NHS Greater Glasgow and Clyde

CLINICAL GUIDELINE

HIV Pre-exposure Prophylaxis (PrEP)

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Guidance for Sandyford Staff on HIV Pre-exposure Prophylaxis (PrEP)

What's New?

- **Eligibility:** PrEP should be offered to anyone who would benefit from a reduction in HIV risk.
- **Young people:** TAF/FTC (Descovy) is recommended for anyone starting PrEP under 18 years old (and continued until age 20)
- **Event-based PrEP**: New "2:7" regimen for receptive vaginal/neovaginal sex and injecting risk.
- **"Quick starting":** PrEP can be initiated while awaiting the result of HIV and Hepatitis B tests, unless there are symptoms suggestive of HIV seroconversion.
- **Bone health:** those aged ≥50 years and/or those with significant risk factors for osteoporosis, should have their fracture risk calculated using the FRAX® online assessment calculator and those at high risk (risk score >10%) should be offered a DXA scan.
- **EBD TAF/FTC (Descovy):** this is now recognised as safe and effective (2:1:1 for anal sex or 2:7 for receptive vaginal/neovaginal sex and injecting risk).
- **Urinalysis at follow up:** routine urinalysis is not required during follow-up in those with normal renal function at baseline and no risks for renal disease.
- **Poor/deteriorating renal function:** helpful new flowcharts for management and follow up.
- **GI side effects:** new advice on how to manage these.
- **Weight loss injections:** new advice for those taking PrEP and Tirzepatide.
- **Window period testing:**
    - An HIV test should be repeated 45 and 90 days after PrEP initiation in individuals where a risk occurred in the 45 days prior to initiating PrEP (and PEPSE was not used).
    - If transitioning from PEPSE to PrEP, HIV testing should be performed 45 days after starting PEP and again 45 days after starting PrEP.
- **Long-acting injectable PrEP (Cabotegravir):** available for patients unable to use oral PrEP (according to strict eligibility criteria, following MDT review). Separate guidelines available.
- **PEPSE to PrEP:** all patients attending for PEPSE should be assessed for PrEP and ideally also be given 1 month of PrEP to start immediately after PEPSE.

Contents

1 Introduction and information sources

1.1 Who is this guidance for?

Staff working in specialist sexual health services in NHSGGC.

1.2 What is HIV PrEP?

HIV pre-exposure prophylaxis (PrEP) are medicines which are taken by someone who does not have HIV, to reduce their risk of acquiring HIV.

Most individuals at Sandyford will be prescribed oral Tenofovir **Disoproxil**/Emtricitabine (TDF/FTC). A small minority of patients will be managed in Complex PrEP clinics and may be prescribed Tenofovir **Alafenamide**/Emtricitabine (TAF/FTC, 'Descovy') or long-acting injectable Cabotegravir (CAB-PrEP) by senior GUM clinicians.

1.3 How does the PrEP service work?

Standard appointments for the vast majority of patients on PrEP are booked online via the Sandyford website. PrEP appointments are face to face. Once established on PrEP, most patients will have 6 monthly PrEP reviews with a clinician, and interim 3 monthly 'grab' appointments with a Health Care Support Worker (HCSW) for monitoring tests.

Our PrEP service is only for people living in NHS Greater Glasgow and Clyde or NHS Arygll and Bute (due to a service level agreement with that health board).

1.4 Information leaflets and links

https://www.sandyford.scot/sexual-health-services/prep/
https://www.nhsinform.scot/hiv-prep-pre-exposure-prophylaxis

Patient information:
https://i-base.info/guides/wp-content/uploads/2025/08/PrEP-guide-UK-August-2025.pdf

Please direct non-Sandyford health care professionals with clinical queries about patients on PrEP to email ggc.sandyfordprofessionalsupport@nhs.scot

2 Who should be offered PrEP?

PrEP should be offered to people, regardless of their gender or sexual orientation, who would benefit from a reduction in HIV risk. This includes:

- People who request PrEP
- People at risk of HIV (see below)
- People who are likely to have condomless anal or vaginal sex with people at risk of HIV (see below)
- People who inject drugs who might share injecting equipment

2.1 Who is at risk of HIV?

Someone is considered at risk of HIV if their risk of acquiring HIV is higher than that of the background UK population.

This includes, but is NOT limited to any of the following groups of people:

1. Current sexual partners, irrespective of gender, of people who have HIV with a detectable viral load
2. GBMSM (including transgender men) and transgender women reporting condomless penetrative anal sex
3. GBMSM who anticipate condomless anal sex in the future
4. People who have chemsex, group sex or sex at 'sex on site premises'
5. Women, transgender or non-binary individuals who have bisexual/GBMSM male partner(s)
6. People from high prevalence countries
7. People who have partners from high prevalence countries
8. People who have transactional sex
9. People who inject drugs or who's partner(s) inject drugs
10. Recent migrants
11. Anyone with a recent STI
12. Anyone who accesses PEPSE
13. Anyone with reduced sexual autonomy including those at risk of sexual exploitation, those with harmful drug and alcohol-use, those in coercive or violent relationships, those with unstable housing etc.

2.2 When should PrEP NOT be offered?

PrEP should NOT be used if the individual has HIV.
PrEP is not required in monogamous couples where one individual has HIV and is on treatment with a viral load consistently <200 copies/ml (U=U). There may be circumstances where the person still opts for PrEP, e.g. when they are uncertain about their partner's adherence to HIV treatment, or any of the other above risk factors are present.
If you are unsure whether someone should be offered PrEP please discuss with GUM doctor of the day

3 Starting HIV PrEP

3.1 Enquiries about starting PrEP

- Direct client to sources of information about PrEP (web links on page 3)
- Advise to book an appointment online using this link (send via SMS):

This is the Sandyford. If you wish to access PrEP, please book a consultation online using https://nashonlinebooking.com/onlinebookingsystem/en

3.2 PrEP Initiation

'PrEP new' appointments are for PrEP initiation including consultation, baseline tests and initial PrEP supply. Window period testing should be booked and patients should be on a 'rebook' list for their next review.

