

# PRE-EXPOSURE PROPHYLAXIS (PREP) FOR HIV - SERVICE GUIDE

# PrEPared

# Prosiect PrEP Cymru Wales PrEP Project

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## BACKGROUND FOR THE PROVISION OF PREP IN WALES

On Friday 28th April 2017, Cabinet Secretary for Health, Well-being and Sport, Vaughan Gething AM, announced an all-Wales study to provide the drug Truvada® as Pre-Exposure Prophylaxis (PrEP) to all those who would benefit from the preventative treatment [1]. The study was intended to last three years, and commence no later than summer 2017. Public Health Wales and the Independent HIV Expert Group were asked to work together to deliver the study.

This decision followed work undertaken by Public Health Wales and the Independent HIV Expert Group in November 2016 in assessing the public health effectiveness of PrEP, 'Preparing for PrEP?' [2], and a Health Technology Assessment (HTA) of the treatment by the All Wales Medicines Strategy Group (AWMSG) in April 2017 [3]. The AWMSG recommendation to the Cabinet Secretary for Health, Well-being and Sport was that Truvada® should not be recommended for provision within NHS Wales, due to concerns around cost-effectiveness. However, the Cabinet Secretary, whilst acknowledging the AWMSG recommendation, chose on the basis of the evidence for clinical effectiveness, to make PrEP available to all of those for whom the medicine is clinically appropriate.

Subsequent discussions have confirmed that this includes those outlined within the 'Preparing for PrEP?' report's eligibility criteria [2, p.38].

The announcement also stated that the study 'will help us to learn how best to provide the preventative treatment to reduce risks of HIV transmission in Wales and answer some of the questions raised by the All Wales Medicines Strategy Group around incidence rates'.

## PROVIDING PREP IN WALES – THE PRACTICALITIES

### WHAT IS BEING PROVIDED?

Currently, under the NHS Wales contract (until July 2018), the drug for use as PrEP for HIV in Wales is Truvada®. NHS procurement advice is that from July 2018 generic TDF/FTC can be used. Truvada® gained licensing approval within the European Union in July 2016 [4].

Therefore, this is the drug to prescribe to individuals who are deemed eligible for PrEP in Wales.

### PRESCRIBING OFF LABEL

For a medicine to be marketed in the United Kingdom, it must receive a market authorisation. It is then said to be licensed. It is recognised that many medicines used within specialist areas in the hospital are not licensed for a particular indication, age group, dosage or route of administration. This position arises when a pharmaceutical company has made an application to the licensing authority for a marketing authorisation for use of the medicine for a specific indication, etc. It may, however, not make an application to use the medicine in other ways, which are safe and legitimate.

The licence extension for Truvada® is for once-daily use only and for adults only. If there is a requirement to prescribe for event based dosing or for individuals aged 16-18 years old then it will be necessary to use off label prescribing in line with health board policy. Each health board will have a policy for the use of licensed medicines outside their market authorisation. This policy will not be drug specific, but will be general across the board.

Prescribing of unlicensed medicines has occurred for many years and is recognised as necessary under the Human Medicines Regulations 2012 [5] (Amended 2014). However, the Medicines Regulations makes it quite clear that if clinicians prescribe medicines without a product licence that they take clinical responsibility.

**WHERE IS PREP BEING PROVIDED IN WALES?**

Potential recipients of PrEP - as defined in the eligibility criteria outlined by the Independent HIV Expert Group – will be offered PrEP within Integrated Sexual Health Clinics within Wales. Potential recipients are to be advised to phone to arrange to be seen.

<b>Health Board</b>	<b>Place of clinic</b>
<b>Aneurin Bevan University Health Board</b>	Cordell Centre, Newport Tel: 01633 234555
<b>Abertawe Bro Morgannwg University Health Board</b>	Phone 01792285017 or 01792285005 for appointment
<b>Betsi Cadwaladr University Health Board</b>	Menai Unit, Ysbyty Gwynedd Tel: 01248 384054
	Glan Clwyd Sexual Health Clinic and Wrexham Maelor Sexual Health Appointment line Tel: 01745443301
<b>Cardiff &amp; Vale University Health Board</b>	PrEP clinic, Department of Sexual Health, Cardiff Royal Infirmary Tel: 029 2033 5208
<b>Cwm Taf University Health Board</b>	Dr led clinics in Dewi Sant Hospital Tel: 01443 443443 ext 5473
<b>Hywel Dda University Health Board</b>	Information and appointment line Tel: 01267 248674

As at 1st March 2018

## WHO IS ELIGIBLE TO RECEIVE PREP?

The criteria should be taken as a minimum, and should not replace clinical judgement.

