent medical attention for any of the indications listed in Adverse Reactions. |
| **Monitoring and follow up** | **<u>Baseline testing</u>**<br>• HIV test within 4 weeks or POCT on the day | |

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| | • Full STI screen (incl syphilis serology and Gc/Ct NAATS)<br>• HBsAg and Hep B markers<br>• Anti HBs<br>• HCV (MSM)<br>• U&E, eGFR<br>• Urine dipstix (and ACR if 1+ or more of protein. PrEP can be commenced whilst awaiting ACR results- needs a prescriber )<br>• Offer an ultra-rapid schedule of Hepatitis B vaccination (0,7 & 21 days) if appropriate.<br>• Pregnancy testing if appropriate.<br>• Emergency contraception and ongoing contraception if relevant.<br>• A telephone appointment for 4 weeks<br>• Blood results will be reviewed from baseline testing and any additional follow up will be initiated from these results.<br>• An appointment at 3 months for repeat testing and further supply<br><br>**Subsequent follow-up should be every 3 months to:**<br>• Check adherence and risk<br>• Identify potential adverse reactions<br>• Check for symptoms of seroconversion<br>• Undertake an HIV test<br>• Perform a full sexual health screen<br>• Undertake renal monitoring if indicated by baseline results(see renal recommendations within PrEP guidelines)<br>• Ensure vaccinations are completed<br>• HBV testing if non immune<br>• HCV testing annually<br>• Book a further follow-up appointment for 3 months |
| **Advice to Patients: Written and Oral advice** (This should include the provision of a patient information leaflet) | • The potential risks and side-effects of PrEP, including the risk of loss of bone mineral density, and when to seek advice.<br>• The PrEP regimen is recommended by BASHH/BHIVA. |

**Baseline testing will include:**

- HIV test within 4 weeks or POCT on the day
- Full STI screen (incl. syphilis serology and Gc/Ct NAATS)
- HBsAg and Hep B markers
- Anti HBs
- HCV (MSM)
- U&E, eGFR
- Urine dipstix
- Offer of an ultra-rapid schedule of Hepatitis B vaccination (0, 7 & 21 days) if appropriate.
- Pregnancy testing, if appropriate.
- Emergency contraception and ongoing contraception, if relevant.

- There will be a telephone appointment after 4 weeks

**Dosing and administration**

- Emtricitabine 200mg plus tenofovir disoproxil 245mg tablet to be taken swallowed whole with food or can be dispersed in approx. 100mL of water, orange or grape juice and taken immediately.
- If PrEP is to be taken daily it should be taken every day and assumed not to be effective until taken for 7 days. As the body takes time to absorb drugs. Continue for 7 days after last sex.
- On demand PrEP should be taken before sex to let the drug levels build up and after sex to keep levels high. On-demand dosing is very effective for anal sex. This involves taking two pills 2 to 24 hours before sex as a double dose, then a single pill 24 hours and 48 hours after the first double dose.
- Take the medicines at the approximate times indicated even if you have not actually had a meal.
- On demand dosing is not recommended for heterosexual man and women.

**Missed doses**

- If a dose of emtricitabine/tenofovir disoproxil is missed within 12 hours of the time it is usually

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| | taken, it should be taken as soon as possible and the normal dosing schedule should be resumed. If a dose of emtricitabine/tenofovir disoproxil 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. However, If one, or even two tablets are missed occasionally, this will be acceptable on a daily regimen. Drug levels will still be high enough to protect against HIV. If they are missing several doses each week, offer adherence support and consider counselling.<br>• If vomiting occurs within 1 hour of taking emtricitabine/ tenofovir disoproxil, another tablet should be taken. If vomiting occurs more than 1 hour after taking emtricitabine/ tenofovir disoproxil a second dose should not be taken.<br>• If they are using daily dosing and miss more than a week of pills, advise restart with a double dose (two pills) and then continue with one pill a day.<br>• One double dose should only be taken when starting PrEP. No more than a total of seven pills should be taken in one week, unless started with a double dose.<br>Emtricitabine 200mg plus tenofovir 245mg patient information leaflet (PIL)<br>• The need to have a follow-up HIV test in 12 weeks.<br>• Coping strategies, assessment of vulnerabilities and social support.<br>• For patients concerned about sexual risk taking, offer ongoing risk reduction work or referral to counselling.<br>• Subsequent follow-up will be every 3 months<br>• Useful resources to signpost people to include:<br>• i-base http://i-base.info/prep and http://i-base.info/guides/prep<br>• Aidsmap www.aidsmap.com<br>• Prepster http://prepster.info/<br>• I Want PrEP Now https://www.iwantprepnow.co.uk/<br>• IMPACT trial website https://www.prepimpacttrial.org.uk |

