

Guidance for Sandyford staff on HIV pre-exposure prophylaxis (PrEP)

| | | |
|---|---|----|
| 1 | Introduction and information sources..... | 2 |
| 2 | Who should be offered PrEP | 3 |
| 3 | Starting HIV PrEP (including dosing info) | 4 |
| 4 | Organising follow up..... | 9 |
| 5 | Ongoing PrEP reviews | 10 |
| 6 | References..... | 11 |
| | Management Summary Flowchart: To START/RESTART PrEP.. | 12 |
| | Management Summary Flowchart: Initiating PrEP after PEPSE . | 13 |
| | Management Summary Flowchart: PrEP Clinical Review..... | 14 |
| | Appendix 1: PrEP documentation Proformas | 15 |
| | Appendix 2: PrEP Coding..... | 17 |
| | Appendix 3: Abbreviations..... | 18 |
| | Appendix 4: How to calculate eGFR by CKD-EPI..... | 18 |
| | Appendix 5: Renal monitoring algorithm..... | 19 |
| | Appendix 6: Use of TAF/FTC based PrEP (Descovy)..... | 20 |

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 can be taken by someone who does not have HIV, to reduce their risk of acquiring HIV. It is generally recommended for adults at higher risk of HIV.

The evidence base for the use of PrEP is included in Appendix 3. Most individuals at Sandyford will be prescribed oral **Disoproxil/Emtricitabine** (TD/FTC) as PrEP. A small minority of patients will be prescribed Tenofovir **Alafenamide/Emtricitabine** (TAF/FTC).

1.3 How does the PrEP service work?

Appointments are generally booked online via the Sandyford website. PrEP appointments are face to face at either Sandyford Central or Sandyford Connects. Once established on PrEP, most patients will have 6 monthly PrEP reviews with a clinician with interim 3 monthly 'grab' appointments with a Health Care Support Worker (HCSW) for monitoring tests.

Please see these useful links for background:

[PrEP \(sandyford.scot\):](https://www.sandyford.scot/)

<https://www.sandyford.scot/sexual-health-services/prep/>

[HIV PrEP \(Pre-Exposure Prophylaxis\) | NHS inform:](https://www.nhsinform.scot/hiv-prep-pre-exposure-prophylaxis)

<https://www.nhsinform.scot/hiv-prep-pre-exposure-prophylaxis>

Patient information:

<https://www.sandyford.scot/media/4214/prep-booklet-generic-220419-web.pdf>

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?

Patients offered PrEP at Sandyford must satisfy these criteria:

1. Be aged **16 years or over**
2. Have a baseline **negative HIV test** (this can be taken at initial appointment)
3. Be able to attend for **regular 3 monthly appointments** for monitoring, sexual health care, and to collect prescriptions
4. Be **resident** in Greater Glasgow and Clyde Health Board

If a patient does not meet above criteria, but a clinician feels PrEP is appropriate, please discuss with GUM doctor of the day

Eligibility criteria

Scottish services will move away from using specific eligibility criteria, at present we are continuing to use these as guidance in GGC. PrEP is suitable for most people who request it, except where HIV risk is very low and therefore the risk of PrEP outweighs the benefit.

1. Current sexual partners, irrespective of gender, of people who have **HIV with a detectable viral load**.
2. MSM & transgender women with a documented **bacterial rectal STI** in the last **12 months**
3. MSM & 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 3 months
4. **Individuals, irrespective of gender, at an equivalent high risk of HIV acquisition, as agreed with another specialist clinician**

**MSM includes trans men with male partners.*

The below are examples of indicators that someone may benefit from PrEP under category 4 and should prompt discussion around PrEP:

- MSM who may have condomless anal sex in the future
- People who have chemsex or group sex
- Women who have bisexual male partner(s)
- People from high prevalence countries (eg in Sub Saharan Africa)
- People who tend to have partners from high prevalence countries
- People who have transactional sex
- People who inject drugs or who's partner(s) inject drugs (*PrEP for injecting risk alone is currently off licence in Scotland. Discuss these cases with GUM consultant/outreach PrEP team to identify whether PrEP indicated*)

Exclusion criteria

PrEP should not be used if the individual has HIV. If HIV is suspected clinically, await test results prior to starting PrEP.