It relates to individuals who are already engaged in care with sexual health services and should be offered at each attendance, if appropriate.

### INCLUSION CRITERIA

<b>Populations</b>	<b>MSM, transgender people having sex with men</b>
<b>Necessary Aspects</b>	<ul style="list-style-type: none"> <li>• A documented confirmed 4<sup>th</sup> generation HIV negative test at initiation of PrEP</li> <li>• Reporting condomless anal intercourse in the previous three months with multiple partners/on multiple occasions</li> <li>• Considered likely to engage in repeated condomless intercourse in the next three months with multiple partners/on multiple occasions</li> <li>• Proof of Welsh residency provided</li> </ul>
<b>Further Guidance</b>	Where available, use point of care testing (fourth generation test).
<b>Population</b>	<b>HIV negative partner of a HIV positive person</b>
<b>Necessary Aspects</b>	<ul style="list-style-type: none"> <li>• HIV positive partner is not virally suppressed or level of suppression is unknown</li> <li>• Condomless intercourse is anticipated or has occurred within the past three months</li> <li>• Proof of Welsh residency provided</li> </ul>
<b>Further guidance</b>	PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion) Treatment as prevention for the HIV positive partner should be considered.
<b>Population</b>	<b>HIV negative heterosexuals</b>
<b>Necessary Aspects</b>	<ul style="list-style-type: none"> <li>• Known to have had condomless sex with a person with HIV with unknown viral suppression within the past three months</li> <li>• Anticipated to have condomless sex with person, or person of similar status, again</li> <li>• Proof of Welsh residency provided</li> </ul>
<b>Further guidance</b>	PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion)

### EXCLUSION CRITERIA

This includes individuals in monogamous relationships with HIV positive partners with an undetectable viral load for 6 months or more, individuals without a current confirmed HIV negative test and those who are already HIV positive.

### RESIDENCY

HIV PrEP should be excluded from the scope of sexual health services as set out in paragraph 4.2 of the Responsible Body Guidance for the NHS in Wales, and instead, HIV PrEP should only be made available to people resident in Wales.

All health boards should ensure that they have proportionate arrangements in place to ensure that individuals being provided with PrEP meet all the criteria agreed by the HIV Expert Group.

All health boards should ensure that for all patients being provided with PrEP, sufficient residency information is sought.

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## TESTING FOR HIV PRIOR TO INITIATION AND AT MONITORING

Until Point of Care testing is available in the services the samples related to PrEP provision need to be highlighted for testing in the laboratory, with the word 'PrEP' on the clinical request form.

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## CLINICAL EVALUATION

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### CLIENT HISTORY

- Timing of last condomless sex acts
- HIV and STI screens in the last year, and date of the last HIV test
- History of bone or renal disease
- Importance of 3-monthly HIV/STI screen
- Importance of taking Truvada as directed
- Risks and benefits of online purchase of generic drug
- Risk reduction including information and support with 'chemsex' as appropriate
- A thorough medical history before initiating PrEP is essential to identify patients at greater risk of adverse events who might require closer renal or bone monitoring
- Discuss possibility of kidney disease with TDF-FTC with individuals who have pre-existing chronic kidney disease or risk factors (>40 years of age, eGFR <90 mL/min/1.73 m<sup>2</sup> at baseline, hypertension, or diabetes)
- Obtain a thorough medication history for concomitant nephrotoxic drugs or drugs that have interactions with TDF-FTC. Discuss risk and benefits

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### RECOMMENDED TESTS

Before or at time of starting PrEP:

- 4th generation venous blood HIV test
- Consider POCT and start PrEP same day if negative
- HBV surface antigen (and start vaccination if immunity unknown; on-demand Truvada is not recommended in chronic hepatitis B infection and if continuous PrEP is started, hepatology review is required before cessation)
- Hep C serology
- Serum creatinine and eGFR (suggested estimated GFR for individuals starting TDF is >60 mL/min/1.73 m<sup>2</sup>).
- For individuals with eGFR <60 mL/min/1.73 m<sup>2</sup> at baseline they should be started on PrEP only on a case-by-case basis and after a full assessment and discussion with the patient of the risk and benefits and obtaining specialist renal advice.
- Urinalysis
- Baseline bone profile (alk phos, calcium and phosphate) on bloods with history of osteoporosis risk factors