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| **Storage** | • locked medicines cupboard – store below 25 °C<br>• locked briefcase for outreach use |
| **Records to be Kept** | The following minimum details must always be documented in the patient's notes and other relevant patient documentation in relation to supplying treatment under PGD.<br><br>Document the following in the patients notes:<br><br>• Any reason for exclusion, including action taken and advice given.<br>• Risk/benefit discussion re: PrEP<br>• If the patient has refused treatment under the PGD, any advice given or cautions taken.<br>• Date.<br>• Time of administration if appropriate.<br>• Name, form, strength and dose of drug supplied<br>• Route of administration.<br>• Advice given to the patient including any possible side- effects and adverse reactions.<br>• EPR signature of staff supplying medicine.<br>• Form of documentation (patient records, letters, etc.).<br>• Any communication with other health care professionals.<br>That PrEP (emtricitabine 200mg & tenofovir disoproxil 245mg) was supplied under a PGD. |
| **Audit Arrangements** | As per current Trust PGD Policy |
| **References** | • National Guidelines for Pre Exposure Prophylaxis (2018)<br>British Association for Sexual Health and HIV:<br>www.bashh.org/guidelines<br><br>• British National Formulary (BNF).<br>www.bnf.org/products/bnf-online<br><br>• Liverpool Drug Interaction website: |

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| | www.hiv-druginteractions.org<br><br>• Summary of Product Characteristics (SPC). Emtricitabine/Tenofovir disoproxil Dr. Reddy's 200 mg/245 mg Film-Coated Tablets https://www.medicines.org.uk/emc/product/8608<br><br>• Nursing and Midwifery Council (NMC). The Code. Professional standards and behaviour for nurses and midwives (2015). www.nmc.org.uk/standards/code/record-keeping<br>• YSH clinic PrEP guidelines |
| **Competency Requirements** (attach any competency frameworks / documents) | • Completion of Trust PGD e-learning session, PGD questionnaire<br>• Band 6 Nurse or above.<br>• Clinical competence in sexual history taking. Clinical competence in the assessment of HIV transmission risk and regime according to BASHH/BHIVA guidelines for PrEP.<br>• Knowledge base of the interactions of emtricitabine, and tenofovir with other drugs, and other exclusions and contra-indications for issuing the above medicines.<br>• Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health.<br>• Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD.<br>• Receiving clinical supervision and/or audit of case notes on an ongoing basis.<br>• Commitment to continuing professional development identified through clinical supervision and appraisal.<br>• Evidence of continuing professional development in sexual health. |

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| | • 5 study days or the equivalent in hours, of study related to the field of sexual health every 3 years.<br>• Regular attendance and participation in the 3 monthly educational clinical governance sessions.<br>• Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development. |

| AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF: PrEP Emtricitabine 200mg &Tenofovir Disoproxil Fumarate 245mg. | | | |
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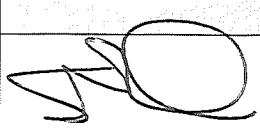
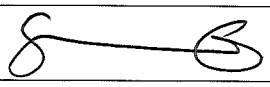
| **PGD Development / Review Team – responsible for PGD content** | | | |
| **Title** | **Name** | **Signature** | **Date** |
| **Lead Author** | Alison Chorlton Lead Sexual Health Nurse |  | 17 08 20 |
| **Clinical Director Lead Approval** | Ian Fairley |  | 17/08/20 |
| **Directorate Pharmacy Lead Approval** | Paul Jackson |  | 23/10/20 |
| **PGD Approved by the NMP/PGD Group** | | | |
| **Title** | **Name** | **Signature** | **Date** |
| **NMP Lead / Lead Nurse Medicines Management** | Jennie Booth |  | |
| **Chief Pharmacist / Deputy Chief Pharmacist** | Stuart Parkes |  | 4 19/20 |

**Authorisation to work within the PGD**

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

**Notes to the NMP/PGD Authorising staff**

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

| Staff authorised to work under this PGD | |
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| **Ward / Department** | Sexual Health |
| **Professionals to whom this Patient Group Direction applies** | Qualified nurses who work within sexual health and have completed the agreed training programme |

***I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:***

| Name (Capitals) | Sign | Job Title | Authorising Manager | Date |
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| When the review date is exceeded, this PGD ceases to be a legal document | |
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| **TEMPLATE DOCUMENTATION CONTROL** | |
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| The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.** | |
| | |
| **Author:** | Jennie Booth, Lead Nurse Medicines Management<br>Carol Belt, Principal Pharmacy Technician<br>Stuart Parkes, Deputy Chief Pharmacist |
| **Owner:** | NMP/PGD Group |
| **Date of issue:** | February 2018 |
| **Version:** | 2 |
| **Approved by** | NMP/PGD Group |
| **Review date:** | February 2021 |