Document using usual NaSH forms and minimum dataset and the HIV PrEP proforma**.**

Record/update: past medical history, sexual history, social history and vaccination history in corresponding forms on NaSH (links in PrEP proforma)

- Medical history: especially a history of low bone mineral density (osteoporosis/osteopenia) and renal disease, or risk factors for these (see below)
- Sexual history: Most recent condomless anal/vaginal sex (or sharing of injecting equipment if relevant) and confirm whether window period testing required**.**
  - **If high risk of exposure <72h then consider PEPSE in first instance**
  - **If last sex between 72 hours and 45 days ago then book appointment for window period testing 45 days and 90 days after PrEP is started.**
- Vaccine history on consolidated vaccine form: Hepatitis A/B, HPV, Mpox and GC vaccines
- All medications including over the counter medication:
  - Especially weight loss injections and medications associated with renal impairment/low bone mineral density (see below)
  - Use ECS on clinical portal if client unsure of drug history.
  - Check drug-drug interactions on http://www.hiv-druginteractions.org/ via 'interaction checker'
  - If transgender, document start date of hormone therapy

Renal Disease
Common medicines associated with renal impairment:

- ACE inhibitors (e.g. ramipril)
- Angiotensin receptor blockers (e.g. candesartan, losartan)
- Diuretics (e.g. bendroflumethazide, furosemide)
- NSAIDs (e.g ibuprofen, naproxen, aspirin)
- COX II inhibitors (e.g. celecoxib)

Common conditions associated with renal impairment:

- High BP
- Diabetes
- Ischaemic heart disease
- Glomerulonephritis

Bone Health

All patients starting PrEP below the age of 18 years should be referred to Medically Complex PrEP for consideration of TAF/FTC (Descovy) due to their increased risk of low bone mineral density when taking TDF/FTC.

Common risk factors for low bone mineral density include:

- Previous fracture(s) at the wrist, spine or hip**
- High-dose oral or systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for ≥3 months) at any time in their life**
- Smoking
- High alcohol intake
- Menopause
- Very low body weight and/or eating disorder
- Other joint or connective tissue disorders e.g. rheumatoid arthritis

Anyone aged ≥50 years old should have their FRAX score calculated every 3 years using: https://fraxplus.org/calculation-tool

If their score if >10% then please discuss with the GUM doctor of the day as they will require DXA scanning, consideration of Descovy (TAF/FTC) and follow up in Medically Complex PrEP Clinic.

Anyone aged <50 years old with another risk factor for low bone mineral density as outlined above (especially those marked **) should be seen at least once in Medically Complex PrEP Clinic but can usually start PrEP in the meantime (discuss with GUM doctor of the day if unsure).

All patients with risk factors for low bone mineral density, as outlined above, particularly those under the age of 25 years should be advised to take Vitamin D and Calcium supplements.

Weight Loss Injections

Tirzepatide is a commonly purchased/privately sourced GLP1 agonist with a unique mechanism of action: gastric emptying delay. This makes people feel full for longer.

While there are no direct interactions between PrEP and Tirzepatide and absorption of TDF/FTC is likely to be duodenal (immediately post-stomach), the advice is as follows:

- Advise the patient to take PrEP daily during Tirzepatide initiation and for 30 days after dose increases starting with 2 tablets ideally well before risk
- Advise the patient to take PrEP with fatty food
- If concurrent absorption problems (Crohn's, gastric surgeries, etc) consult with GUM doctor of the day or specialist pharmacist.
- Avoid EBD and TTSS dosing:
    - This is because the delay in gastric emptying may affect tmax and Cmax for TDF/FTC, which in other words is the time taken for PrEP medication to reach max/therapeutic levels and the maximum drug levels in the blood. EBD taken only 2 hours before sex may not give enough time to achieve therapeutic drug levels.
    - Note this is pragmatic advice and current evidence is limited.

3.3 Socially Complex PrEP Clinic

Patients identified as having vulnerabilities or social complexity should be referred to Socially Complex PrEP for follow up.

Those suitable for Socially Complex PrEP clinic include, but is NOT limited to those who:

- Require an interpreter
- Are unable to use the online booking system
- Have harmful drug and alcohol-use or other complex mental health difficulties
- Are in unstable housing
- Are experiencing, or are at risk of, sexual exploitation/trafficking and GBV

These patients can be booked directly into a Socially Complex PrEP clinic or referred to the Sandyford Inclusion Team.

If you are unsure then please discuss with the GUM doctor of the day or the Inclusion Team.

3.4 Medically Complex PrEP Clinic

Patients identified as having medical complexity should be reviewed in the Medically Complex PrEP Clinic. This includes, but is NOT limited to:

- Anyone starting PrEP under 18 years old – this is due to new guidance that these patient should be on Descovy (TAF/FTC) PrEP
- eGFR <60
- uPCR >30
- Individuals with possible adverse reactions to PrEP
- Pregnant individuals
- Osteoporosis, osteopenia or other significant concern about their bone health (see page 6)
- HBsAg positive
- Multiple significant co-morbidities and medications which may affect their kidney or bone health

Most of these patients should NOT be started on PrEP without discussion with a senior GUM clinician first. Please discuss with the GUM doctor of the day and book them directly into a Medically Complex PrEP clinic for follow up.

Those with a significant drop in their eGFR since starting PrEP (*confirmed* drop in eGFR of 15 ml/min or more than 25%) may be suitable for Medically Complex PrEP but please discuss with GUM doctor of the day or add to GUM advice tab on NaSH first.

3.5 Information for patients starting PrEP

At PrEP initiation counsel the patient on the following:

- What PrEP is and the indication for taking it
- Effectiveness: PrEP has shown to be highly effective – approximately 99% if taken correctly.
- Dosing including start/stop rules (see below)
- Risks and benefits: common side effects and renal/bone risk
- Importance of adherence
- Risk of interactions with other medication including NSAIDS
- The need for 3-monthly HIV and STI testing and monitoring of kidney function at appropriate intervals
- Following the discontinuation of PrEP, we recommend retesting for HIV 45 days after the last risk
- Benefits of informing GP to improve prescribing safety
- Supply a patient information leaflet (PIL) – links on page 3

3.6 PrEP dosing

PrEP can be taken either through:

- Daily dosing
- Event Based Dosing (EBD)

However it is important to think of how to stop and start PrEP safely as many patients will switch between daily and EBD depending on their levels of sexual activity.