Whilst on PrEP:

- 3-monthly 4<sup>th</sup> generation venous blood HIV test +/- POCT
- 3-monthly STI screen for MSM, as per BASHH 2014 MSM guidance [9]; STI screen as appropriate for heterosexuals
- Urinalysis every visit (further investigation if protein 1+ or more)
- Annual creatinine/eGFR (more frequent if abnormal at baseline or proteinuria or on concomitant medications that are relevant to renal function:
  - If eGFR >90 mL/min at baseline (and follow up) and the person is aged <40 years then annual eGFR should be conducted.

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- If eGFR 60–90 mL/min, aged >40 years or concomitant risk factors for renal impairment recommend more frequent monitoring of renal function at physician discretion, but at least 6 monthly.
- If eGFR <60 mL/min, the risks and benefits of continuing PrEP should be assessed on a case-by-case basis. Specialist renal input should be obtained to determine further investigations and frequency of monitoring.

**Note:** POCT useful on the day of starting, and at any visit if risks were taken during a period when PrEP was not taken as per national guidelines on HIV testing.

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## SPECIAL CONSIDERATIONS

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### CHRONIC HBV INFECTION

Before PrEP is initiated, HBV serology status should be documented. TDF and FTC are each active against both HIV infection and HBV infection and thus may prevent the development of significant liver disease by suppressing the replication of HBV.

All persons screened for PrEP who test positive for hepatitis B surface antigen (HBsAg) should be evaluated by a clinician experienced in the treatment of HBV infection. For clinicians without this experience, co-management with an infectious disease or a hepatic disease specialist is advised. Clinician, in conjunction with patient, should ascertain the next course of action.

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### PREGNANCY/BREASTFEEDING

The use of Truvada may be considered during pregnancy, if necessary. (see Truvada SPC) Clinical judgement should consider other options such as Treatment as Prevention in the positive partner of pregnant women and advise to use condoms.

The Centers for Disease Control and Prevention (CDC) have produced an information sheet regarding PrEP during conception, pregnancy and breastfeeding, and is a recommended resource for service providers [7].

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## COUNSELLING AT INITIATION

- Counsel that PrEP does not prevent other types of STIs; screen for STI (including HCV) when starting PrEP and regularly during use of PrEP.
- Counsel that PrEP may impact renal and bone health.
- Counsel that PrEP, like other prevention methods, only works when it is taken. Adherence counselling is recommended.
- Counsel that PrEP can be privately prescribed long-term, however it will be prescribed for a maximum period of 3 months (90 tablets) to ensure appropriate monitoring.

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## ADHERENCE

### Defining PrEP adherence in the context of actual risk (Instead of perceived risk)

*'In the context of contraception for pregnancy prevention, providers present a suite of options and methods and ask the woman which method they prefer to use at the time. Likewise, at an HIV clinic, a provider may discuss risk, present a range of HIV prevention options to an HIV negative person and ask: Which HIV prevention method are you going to use (e.g. not having sex, know partners status, partner on ART, condoms, PrEP)? The goal is to determine if and how the individual is achieving highly-effective prevention.'*

Guidance within a WHO Meeting Report on Adherence [11]

While it is generally agreed that PrEP adherence is crucial, it is important to consider and understand what PrEP adherence is and what PrEP non-adherence is.

Periodic PrEP or “seasons of PrEP” may entail the use of PrEP during certain timeframes of HIV risk with defined starts and stops.

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## MESSAGES FOR PREP ADHERENCE AND IMPLEMENTATION

### PrEP adherence:

- It works if you take it. Do you want it?
- It is highly effective if taken every day (*this is the licence for use*)
- Optimal protection from HIV and other STIs, as well as pregnancy, can be achieved with concurrent condom use
- Take it every day (one pill per day)
- Routine (taking at the same time) is important for remembering to take it every day.
- If you forget, take your pill as soon as you realize. If within 12hours take one, if longer take two tablets to ensure appropriate drug levels.
- There are occasional side effects (especially the first month)
- Before:  
*for anal sex: at initiation for daily dosing two tablets taken 2-24 hours before condomless sex*  
*for vaginal sex: one tablet a day taken for 7 days before condomless sex*
- After:  
*for anal sex: One tablet 24 hours and one 48 hours after last condomless sex*  
*for vaginal sex: one tablet a day taken for 7 days after last condomless sex*
- If you are unable to take PrEP on a daily basis, use other HIV prevention methods during that time
- Talk to your partner and family about having tablets. Address the potential of false disclosure (the potential assumption that as you are taking ARVs it indicates that you are HIV positive and taking treatment. It must be noted that the same treatment is also used for Hepatitis B)