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)

3 Starting HIV PrEP

3.1 Enquiries about starting PrEP

- Direct client to sources of information about PrEP (links on page 2)
- Advise they can 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>*
- If they are unable to use online booking or need an interpreter booked, make them an appointment on 'PrEP New' at appropriate location

Initiating/continuing PrEP at other appointments eg urgent care:

- If clinically appropriate and time allows, PrEP can and should be commenced at other appointments such as urgent care. If someone is running out of PrEP, review and prescription can occur at other appointments. Ensure standard documentation and follow up organised.

3.2 PrEP initiation consultation

'PrEP new' appointments are for PrEP initiation. These are with a nurse/doctor plus a HCSW for **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.**

Appendix 15 has a proforma for documentation

Document in the clinical notes: (using proforma in Appendix 1)

- Background: Summary of why individual is at higher risk of HIV and corresponding eligibility criteria.
- 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**
- Vaccine history: Hepatitis A/B, HPV and Mpox

- Medical history including risk factors for and history of osteoporosis and renal disease. This includes age > 40 years, hypertension, diabetes, ischaemic heart disease, alcohol dependence, chronic steroid use (>3m).
- All other medications including over the counter medication, focussing especially on medication associated with renal impairment and regular NSAID use
 - 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

• Some common medicines associated with renal impairment which may put individual at increased renal risk

- ACE inhibitors (eg lisonopril)
 - Angiotensin receptor blockers (eg candesartan, losartan)
 - Diuretics (bendroflumethazide, furosemide)
- NSAIDs (such as ibuprofen, naproxen) or COX II inhibitors

- Use of chems, recreational drugs and protein/gym supplements
- Discussion of other risk reduction methods
- Offer referral to Choices if patient is MSM and would benefit from additional support around risk reduction or for those involved in chemsex.
- If you are uncertain about a patient's eligibility for PrEP, or concerned about medical appropriateness (e.g. comorbidities, co-prescribed interacting meds) please seek advice from GUM doctor of the day or add to GUM advice list

Patients who should not be prescribed PrEP without discussion with senior GUM doctor:

- Known significant renal disease/impairment, inc eGFR <60
- Known osteoporosis
- Individuals with current Hepatitis B (Hep B sAg positive)

Highlight to GUM DOD and book into next SC PrEP med complex appt

3.2.1 Information for patients starting PrEP

At PrEP initiation, discuss with individual:

- What PrEP is and indication
- Effectiveness
- Dosing inc start/stop rules (NB different if not exclusively for anal sex)
- Risks and benefits: common side effects and renal/bone risk.
- Importance of adherence
- Risk of interactions with other medication
- The need for 3-monthly HIV and STI testing and monitoring of kidney function at appropriate intervals
- Symptoms of seroconversion and when to seek an urgent HIV test
- Benefits of informing GP to improve prescribing safety

Supply a patient information leaflet (PIL) – links on page 2

3.2.2 Effectiveness of PrEP

PrEP has shown to be highly effective – approximately 99% if taken correctly.

3.2.3 PrEP dosing (for standard oral TD/FTC PrEP)

PrEP can be taken either through:

- Daily dosing – can be used by all individuals
- Event Based Dosing (EBD) – for MSM and trans patients exclusively having anal sex

Daily dosing

- One dose taken every day at the same time regardless of sexual activity.
- For vaginal sex/injecting:
 - Start rule: take PrEP for 7 days prior to potential exposure (followed by ongoing daily dosing).
 - Stop rule: take PrEP for 7 days after last potential exposure
- If exclusively having anal sex can use these instead:
 - Start rule: take 2 tablets (double dose) at least 2 hours prior to anal sex (followed by ongoing single tablet daily dosing)
 - Stop rule: take 1 PrEP tablet daily for 2 days after anal sex