Starting PrEP
For all types of sex (both insertive and receptive anal/vaginal/neovaginal) and for injecting drug use, PrEP should be started with a double dose (2 tablets) 2-24 hours before sex/infecting.

Stopping PrEP
After anal sex (insertive and receptive) or penile sex (insertive vaginal/neovaginal/anal) PrEP can be safely stopped with a single dose daily for 2 days after the last risk.

After receptive vaginal/neovaginal sex or injecting drug use, PrEP can be safely stopped after a single dose daily for 7 days after the last risk.

Daily dosing

- Starting and stopping rules as above
- One dose is taken every day at the same time regardless of sexual activity.

Event-based dosing

The dosing schedules for EBD are outlined below according to the type of sex or injecting drug use:

Exposure Type	Time to Start Protection	Safely Stopping	Restarting
Receptive anal	Double-dose (2 pills) 2–24 h before risk	Continue single dose daily for 2 days after last risk	Restart with a single dose if < 7 days since last dose
Insertive vaginal / neovaginal / anal	Double-dose (2 pills) 2–24 h before risk	Continue single dose daily for 2 days after last risk	Restart with a single dose if < 7 days since last dose
Receptive vaginal / neovaginal	Double-dose (2 pills) 2–24 h before risk	Continue single dose daily for 7 days after last risk	Restart with a single dose if < 3 days since last dose
People who inject drugs	Double-dose (2 pills) 2–24 h before risk	Continue single dose daily for 7 days after last risk	Restart with a single dose if < 4 days since last dose

Table 1: EBD dosing (adapted from BHIVA/BASHH 2025 PrEP Guidelines)

3.7 Risks and side effects of TDF/FTC (standard oral) PrEP

- Most people taking PrEP will not experience any major side effects
- Mild nausea, change in stool consistency, bloating and headache are reported by fewer than 10% and usually improve within the first month
- The most serious side effect is the potential for renal toxicity and reduced bone mineral density (see page 6). These are more likely to affect people who already have kidney issues/low bone density.

3.8 Baseline tests prior to starting PrEP

Patients can start PrEP immediately while awaiting the results of their baseline tests – unless they have symptoms of HIV seroconversion, in which case please discuss this urgently with the GUM doctor of the day.

Positive baseline HIV and Hepatitis B results should be managed urgently as per the respective CEGs.

Baseline Test	**Indicated for**
HIV 4th generation	All
Syphilis	All
Hep B core Ab	All
Hep C PCR	All
CT/GC NAAT at appropriate sites	All
Pregnancy test	If appropriate
U&E	All
Urinalysis +/- uPCR	uPCR if urinalysis has protein 1+ or more

Table 2: Baseline tests

3.8.1 What do I do if the urinalysis is positive?

- Ensure the sample is mid stream (not the first pass sample used for NAAT)
- If 1+ or more protein on baseline urinalysis, discuss with GUM doctor of the day and send urine for uPCR (biochemistry form)
- If urinalysis shows **protein ++** or **+++,** check Blood Pressure and send uPCR. Discuss with GUM doctor of the day prior to commencing PrEP as it may be recommended to await further test results.
- If blood/glucose in urine and not expected (known diabetes/menstruating), seek advice from GUM doctor of the day.

3.8.2 How is renal monitoring done?

eGFRs are calculated by HCSWs (Appendix 4). Abnormal results are escalated for review to 'daily results' or 'GUM results'.

Patients are assigned a pathway according to their risk for renal dysfunction – Green, Amber or Red. This is covered in the next section (4.2) and in appendix 5 and determines the frequency of renal monitoring.

If renal results alter the follow up plan, document new pathway in clinical notes/purple triangle and edit follow up in place if needed (i.e. if switching to Medically Complex PrEP).

3.9 Prescribing HIV PrEP

At PrEP initiation, prescribe (or use PGD) and supply 4 months (3 months plus 1 month buffer*). It may be appropriate to prescribe PrEP for 7 months (6 months plus 1 month buffer*) at PrEP initiation for some patients e.g. they have been on PrEP in the past, they have very low medical complexity, they are good at attending arranged follow-up, do not require window period HIV testing etc.

*If the patient uses EBD PrEP then they are likely to use less than this and should be prescribed the amount of PrEP that they are estimated to use.

3.10 Communication with GP (and other healthcare providers)

Offer every patient a letter to GP to inform them about PrEP use. This is useful to identify side effects, reduce the risk of interacting medications being prescribed and support other health professionals to contact us with queries. In the case of complex co-morbidities it may be appropriate to communicate with other care providers.

A template can be found under 'GP PrEP' in NaSH document library. Please Q these letters to GGC med secretaries to be sent out.

3.11 Initiating/continuing PrEP at other appointments e.g. urgent care:

If clinically appropriate and time allows, PrEP can be initiated/continued at other appointments especially if someone has < 1 month supply of PrEP.

Ensure standard documentation completed and follow up arranged.

4. Follow-Up

4.1 HIV window period test

An HIV test should be repeated 45 days after PrEP initiation in individuals where a risk occurred in the 45 days prior to initiating PrEP, and then at 90 days post-PrEP initiation.

4.2 Arranging Follow-Up

Follow up depends on categorisation of patient.

GREEN: Aged <40 years. No medical conditions which increase bone/renal risk. Maximum 1+ protein in urine (or UPCR <20). No co-prescribed medicines which interact or associated with renal impairment. No significant social or other medical complexity.