### PrEP adherence support

- What is your plan for remembering to take a pill every day?
- What are your facilitators and barriers to consistent pill use?
- Daily routines and habits can be good reminders for pill taking
- Engage your partner for adherence support if you can
- Make a plan for how to deal with false disclosure if you are seen taking PrEP
- Routine assessment of PrEP adherence
- Are you still taking PrEP to protect you from HIV?
- Have you taken a break from taking PrEP / stopped taking PrEP?
  - Why did you stop?
  - Were you protected during the time you stopped taking PrEP?
- Side effect assessment
  - Have you had any problems?
  - How have side effects affected your adherence?
  - Is there anything you can do to make the situation better?
    - Recommend urine dipstick testing every three months to monitor for side effects impacting renal function
- Intensive adherence measurements are not advocated in routine practice
- If poor adherence: Do you still want it? If yes, identify and address barriers to adherence.
  - If no, suggest other HIV prevention methods

### Event-Based Dosing

Though event-based dosing will not be licensed under the proposed licensing application, clients may have purchased online to use in this manner. In this instance, clinicians should advise that event-based dosing for a



single sex act comprises two tablets 2–24 hours before sex, one tablet 24 hours (22–26 hours) after the first dose, and another tablet 48 hours (46–50 hours) after the first dose.

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## TESTING FOR OTHER ISSUES

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### RENAL FUNCTION

#### ARV Associated Nephrotoxicity [8]

Renal abnormality*	ARV	Management
<b>Proximal tubulopathy with any combination of:</b> 1. Proteinuria: urine dipstick $\geq 1$ , or confirmed increase in UP/C $> 30$ mg/mmol <sup>(i)</sup> 2. Progressive decline in eGFR and eGFR $< 90$ mL/min <sup>(ii)</sup> 3. Phosphaturia <sup>(iii)</sup> : confirmed hypophosphataemia secondary to increased urine phosphate leak	TDF <sup>**</sup>	<b>Assessment:</b> <ul style="list-style-type: none"> <li>• Tests for proximal renal tubulopathy/renal Fanconi syndrome<sup>(iii)</sup></li> <li>• Consider renal bone disease if hypophosphataemia of renal origin: measure 25(OH) vitamin D, PTH, DXA</li> </ul> <b>Consider stopping TDF if:</b> <ul style="list-style-type: none"> <li>• Progressive decline in eGFR and no other cause</li> <li>• Confirmed hypophosphataemia of renal origin and no other cause</li> <li>• Osteopenia/osteoporosis in the presence of increased urine phosphate leak</li> </ul>
Progressive decline in eGFR, but none of the above <sup>(v)</sup>	TDF <sup>**</sup> PI/r	<b>Complete assessment:</b> <ul style="list-style-type: none"> <li>• Risk factors for CKD<sup>(v)</sup> (see <a href="#">Kidney Disease: Definition, Diagnosis and Management</a>)</li> <li>• PRT, UA/C, UP/C (see <a href="#">Kidney Disease: Definition, Diagnosis and Management</a> and <a href="#">Indications and Tests for Proximal Renal Tubulopathy (PRT)</a>)</li> <li>• Renal tract ultrasound</li> </ul> <b>Consider stopping ARVs with potential nephrotoxicity if:</b> <ul style="list-style-type: none"> <li>• Progressive decline in eGFR and no other cause<sup>(v)</sup></li> </ul>

\*\* TAF has shown lower tenofovir-related renal adverse effects due to lower systemic tenofovir exposure. Switch-studies from TDF to TAF suggest potential reversion of renal toxicity, however, long-term experience with TAF is lacking.

i UP/C in spot urine detects total urinary protein including protein of glomerular or tubular origin. The urine dipstick analysis primarily detects albuminuria as a marker of glomerular disease and is inadequate to detect tubular disease.

ii For eGFR: use CKD-EPI formula. The abbreviated MDRD (Modification of Diet in Renal Disease) or the Cockcroft-Gault (CG) equation may be used as an alternative, see <http://www.chip.dk/Tools>

iii See Indications and Tests for Proximal Renal Tubulopathy (PRT)

v Different models have been developed for calculating a 5-years CKD risk score while using different nephrotoxic ARVs integrating HIV-independent and HIV-related risk factors [10,11]

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## BONE MINERAL DENSITY

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### BONE DISEASE: SCREENING AND DIAGNOSIS [8]

Bone abnormalities (infrequently contributing to fractures) may be associated with proximal renal tubulopathy. If bone abnormalities are suspected then appropriate consultation should be obtained.