Event-based dosing – for anal sex only (Figure 3)

- Single act of condomless anal sex:
 - Loading dose of 2 tablets 2-24 hours before sex
 - 1 tablet 24 hours (22-26 hours) after the first dose
 - Another tablet 48 hours (46-50 hours) after the first dose
- Multiple sex acts of condomless anal sex:

- Loading dose of 2 tablets 2-24 hours before first sex
- 1 tablet daily continuously until last condomless anal sex, then for two further days.
- If restarting EBD within 7 days of last dose, the loading dose can be 1 tablet instead of 2

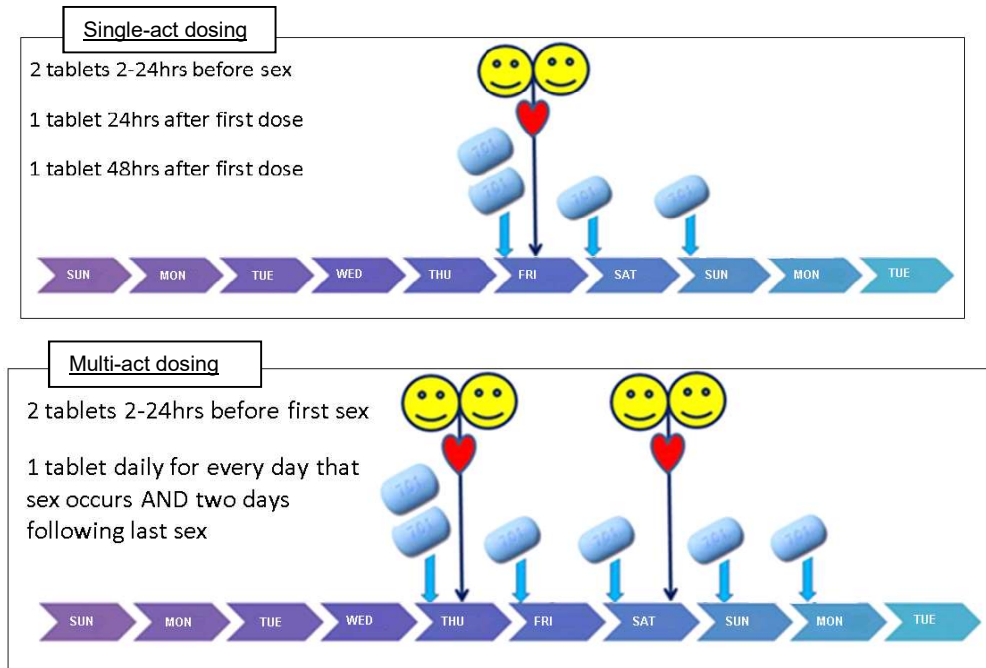


Figure 3: Event based dosing

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

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

3.3 Baseline tests prior to/at PrEP initiation

The individual should **wait for the results of the HIV and Hepatitis B tests prior to commencing PrEP** due to the risk of drug resistance in HIV and the risks associated with event based dosing in Hepatitis B. Baseline renal function will help determine frequency of ongoing monitoring.

| Baseline Test | Indicated for |
|--------------------------------|---------------|
| HIV 4 th generation | All |
| Syphilis | All |
| Hep B core Ab | All |

| | |
|---------------------------------|---------------------------------------|
| Hep C PCR | All |
| CT/GC NAAT at appropriate sites | All |
| Pregnancy test | where appropriate |
| U&E | All |
| Urinalysis +/- uPCR | UPCR if urinalysis protein 1+ or more |

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 DOD and send urine for uPCR (biochemistry form).
- If urinalysis shows **protein ++** or **+++**, check Blood Pressure, send uPCR. Discuss with GUM DOD 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.

How is renal monitoring done

eGFRs are calculated by HCSWs (Appendix 4). Abnormal results are escalated for review to 'daily results' or 'GUM results'. If renal results alter follow up plan, document new pathway in clinical notes/purple triangle and edit follow up in place if needed (ie if switching to SC PrEP med complex)

Follow algorithm in Appendix 5.