- ➔ 6 monthly PrEP reviews with 3 monthly HIV/STI screens in between.
- ➔ Routine urinalysis at follow-up appointments not required.
- ➔ **At every PrEP review, book 'SC PrEP grab rebook' in 3m and 'SC PrEP rebook' in 6m***

AMBER: eGFR >60, but < 90 **or** aged > 40 years **or** comorbidity/medications which can affect the kidneys. Or downgraded from RED by senior GUM doctor. No significant social or other medical complexity.

- ➔ 6 monthly PrEP reviews with 3 monthly HIV/STI screens in between.
- ➔ 6 monthly U&E/urine dip (unless 3 monthly recommended for specific reason).
- ➔ Add purple triangle to "PrEP Amber Pathway" and if 3 or 6 monthly U&Es required
- ➔ **At every PrEP review, book 'SC PrEP grab rebook' in 3m and 'SC PrEP rebook' in 6m***

**When patients are on SC grab rebook, or SC PrEP rebook, they are sent an SMS that week with a link to book their next appointment online.*

RED: as per medically complex clinic details on page 8.

4.3 PrEP Return Appointments

These occur at **SC PrEP return** appointments. At every PrEP appointment please **complete the PrEP proforma and minimum dataset on NaSH and discuss with the patient:**

- Reason for continuing PrEP
- New co-medications or illnesses
- Regimen followed and any adherence challenges
- Recreational drug use and whether other support is needed
- Reassess category, tests, prescription and document follow up plan
- Prescribe and supply enough PrEP to last until their next review

4.4 What investigations do people need while taking PrEP?

Test	GREEN	AMBER	RED
Syphilis	Every 3m	Every 3m	Every 3m
HIV 4th generation	Every 3m	Every 3m	Every 3m
CT/GC NAAT at appropriate sites	Every 3m	Every 3m	Every 3m
Pregnancy test	If indicated by history	If indicated by history	If indicated by history
HCV PCR*	Annual	Annual	Annual
U&E	Annual	Every 3 or 6m	As per clinician
Urinalysis	Only if renal concern	Every 3 or 6m	As per clinician
uPCR	If urinalysis protein 1+ or more	If urinalysis protein 1+ or more	If urinalysis protein 1+ or more
Hep B core Ab	Consider annually if individual unvaccinated or known to be a non-responder to the vaccine		

Table 3: follow up tests

Consider 3 monthly HCV PCR if history of chems/group sex.

4.5 Stopping PrEP

Individuals can stop PrEP when no longer required, and most patients will stop PrEP themselves i.e. stop attending clinic. A clinician should only stop PrEP when the risks outweigh the benefits (e.g. not at increased risk of HIV but at risk of PrEP-associated adverse effects).

If the patient has significant bone/renal disease or has had toxicity from standard PrEP, TAF/FTC PrEP (Descovy) should be considered – please discuss with GUM doctor of the day and consider referral to the Medically Complex PrEP clinic (see page 8).

Advise patients of stop rules if stopping PrEP (see page 9).

5 References and further information

British HIV Association and British Association of Sexual Health and HIV. *BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2025* Available at: BASHH/BHIVA guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2025 – BHIVA [accessed 26/08/2025]

McCormack S *et al*; Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial Lancet 2016; 387: 53–60

Molina JM et al. On-Demand Pre-exposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015; 373:2237-2246

Eligibility criteria for Tenofovir AF/Emtricitabine (Descovy®) for Pre-exposure Prophylaxis for HIV (PrEP) in Scotland 2022

Appendix 1: Management Summary Flowchart: To START/RESTART PrEP

At 1st SC PrEP New consultation:

- Assess patient as per PrEP guidelines
- If patient would benefit from PrEP and opts to start:
  - Do baseline tests
  - Offer and administer outstanding recommended vaccines
  - Supply PrEP to last at least 3 months (or 6 months if appropriate – see page 12)
- **Book grab appointment for 45 and 90 days after starting PrEP if patient has had UPSI in the preceding 45 days (if very high risk add to SC SHA virtual diary to check this happened)**
- Send SMS Patient Information leaflet link**:**

https://i-base.info/guides/wp-content/uploads/2025/08/PrEP-guide-UK-August-2025.pdf

- Offer GP letter

No social or medical complexity

Add to SC PrEP Rebook in 3 months

(if appropriate, as per page 12, then patients can be added to SC PrEP Grab Rebook in 3 months for tests and SC PrEP Rebook in 6 months for PrEP review)

Social or medical complexity

Amber pathway

- add alert for 3 or 6 monthly U&E
- add to SC PrEP rebook in 3 months

Medically Complex (Red pathway):

- book directly in to SC PrEP med complex in 3 months

Socially complex:

- Add to SC PrEP soc complex for 3 months +/- refer to SIT if particular concern

Appendix 2: Management Summary Flowchart: PrEP after PEPSE pathway

If PEPSE is initiated:

- Ensure baseline investigations performed as per PEPSE protocol
- Supply enough PEPSE to last 28 days
- Assess at point of supplying PEPSE if patient would benefit from PrEP and opts to start this (Note: most patients given PEPSE will benefit from PrEP)
- **Ideally give 1 month of PrEP to start immediately after completing PEPSE in case of delays getting into PrEP clinic**

Opts to start PrEP

1. **Send SMS** with link to PrEP patient information leaflet
2. https://i-base.info/guides/wp-content/uploads/2025/08/PrEP-guide-UK-August-2025.pdf
3. Place patient in **SC PrEP Rebook list** for week they are due to complete PEPSE

- Automated SMS with link to book a PrEP callback online will be sent from this list
- Advise patient to use condoms for any anal/vaginal sex after they complete PEPSE until they initiate PrEP and window period tests are done

4. Add to SC SHA virtual diary in 12 weeks as a failsafe in case they do not attend for PrEP

Decision not to start PrEP

1. Arrange grab appointment for SHS and BBV bloods out with **window period (45 days post completion of PEPSE – usually at 12 weeks to coincide with syphilis and hepatitis window period bloods.)**
2. Add to SC SHA virtual diary in 12 weeks as a failsafe to ensure they attend for window period testing

At **SC PrEP New** consultation:

- Use the "new start" proforma for documentation on NASH
- Review adherence to PEPSE
- HIV testing should be performed 45 days after starting PEP and again 45 days after starting PrEP – this can be via grab clinics.
- Follow flowchart to start/restart PrEP (appendix 1)

Appendix 3: Management Summary Flowchart: PrEP Clinical Review

At SC PrEP return consultation:
Update PrEP proforma and NaSH forms
Perform follow-up clinical assessment as per protocol
If patient remains eligible for and wishes to continue PrEP:

Green or Amber Pathway

Patients categorised as Green/Amber:

- Carry out monitoring tests required
- Enquire how much PrEP they have in supply and prescribe enough to last next 6 months (plus 1 month buffer). Use estimated use with patient for EBD
- Prescribe/administer vaccinations as indicated
- Add to **SC PrEP Grab Rebook** list in 3 months
- Add to **SC PrEP Rebook** list in 6 months

Red Pathway (Medically or Socially Complex)

Patients categorised as Red:

- Carry out monitoring tests required
- Enquire how much PrEP they have in supply and prescribe enough to last next 3 months (plus 1 month buffer). Use estimated use with patient for EBD
- Prescribe/administer vaccinations as indicated
- Book directly into **SC PrEP med complex** or **SC PrEP soc complex** in 3 months
- Some patients in complex clinics may be appropriate for 6 monthly monitoring (including 6 monthly prescriptions of TAF/FTC, Descovy) at the discretion of the senior GUM clinician who reviews them

Appendix 4: How to calculate eGFR by CKD-EPI

Please use the National Kidney foundation calculator:

https://www.kidney.org/professionals/kdoqi/gfr_calculator

There are a few options on the page, these are the default settings and DON'T need to be changed:

- Leave Cystatin C blank
- Use standardised assay – YES
- Body measurements adjustments - NO

If patients are under the age of 18 you need a different equation due to lower muscle mass.

Please use: http://labtestsonline.org.uk/understanding/analytes/gfr/tab/test/ or http://nephron.com/bedside_peds_nic.cgi

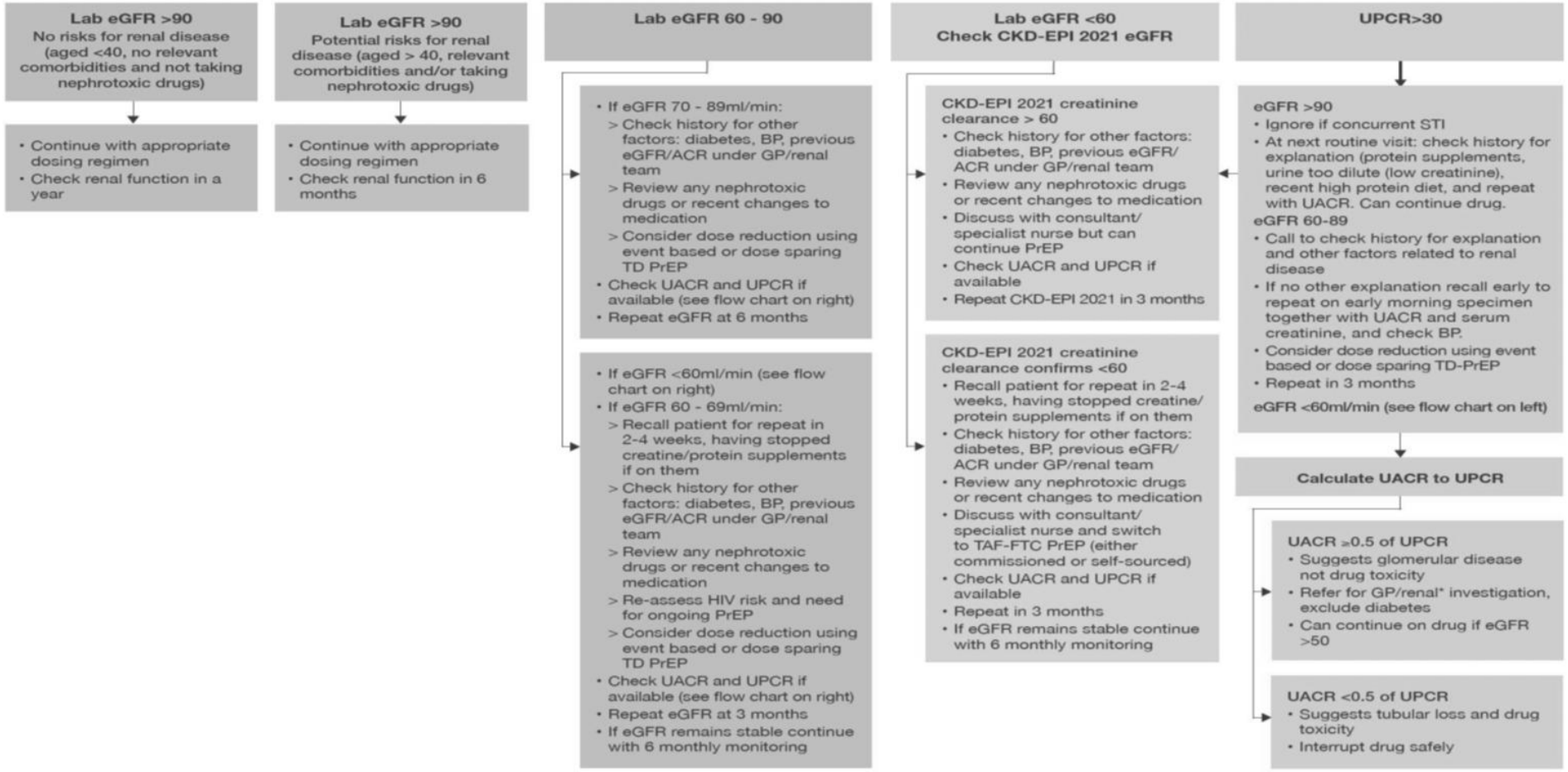
Transgender patients

Use sex assigned at birth if not on gender affirming hormone therapy or have been on gender affirming hormone therapy for < 1 year.

