Patient Group Direction for the supply of : Emtricitabine 200mg &Tenofovir Disoproxil Fumerate 245mg and Raltegravir 400mg	
Title of patient group direction	**PEPSE- PGD Emtricitabine 200mg &Tenofovir Disoproxil Fumerate 245mg and Raltegravir 400mg**
Approved at	NMP/PGD Group
PGD approved / valid from	July 2019
Review date	April 2022
Expiry date	July 2022
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	Yes
Reviewed Document	No
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	
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 Alison Chorlton, Lead Nurse Sexual health Dr Ian Fairley, Consultant

Condition	For the prevention of HIV acquisition where there has been known or suspected transmission of HIV via sexual contact.
Inclusion criteria	• Patients aged 18 to 65 years who have been at risk of acquiring HIV in the last 72 hours and have a negative POCT HIV test. • Patients who present and meet the British Association of Sexual Health & HIV (BASHH) guidelines as 'Recommended' for PEPSE – see PGD Appendix A this includes receptive anal sex, insertive anal sex and receptive vaginal sex with a source HIV positive individual whereby the HIV Viral load count is unknown or detectable .Additionally when the source HIV status is unknown and the source is from a high prevalence country or risk group and receptive anal sex has occurred. **The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV www.bashh.org.uk**
Exclusion criteria	• Patients under the age of 18 or over 65 years. • Pregnant or suspected pregnancy. • Patients who are breastfeeding. • Patients who refuse treatment under PGD. • Allergy or hypersensitivity to tenofovir, emtricitabine or raltegravir and/or excipients of these products. • Where patient is known to be HIV positive. • Reactive result on HIV POCT. • Where exposure to HIV is more than 72 hours. • Patient is classified as a BASHH 'consider or not recommended "guidelines for PEPSE (Refer to Appendix A of PGD). • Known blood disorders and liver disease. • Acute or chronic hepatitis B & C disease.

	• Diabetes. • High cholesterol. • Kidney disease or receiving haemodialysis. • Proteinuria on urinalysis of >+. • History of depression or psychiatric illness, resulting in hospitalisation. • Suicidal thoughts • History of myopathy and rhabdomyolysis. • Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. • Taking adefovir, atazanavir cidofovir, darunavir, didanosine, fosamprenavir, lopinavir, rifampicin, telaprevir, gemfibrozil, orlistat or aluminium and magnesium containing antacids. • Interacting medicines – see current British National Formulary for interactions in Appendix 1 under raltegravir, emtricitabine and tenofovir
Action if excluded	• Refer to medical practitioner that clinical session • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner. Alternatively arrange immediate assessment in the Emergency Department if patient presents with an acute presentation and no doctor is available that clinical session. Record within the patient records and discuss with a senior colleague when PEPSE is recommended but the patient decides not to take the medication

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			
Name of Medicine	• Emtricitabine plus tenofovir disoproxil fumerate • Raltegravir		
Legal Classification	Prescription only medicine (POM)		
Licensing information	Not licensed but BASHH recommended		
	Is the medicine licensed for the intended use?	**NO**	
	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 245mg • Raltegravir 400mg		
Dose	• Emtricitabine 200mg plus tenofovir 245mg – One tablet once daily • Raltegravir 400mg - One tablet twice daily taken 12 hours apart.		
Frequency	• Emtricitabine 200mg plus tenofovir 245mg – One tablet once daily • Raltegravir 400mg - One tablet twice daily taken 12 hours apart.		
Route	Oral		
Total Treatment Quantity	At initial visit: • Emtricitabine 200mg plus tenofovir 245mg supply of x 5 tablets. • Raltegravir supply of x 10 tablets. • Total supply for 5 days course is 15 tablets At follow up visit: • Emtricitabine 200mg plus tenofovir 245mg supply of x 23 tablets. • Raltegravir supply of x 46 tablets.		

	• Total supply for 23 days course is 69 tablets	
Interactions with other medicines (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 See Appendix 1 in British National Formulary under emtrictibine, raltegravir and tenofovir. • Check Liverpool Drug Interaction website: www.hiv-druginteractions.org There is the potential for numerous drug interactions with these medicines, if in doubt then contact Medicines Information on ext: 5960 • Co-administration of raltegravir with antacids is not recommended. Multivitamins are also ideally avoided. • Calcium and iron supplements can be taken with raltegravir but should be taken at least 6 hours before or 6 hours after taking raltegravir.	
Adverse Reactions (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:** • Nausea and vomiting • Muscle breakdown, pain or weakness • Allergy, rash, itching. • Swelling of face, lips or tongue • Fatigue, insomnia, fever • Depression including suicidal ideation and behaviour. • Liver inflammation and jaundice. • Kidney failure or impairment. • Abdominal pain and pancreatitis • Lactic acidosis	**Treatment of adverse reactions:** Seek urgent medical attention for any of the indications listed in Adverse Reactions.

Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• The lack of conclusive data for the efficacy of PEPSE. • The potential risks and side-effects of PEPSE and when to seek advice. • The drugs given for PEPSE are not licensed for PEPSE but are licensed for HIV treatment. The PEPSE regimen is recommended by the Department of Health. • The need to continue PEPSE for 28 days if the baseline result is negative. • Pre-test discussion and HIV test (4th generation laboratory test) including an HIV point of care test (POCT) • To include the following baseline blood tests: syphilis, hepatitis B (HBsAg & Anti-HBc), anti-HBs if previously vaccinated hepatitis C, liver function tests (LFT's) and urea & electrolytes (U&E's). • Urinalysis to check for proteinuria. • Screening for chlamydia and gonorrhoea. • Offer 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. • Provide the BHIVA/BASH/HPVA patient information leaflet. • Emtricitabine 200mg plus tenofovir 245mg tablet to be taken in the morning swallowed whole with food or can be dispersed in an approx. 100mL of water, orange or grape juice and taken immediately. • Raltegravir tablet to taken in the morning (with or without food). Swallow whole with plenty of water whilst sitting or standing in an upright position. Advise that these should not be chewed, crushed or split. Take again 12 hours later the same day. • Take the medicines at the approximate times indicated even if you have not actually had a meal. • Take any forgotten dose as soon as possible and then continue as before. • If more than 48 hours of medication omitted discontinue and seek advice • If taking calcium or iron supplements, then take at least 4 hours after or 6 hours before taking raltegravir. • Emtricitabine 200mg plus tenofovir 245mg and raltegravir patient information leaflet (PIL) • The need to have a follow-up HIV test in 4-6 weeks and 8-

	12 weeks post-exposure. • Partner notification details if source known suspected or known HIV positive. • Follow-up process in the event of HIV positive serology. • The need to have safer sex (at least 2 months and until confirmed HIV negative) and offer condoms. • Coping strategies, assessment of vulnerabilities and social support. • For patients concerned about sexual risk taking, offer ongoing risk reduction work or referral to counselling.
Follow up action	An appointment to be seen within 5 days for blood result review and further supply
Storage	• locked medicines cupboard – store below 25 °C • 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. Document the following in the patients notes: • Any reason for exclusion, including action taken and advice given. • Risk/benefit discussion re:PEPSE • If the patient has refused treatment under the PGD, any advice given or cautions taken. • Date. • Time of administration if appropriate. • Name, form, strength and dose of drug supplied • Route of administration. • Advice given to the patient including any possible side-effects and adverse reactions. • EPR signature of staff supplying medicine. • Form of documentation (patient records, letters, etc.). • Any communication with other health care professionals. That PEPSE (emtricitabine 200mg & tenofovir disoproxil fumerate

	245mg and Raltegravir) was supplied under a PGD.
Audit Arrangements	As per current Trust PGD Policy
References	• National Guidelines for Post Exposure Prophylaxis Following Sexual Exposure.(2015) British Association for Sexual Health and HIV: www.bashh.org/guidelines • British National Formulary (BNF). www.bnf.org/products/bnf-online • Liverpool Drug Interaction website: www.hiv-druginteractions.org • Summary of Product Characteristics (SPC). Raltegravir: www.medicines.org.uk/emc/medicine/20484 Emtricitabine/Tenofovir disoproxil Dr. Reddy's 200 mg/245 mg Film-Coated Tablets https://www.medicines.org.uk/emc/product/8608 • Nursing and Midwifery Council (NMC). The Code. Professional standards and behaviour for nurses and midwives (2015). www.nmc.org.uk/standards/code/record-keeping • Nursing and Midwifery Council (NMC) Standard for Medicines Management (updated 2015) www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management • YSH clinic PEPSE guidelines
Competency Requirements (attach any competency frameworks / documents)	• Completion of Trust PGD e-learning session. • Band 6 Nurse or above. • Clinical competence in sexual history taking. Clinical competence in the assessment of HIV transmission risk according to BASHH guidelines for PEPSE. • Knowledge base of the interactions of emtricitabine,

	raltegravir and tenofovir with other drugs, and other exclusions and contra-indications for issuing the above medicines. • 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. • 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. • Receiving clinical supervision and/or audit of case notes on an ongoing basis. • Commitment to continuing professional development identified through clinical supervision and appraisal. • Evidence of continuing professional development in sexual health. • 5 study days or the equivalent in hours, of study related to the field of sexual health every 3 years. • Regular attendance and participation in the monthly educational clinical governance sessions. • Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.

Staff authorised to work under this PGD	
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

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF: PEPSE Emtricitabine 200mg &Tenofovir Disoproxil Fumerate 245mg and Raltegravir 400mg

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Alison Chorlton Lead Sexual Health Nurse		20 06 19
Clinical Director Lead Approval	Ian Fairley		27-06-19
Directorate Pharmacy Lead Approval	Paul Jackson		1/8/19

PGD Approved by the NMP/PGD Group

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		5·8·2019.
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		5/8/2019

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

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
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 Carol Belt, Principal Pharmacy Technician 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