3.4 Prescribing HIV PrEP

- **At PrEP initiation, prescribe and supply 4 months** (3 months plus 1 month buffer). If EBD, this may be fewer than 120 tablets depending on expected usage.
 - Inform patients they should NOT start taking PrEP until they have received their negative HIV and Hepatitis B results.

3.5 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, avoid prescribing of interacting medications and facilitate other health professionals to contact us with queries. In the case of complex co-morbidity 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.

4. Organising follow up

4.1 HIV window period test

- If HIV PrEP is started whilst the patient is in the 45 day window period for HIV, book an appointment for **HIV test only** in grab clinic for 45 days post potential exposure.

4.2 Ongoing 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 complexity.

- ➔ 6 monthly PrEP reviews with 3 monthly HIV/STI screens in between. Annual renal function/urine dip
- ➔ **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 which can impact kidneys/co-prescribed medication which can affect kidneys. Or downgraded from RED by senior GUM doctor. No significant social complexity.

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

RED: Clients aged over 70 years. eGFR < 60. Significant drop in eGFR on recommendation of DOD. uPCR > 30. Individuals with significant renal comorbidities (eg transplant) Individuals with Hep B or C coinfection. Individuals with possible adverse reactions to PrEP. Individuals with reduced bone density (osteopenia/osteoporosis) or significant risk factors (previous fractures/alcohol/steroid). Concerning drug interactions. Pregnant individuals. Individuals aged under 18. Significant social complexity. On TAF. Clinical concern/inability to PGD.

- ➔ 3 monthly reviews at SC PrEP med complex or SC PrEP soc complex (if for social complexity). These are booked directly by clinicians and not through online booking

- At every PrEP review, book directly into next clinic. If no capacity, add to 'SC GUM complex rebook' with appointment note saying PrEP.

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.

Please refer to Sandyford inclusion team if individual:

- Is experiencing homelessness
 - Injects drugs
 - Is prescribed opiate substitution eg methadone
- These patients may benefit from the outreach PrEP service.

5. Ongoing PrEP reviews

These occur at **SC PrEP return** appointments

5.1 What to discuss/document (see appendix for proforma)

- 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

4.3 What investigations do people need while taking PrEP?

| Test | GREEN | AMBER | RED |
|---------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Syphilis | Every 3m | Every 3m | Every 3m |
| HIV 4 th 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 | Annual | 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 |

****Consider 3 monthly HCV PCR if history of chems/group sex. Consider Annual Hep B core Ab if individual unvaccinated***

5.1 Stopping PrEP

Individuals can stop PrEP when no longer required. A clinician should only stop PrEP when the risks outweigh the benefits (eg not at increased risk of HIV but at risk of PrEP-associated side effects). If patient has significant bone/renal disease or has had toxicity from standard PrEP, TAF/FTC PrEP (Descovy) should be considered. **Advise patients of stop rules if stopping PrEP**

5.2 Switching to TAF/FTC PrEP (Descovy).

If a patient has osteoporosis or an eGFR <60 at baseline, patient should be booked into SC PrEP med complex for consideration of Descovy. Discuss with DOD about PrEP use in the interim.

If PrEP-induced renal toxicity is suspected or renal function declines whilst on PrEP, a switch to TAF/FTC PrEP (Descovy) may need to be considered.

Decision to use Descovy requires MDT input and should involve 2 GUM consultants.