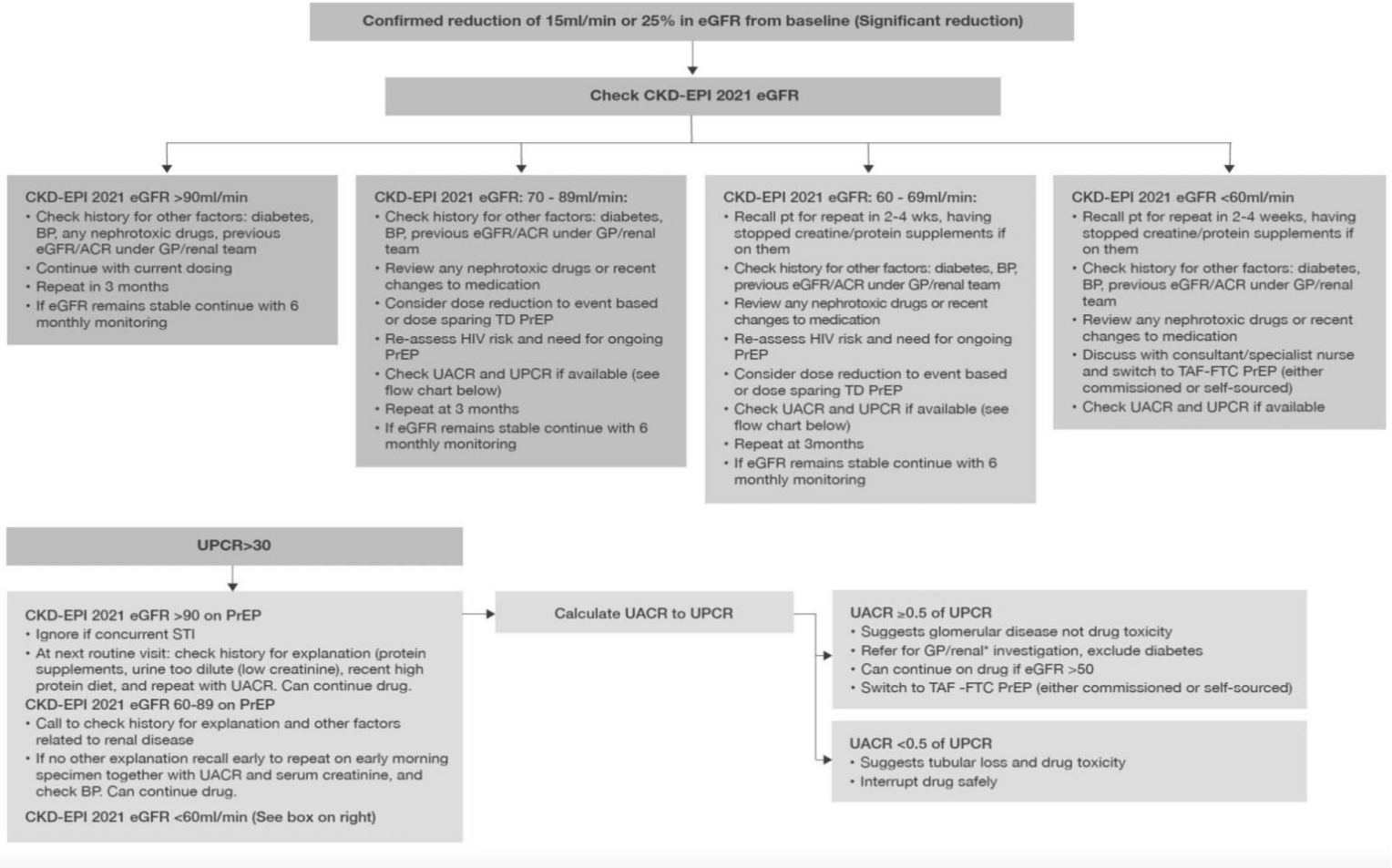
If established on hormone therapy > 1 year, use gender identity for this component of calculation.

Appendix 5: Renal Monitoring

Managing baseline renal function



Managing changes in renal function during follow up:



If clinical concerns or the drop in eGFR is very significant, please discuss with GUM doctor of the day.

Appendix 6: Bone Mineral Density

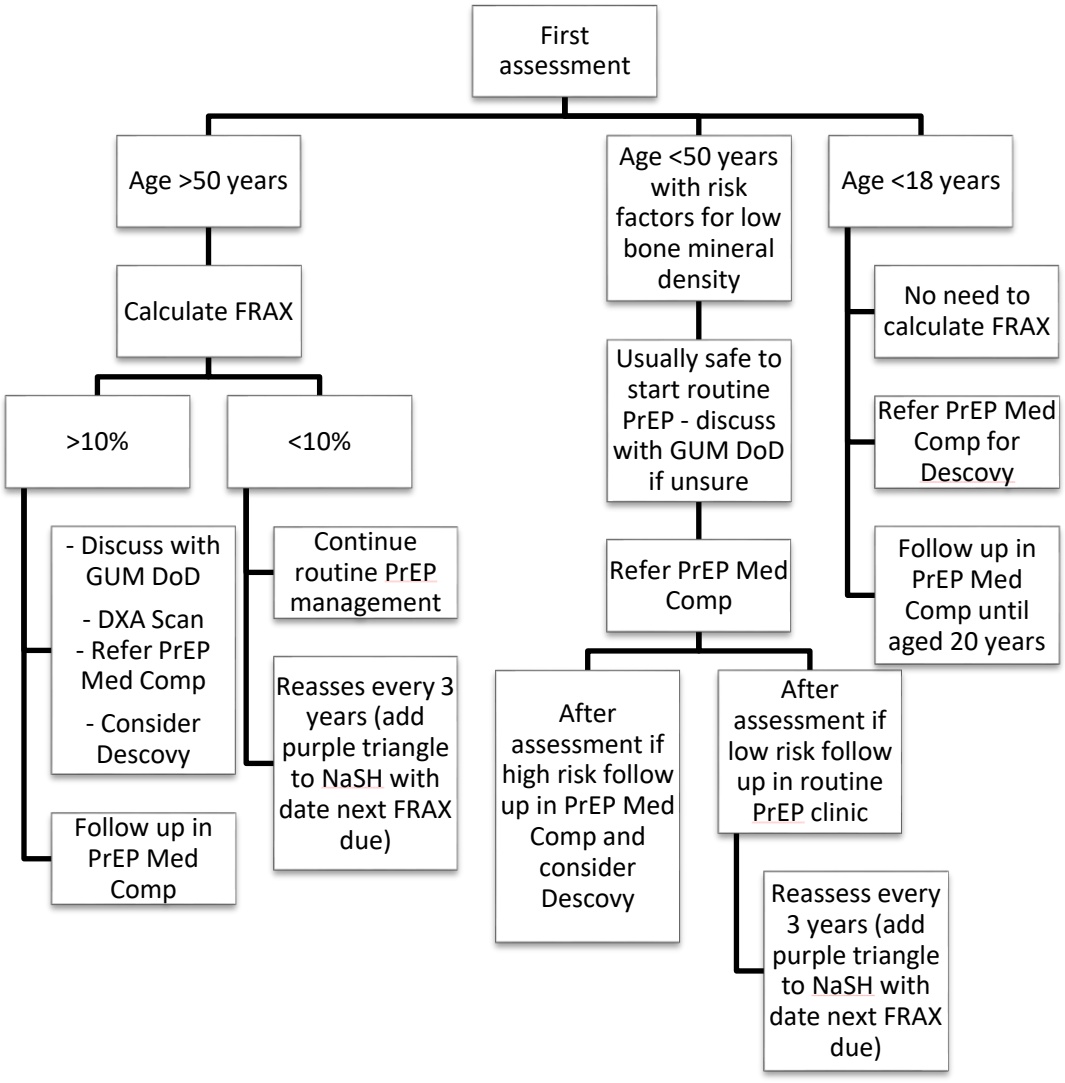
Assessment of bone mineral density:

Anyone aged ≥50 years old should have their FRAX score calculated <u>every 3 years</u> using: https://fraxplus.org/calculation-tool

If their score if >10% then please discuss with the GUM doctor of the day as they will require DXA scanning, consideration of Descovy (TAF/FTC) and follow up in Medically Complex PrEP Clinic.

Anyone aged <50 years old with another risk factor for low bone mineral density as outlined on page 6 should be seen at least once in Medically Complex PrEP Clinic but can usually start PrEP in the meantime (discuss with GUM doctor of the day if unsure).

Anyone aged <18 years old should be referred to Medically Complex PrEP for Descovy due to their increased risk of low bone mineral density.



Appendix 7: How to do a FRAX score

Calculating a FRAX Score

At the top of the page select "Europe" and "UK" for all patients (regardless of their ethnicity or place or birth). Leave "local reference" blank.

Questionnaire:

1) Age – must be between 40 and 90 years old. Only those 50 years or over old require a FRAX score calculated in routine PrEP clinics. Those under 50 with risk factors for low bone mineral density should be seen at least once in Medically Complex PrEP Clinic.
2) Sex – select male or female. Use sex assigned at birth if not on gender affirming hormone therapy or have been on gender affirming hormone therapy for < 1 year. If established on hormone therapy > 1 year, use gender identity for this component of calculation.
3) Weight – please use accurate up-to-date weight
4) Height – please use accurate up-to-date height
5) Previous fracture – this refers only to a previous "fragility fracture" which is a previous fracture in adult life occurring spontaneously, or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture. Answer "yes" or "no".
6) Parent fractured hip – has either of their parents ever fractured a hip? Answer "yes" or "no".
7) Current smoking – are they a current tobacco smoker? Answer "yes" or "no".
8) Glucocorticoids – this refers to high-dose oral or systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for ≥3 months) at any time in their life. Answer "yes" or "no".
9) Rheumatoid arthritis – has the patient ever been diagnosed with this? Answer "yes" or "no".
10) Secondary osteoporosis – enter yes if the patient has a specific condition strongly associated with osteoporosis such as type I diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition or malabsorption, chronic renal failure and chronic liver disease.
11) Alcohol, 3 or more units per day – answer "yes" or "no"
12) Femoral neck BMD – leave blank unless you have this information from a previous DXA scan

There is more detailed information at the bottom of FRAX website about the individual risk factors. Please discuss with GUM doctor of the day if you are not sure.

Interpreting the FRAX Score

The FRAX score calculates the 10-year probability of a fracture occurring.

Anyone with a risk of having a "Major Osteoporotic" fracture of >10% should be discussed with GUM doctor of the day and be referred for DXA.

Do not use the risk of "Hip Fracture" or the "View NOGG Guidelines" to decide when to request a DXA.

Appendix 8: Use of TAF/FTC PrEP (Descovy)

TAF/FTC based PrEP should be considered for the following individuals:

High Risk for TDF-associated renal dysfunction:

Moderate or severe reduction in glomerular filtration **(eGFR) ≤ 49 ml/min**, at baseline or during follow-up) and clinical assessment suggests that TAF-FTC would have a lower risk profile than standard PrEP

OR

- Individuals with **proven renal toxicity** with TD-FTC (acute or chronic)

Medium Risk for TDF-associated renal dysfunction:

Individuals with an eGFR ≥ 50 ml/min (and <90ml/min) in which:

1. A sustained **progressive reduction** in estimated glomerular filtration rate on TDF-FTC is seen of **15ml/min or 25%**
   AND
2. Significant concurrent **medical issues** or **monitoring/prescribing concerns** which suggest TAF/FTC would have a lower risk profile to TDF/FTC.

Progressive reduction should be demonstrated over 3 separate readings.

High Risk for low bone mineral density:

Individuals with **confirmed osteoporosis** on DXA or a high risk of a major fracture as determined by an appropriate fragility risk score.