Please see Appendix 5 for full guidance on TAF/FTC (Descovy) based PrEP

6 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) 2018*

Available at: <https://www.bhiva.org/PrEP-guidelines> [accessed 12/12/2018]

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

Management Summary Flowchart: To START/RESTART PrEP

At 1st SC PrEP New consultation:

- Use 'New Start Proforma'
- Assess patient as per PrEP protocol
- If patient would benefit from PrEP and opts to start:
 - Do baseline tests (advise not to start PrEP until HIV/Hep B results)
 - Offer and administer outstanding recommended vaccines
 - Supply PrEP to last 4 months
- **Book grab appointment for 45 days post UPSI if patient is in WP (if very high risk add to HA virtual diary to check this happened)**
- Send SMS Patient Information leaflet link:
<https://www.sandyford.scot/media/3624/prep-in-scotland-2nd-ed-final.pdf>
- Offer GP letter

No social or medical complexity

Add to SC PrEP Rebook in 3 months

Social or medical complexity

Medically complex:

Amber pathway

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

Red pathway

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

Socially complex:

Add to SC PrEP soc complex for 3 months

History of homelessness/injecting drug use:

Internal referral to inclusion team

Management Summary Flowchart: Initiating 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

Opts to start PrEP

1. **Send SMS** with link to PrEP patient information leaflet <https://www.sandyford.scot/media/3624/prep-in-scotland-2nd-ed-final.pdf>
2. 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.

Decision not to start PrEP

Arrange grab appointment for SHS and BBV bloods out with **window period (45 days post completion of PEPSE)**

At SC PrEP New consultation:

- Use the “new start” proforma for documentation on NASH
- Review adherence to PEPSE
- Book grab appointment for WP testing **45 days** after completing PEPSE
- Follow flowchart to start/restart PrEP (previous page)

Management Summary Flowchart: PrEP Clinical Review

**At SC PrEP return consultation:
Use 'PrEP Clinical Review Proforma'
Perform follow-up clinical assessment as per protocol
If patient remains eligible for and wishes to continue PrEP,**



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). NB 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

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). NB 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

Appendix 1: PrEP Proformas

PrEP– New Start/Restart

Background including risk factors for HIV: (eg. MSM with >1 partner)

Last UPSI:

Last HIV test:

Hep A/B vaccination status:

HPV vaccination status:

MPX vaccination status:

PMH:

DH:

Chemsex/recreational drugs/gym supplements:

Counselled as per Prep checklist: indication, effectiveness, dosing and start/stop rules, side effects inc renal/bone, adherence, interactions inc NSAIDs, seroconversion symptoms, monitoring

PIL sent as SMS

Dosing regimen opted for:

GP letter: *accepted/declined*

Baseline tests to be carried out today by HCSW: HIV, syphilis, Hep B, Hep C, GC/CT naat all sites, U&E, urinalysis (+/- uPCR)

Advised not to commence PrEP until negative HIV and Hep B result confirmed.

Urinalysis: *trace or less / more than trace, discussed with DOD*

PrEP pathway: *green/amber/red*

Plan:

Results line card given.

PrEP dispensed:

WP test booked for:

Follow up booked: *SC PrEP rebook/other*

PrEP return clinical review

Background including risk factors for HIV: *(eg. MSM with >1 partner)*

Dosing regimen:

Stop/start rules discussed

Any UPSI not covered by PrEP:

Outstanding vaccinations:

PMH:

DH:

Chemsex/recreational drugs/gym supplements:

Annual bloods due today: *yes/no*

PrEP pathway: *Green/Amber/Red*

Existing supply of PrEP:

Plan:

Tests to be done today by HCSW: HIV, syphilis, CT/GC all sites, U&E, Hep C, urinalysis (+/- uPCR)

Vaccines given:

PrEP dispensed:

Follow up: *SC PrEP grab rebook 3m and SC PrEP rebook 6m / other*

Appendix 2: PrEP Coding

STISS Coding is a tool for monitoring PrEP use in Scotland. PrEP clinicians will be informed when to carry this out.

If PrEP advice or monitoring is the main focus of the consultation, use NaSH to record “STI-PrEP” as the Main Reason for attending (figure 1):

The screenshot shows the 'Special Forms' interface for 'Episode NaSH v0.3'. The 'Reason for Attending' dropdown is open, showing a list of reasons. 'STI-PrEP' is highlighted under the 'STI-PrEP / PEPSE' category. Other categories include 'Contraception', 'STI-Test', 'STI-Partner has infection / Partner Notification', 'STI-Treatment', and 'Pregnancy Concerns'. The 'Main Reason' field is set to 'STI-PrEP'.

Figure 1: Episode reason

The screenshot shows the 'Special Forms' interface for 'Episode NaSH v0.3'. The 'Main Reason' is 'STI-PrEP'. In the right-hand navigation menu, the 'STISS Clinical' button is highlighted with a red box. Other buttons in the menu include 'Episode', 'Recent Sx Hx', 'Female Exam.', 'EC', 'Procedures', 'PN', 'Counselling', and 'External Ref'.

Figure 2: STISS coding

Appendix 3: Abbreviations

- CKD: chronic kidney disease: reduction in filtration or evidence of glomerular or tubular damage
- eGFR: estimated glomerular filtration rate
- FTC - emtricitabine
- MSM – men who have sex with men
- PEPSE – Post Exposure Prophylaxis for sexual exposure to HIV
- PIL – patient information leaflet
- TDX - tenofovir disoproxil (the X stands for the range of salts)
- U&E – urea and electrolytes
- uPCR – urinary protein creatinine ratio

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

If patients are transgender:

- 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 algorithm

GREEN pathway patients (no relevant comorbidities etc):

| | |
|---------------------------|---|
| eGFR >90 | Remain on annual monitoring |
| eGFR drops to <90 but >75 | Move to AMBER 6 monthly monitoring |
| eGFR drops to <75 | Move to AMBER 3 monthly monitoring and add to GUM advice |
| eGFR drops to <60 | Add to GUM advice (GUM consultant should move to RED and book into SC PrEP med complex) |

AMBER pathway patients

| | |
|--|---|
| eGFR not dropped by >15 ml/min and remains >60 | Continue current monitoring frequency |
| eGFR >60 but <90 and dropped by >15 ml/min | Repeat at 3 months. Add to GUM advice. |
| eGFR dropped below 60 | Add to GUM advice (GUM consultant should move to RED, and book into SC Prep med complex for next apt) |

RED patients: frequency as per reviewing clinician. If >60 and <90 and dropped by 15ml/min or if <60 and any drop, please add to GUM advice.

If clinical concerns/drop is very significant, please discuss with GUM DOD

Appendix 6: TAF/FTC PrEP (Descovy)

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

- **People with High risk renal factors for TD-FTC:**
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)
- **People with medium risk renal factors for TD-FTC:**
 - Individuals with an eGFR ≥ 50 ml/min (and <90 ml/min) in which:
 1. A sustained **progressive reduction** in estimated glomerular filtration rate on TD-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 TD-FTC.
Progressive reduction should be demonstrated over 3 separate readings.

- **People with high risk bone factors for TD-FTC:**
 - Individuals with **confirmed osteoporosis** on DEXA or a high risk of a major fracture as determined by an appropriate fragility risk score.
High fracture probability defined as $>10\%$ (major osteoporotic or hip fracture absolute risk using FRAX)

- **People with medium risk bone factors for TD-FTC:**
 - Individuals who are < 18 years

There may be other unusual circumstances where a patient at risk of HIV is unable to take tenofovir disoproxil and tenofovir alafenamide may be indicated. These cases should be discussed at the local MDT then the national MDT as above.

Tenofovir AF/Emtricitabine (Descovy®) should not be used in

- Individuals <35 kg
- Event-based dosing (EBD)
- Where the risk for HIV is from vaginal intercourse due to lack of efficacy data
- In those currently prescribed/taking – adefovir disoproxil, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, primidone, St John's Wort

If current Hepatitis B – decision to use TAF should be discussed with hepatitis specialist

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-based PrEP consideration 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 5 but GUM team feels requires TAF/FTC, patient should be referred to National Complex PrEP MDT for discussion
4. Agreement is reached to commence TAF/FTC at either meeting
5. Inform pharmacist to facilitate ordering and logging in database
6. Once available, tenofovir alafenamide/emtricitabine (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 DoD and pharmacist with circumstances documented