Medium Risk for low bone mineral density:

- Individuals who are < 18 years when they commence PrEP

All patients who may require TAF/FTC (Descovy) should be discussed at the local MDT +/- the national PrEP MDT

TAF/FTC (Descovy®) should not be used in:

- Individuals <35 kg
- In those currently prescribed/taking – adefovir disoproxil, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, primidone, St John's Wort

Protocol for TAF/TFC (Descovy) prescribing:

1. Patient (if not already) referred to GUM consultant (Add to SC GUM Advice list on NaSH)
2. If TAF/FTC (Descovy) PrEP is appropriate, patient is then discussed at fortnightly GUM team meeting (1st and 3rd Tuesday of month, 1pm – SC GUM Peer Review Tab on NaSH).
3. If patient does not meet usual criteria in Appendix 7 but GUM team feels requires TAF/FTC (Descovy), patient may be referred to National Complex PrEP MDT for discussion
4. Agreement is reached to commence TAF/FTC (Descovy) at either meeting
5. Inform pharmacist to facilitate ordering and logging in database
6. Once available, TAF/FTC (Descovy) is stored in locked cupboard in Sandyford Central
7. Patient should be on RED pathway and seen at **SC PrEP med complex**. If this is challenging due to geographical distance, tailored arrangements could be made. This is due to the different advice given and not covered by PGD.

Note: patients must be reminded of importance of safeguarding their supply of emtricitabine/tenofovir alafenamide at each appointment. Should a patient run out of this or misplaces their supply, an ad hoc order can be provided once each year but this must be approved by GUM doctor of the day and specialist pharmacist with circumstances documented

Appendix 9: Hepatitis B Infection

Anyone with positive HBsAg should be referred to their local specialist hepatitis B clinic for follow-up and management. If these patients would benefit from PrEP then **they should be referred to the Medically Complex PrEP clinic.**

Individuals with HBV but not requiring treatment for HBV should be offered daily oral PrEP as the preferred option, but event-based oral PrEP can also be offered.

Individuals with chronic HBV should be counselled that there is a potential risk of HBV reactivation if PrEP is stopped, and that following PrEP discontinuation they will require monitoring with HBV DNA and liver function tests for 12 months if not on other HBV treatment.

Appendix 10: When to offer PEPSE to those on PrEP

Sexual risk (no condom)	Time between last PrEP dose before exposure and resumption of PrEP	Recommendation after exposure
Insertive/receptive anal sex or insertive vaginal sex	≤7 days	Resume PrEP with a double dose as prescribed
	>7 days	Take a double dose of PrEP as soon as possible in the 24 hours after exposure, continue daily and seek urgent advice from clinical services for intensification to PEP
Receptive vaginal sex	≤3 days	Resume PrEP with a double dose as prescribed
	>3 days	Take a double dose of PrEP as soon as possible in the 24 hours after exposure, continue daily and seek urgent advice from clinical services for intensification to PEP
Receptive neovaginal sex	≤3 days	Resume PrEP with a double dose as prescribed
	>3 days	Take a double dose of PrEP as soon as possible in the 24 hours after exposure, continue daily and seek urgent advice from clinical services for intensification to PEP
Injecting drug use	≤4 days	Resume PrEP with a double dose as prescribed
	>4 days	Take a double dose of PrEP as soon as possible in the 24 hours after exposure, continue daily and seek urgent advice from clinical services for intensification to PEP

Table 4: When to Offer PEPSE to those taking PrEP

Missed post-coital dose for event-based PrEP

People using EBD PrEP (2:1:1 dosing) who are late with, or missed, the first post-coital dose, the first post-coital dose can still be taken up to 48 hours after sex, provided at least one tablet was taken before sex; the second post-coital dose should be taken 24 hours after the first to complete the course.

If more than 48 hours elapsed since the risk or for people using 2:7 dosing for EBD then an assessment for PEPSE should be made.

Appendix 11: Long-acting Injectable PrEP

Cabotegravir (CAB-PrEP) is now available on the NHS in Scotland as a long-acting injectable PrEP option. However it is only available after careful consideration by a senior GUM clinician and MDT discussion. People who *may* be eligible for CAB-PrEP includes:

- Those for whom oral tablets are not an option but adherence to treatment regimen is assured
- Those who may benefit from, but have issues with consumption of, oral PrEP e.g. tablets cannot be hidden from partner or family but adherence to treatment regimen is assured
- Those with significant renal dysfunction (both oral PrEP options not suitable)

If you think someone should be considered for injectable PrEP then please discuss this with the GUM doctor of the day. A separate guideline has been produced for those on Cabotegravir PrEP and each patient requires MDT discussion and follow up in the Medically Complex PrEP clinic.

Appendix 12: Managing Gastrointestinal Side Effects

Mild GI side effects are common (affecting approximately 10% of people using PrEP) including nausea, vomiting, bloating and diarrhoea.

These side effects settle within 3 months for the vast majority of people.

Ways of managing GI side effects:

- Taking PrEP with meals (especially fatty foods)
- People using EBD PrEP who experience GI side effects following the double dose can take the dose as two separate tablets 6–12 hours apart within the 2- to 24-hour window period. The second tablet should be taken at least 2 hours before risk.
- People using daily PrEP may find side effects are less when taken in the evening or before bed

If side effects are very severe then they may need other medications to manage the symptoms such as anti-emetics – please discuss with GUM doctor of the day and consider referral to Medically Complex PrEP clinic.

Appendix 13: Abbreviations

- CAB – cabotegravir (long-acting injectable PrEP)
- CKD – chronic kidney disease: reduction in filtration or evidence of glomerular or tubular damage
- EBD – event based dosing
- eGFR – estimated glomerular filtration rate
- FTC – emtricitabine
- GBMSM – gay, bisexual, men who have sex with men
- PEPSE – Post Exposure Prophylaxis for sexual exposure to HIV
- PIL – patient information leaflet
- TDF – tenofovir disoproxil
- TAF – tenofovir alafenamide
- TTSS – Tuesday, Thursday, Saturday, Sunday dosing of PrEP (not routinely recommended in our service but may be advised after discussion with a senior GUM clinician)
- U&E – urea and electrolytes
- uPCR – urine protein creatinine ratio
- WP – window period