## PREP RESOURCES

A range of information materials are available online regarding PrEP. A selection of the key publications is available below.

Resource	Provider	Overview
<a href="#">PrEP: A UK Guide</a>	i-base	An A7-sized leaflet on PrEP in the UK. This is an introduction to how PrEP works and buying PrEP online. <a href="#">Print copies can be ordered online.</a>
<a href="#">PrEP for women</a>	i-base	An A7-sized leaflet on PrEP for women including trans women. <a href="#">Print copies can be ordered online.</a>
<a href="#">How to get PrEP in the UK</a>	Aidsmap	Factsheet outlining the different approaches to PrEP within the UK
<a href="#">PrEPARED in Wales</a>	Frisky Wales	The webpage for service users, outlining key FAQs on the PrEPARED in Wales project. Also in <a href="#">Welsh</a> .
<a href="#">PrEP (Pre-Exposure Prophylaxis)</a>	Terrence Higgins Trust	Webpage outlining details about PrEP.
<a href="#">Women and PrEP</a>	Sophia Forum	Website outlining benefits of PrEP for women.

## ONLINE PURCHASING

It is legal for a patient to obtain 3 months of generic drug via the internet for personal use. A prescription is not required but some sellers may request this.

The website [www.iwantprepnnow.co.uk](http://www.iwantprepnnow.co.uk) [17] has been set up by community advocates to provide information about PrEP and links to sellers. Sellers are added to the site only when generic drug has been purchased with no problems and therapeutic drug monitoring (TDM) has been carried out in at least one person showing presence of the drug at appropriate levels.

Supportive clinicians are working with 'I Want PrEP Now' to ensure generic drug efficacy, as far as possible, by sharing TDM results with an agreement to disseminate information if an unsatisfactory TDM result is obtained.

## DATA COLLECTION FOR MONITORING

Patients taking up the offer of PrEP will be closely monitored, with data collated and analysed by Public Health Wales on a quarterly basis. Reasons for those declining the offer of PrEP will also be collected and analysed to better understand these decisions.

There are 33 codes to allow monitoring of PrEP for HIV via the existing Sexual Health in Wales Surveillance System.

### WHY ARE THE CODES NEEDED?

The codes are designed to capture the use of PrEP among Sexual Health Clinic attendees who may access PrEP from the clinic or have purchased PrEP drugs over the internet. The extent of the use of PrEP in the community is unknown at present.

The introduction of PrEP SHHAPT codes will allow the monitoring of the eligibility assessment and uptake of PrEP.

### WHAT CODES ARE BEING INTRODUCED?

The additional codes are set out below. They are aligned with the PrEP eligibility criteria introduced in 2016 and are consistent with the current structure of SHHAPT codes.

**HOW OFTEN SHOULD THE CODES BE COMPLETED?**

The relevant codes should be completed at each PrEP visit or for each new episode of care.

The additional codes are as follows:

**PRE-EXPOSURE PROPHYLAXIS CODES TO BE USED FOR MONITORING**

<b>Eligibility</b>		
031W	PrEP eligibility: category 1	For those who, after a risk assessment, meet PrEP eligibility category 1 – <i>MSM who have had an HIV negative test on the day of starting PrEP and have had another HIV negative test in the preceding year and report condomless intercourse in the past 3 months and affirm likelihood of condomless intercourse in the next 3 months</i>
032W	PrEP eligibility: category 2	For those who, after a risk assessment, meet PrEP eligibility category 2 – <i>HIV negative partner of an HIV positive person not known to be virally suppressed and condomless intercourse is anticipated before treatment of the HIV positive partner takes effect</i>
033W	PrEP eligibility: category 3	For those who, after a risk assessment, meet PrEP eligibility category 3 – <i>HIV negative persons who are considered to be at a similar risk of HIV acquisition as those in category 2</i>
034W	PrEP eligibility: not eligible	For those who, after a risk assessment, did not meet PrEP eligibility categories 1, 2 or 3
PrEP999	Medically contra-indicated	For those who are eligible by risk but for whom the treatment would be contra-indicated due to co-morbidities
<b>PrEP Offered and Declined</b>		
035W	Outcome of the offer of PrEP: PrEP offered and declined	For those offered a new course of PrEP at the current attendance who decline to take up PrEP.
035aW	<i>Reasons for PrEP decline*: Do not believe themselves at risk</i>	<i>Does not believe that they are at risk of HIV *use all that apply</i>
035bW	<i>Reasons for PrEP decline*: Prefers other methods</i>	<i>Prefers to use other risk reduction methods *use all that apply</i>
035cW	<i>Reasons for PrEP decline*: side effects concern</i>	<i>Concerned about side effects *use all that apply</i>
035dW	<i>Reasons for PrEP decline*: Does not want medication</i>	<i>Does not want to have medication *use all that apply</i>

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035eW	<i>Reasons for PrEP decline*: Does not want to be monitored</i>	<i>Does not want to be monitored *use all that apply</i>
035fW	<i>Reasons for PrEP decline*: Had it in the past and did not like it</i>	<i>Had it in the past and did not like it *use all that apply</i>
036W	Outcome of the offer of PrEP: PrEP being obtained online	For those eligible for PrEP but are already obtaining online and will continue to do so
<b>PrEP Commenced</b>		
037W	Outcome of the offer of PrEP: PrEP started	For those starting a new course of PrEP at the current attendance.
038W	Outcome of the offer of PrEP: PrEP continued	For those continuing PrEP at the current attendance regardless of who supplied. - PrEP patients should be coded at every attendance (even where the attendance is not specifically related to PrEP e.g attended with STI symptoms to be treated please also code 038).
040W	PrEP regimen: daily	Daily PrEP regimen prescribed at this attendance for those starting or continuing PrEP
041W	PrEP regimen: event based	Event-based PrEP regimen prescribed at this attendance for those starting or continuing PrEP
042W	PrEP prescribed: 30 tablets	To indicate the number of tablets prescribed to those starting or continuing PrEP (30 tablets)
043W	PrEP prescribed: 60 tablets	To indicate the number of tablets prescribed to those starting or continuing PrEP (60 tablets)
044W	PrEP prescribed: 90 tablets	To indicate the number of tablets prescribed to those starting or continuing PrEP (90 tablets)
045W	PrEP dose taken: daily (or nearly daily)	To assess whether daily doses of PrEP were taken for those continuing or stopping PrEP at this attendance - Patients must be taking at least 5 doses of PrEP per week to qualify as 'daily/nearly daily' usage
046W	PrEP dose taken: event based	To assess whether event based doses of PrEP were taken for those continuing or stopping PrEP at this attendance
047W	PrEP dose taken: other	To assess how doses of PrEP were taken for those continuing or stopping PrEP at this attendance where dosing was neither daily nor event based)

<b>PrEP Adherence</b>		
048W	PrEP adherence: All risk episodes covered	To assess the proportion of sexual risk episodes covered by PrEP (all) since last visit
049W	PrEP adherence: Most risk episodes covered	To assess the proportion of sexual risk episodes covered by PrEP (most) since last visit
050W	PrEP adherence: Some risk episodes covered	To assess the proportion of sexual risk episodes covered by PrEP (some) since last visit
051W	PrEP adherence: No risk episodes covered	To assess the proportion of sexual risk episodes covered by PrEP (none) since last visit
CHEM	Chem sex	Use of recreational drugs before/during sex in the last 3 months
060W	PrEP patient characteristic: Transgender	Gender identity changed since birth
<b>PrEP Stopped</b>		
039W	PrEP stopped	PrEP stopped at the current attendance
039aW	Reasons to stop PrEP: no longer eligible	No longer eligible (e.g. change in risk behaviour)
039bW	Reasons to stop PrEP: personal choice	Personal choice (but still eligible). Please code further with "Reasons for decline code" (see 035a-035f)
039cW	Reasons to stop PrEP: now contraindicated	Now contraindicated (e.g. toxicity)

As at 1<sup>st</sup> March 2018

## **FUNDING**

In order to claim re-imburement for prescribed PrEP, the services must submit the monitoring data centrally to Public Health Wales via the existing Sexual Health in Wales Surveillance System.

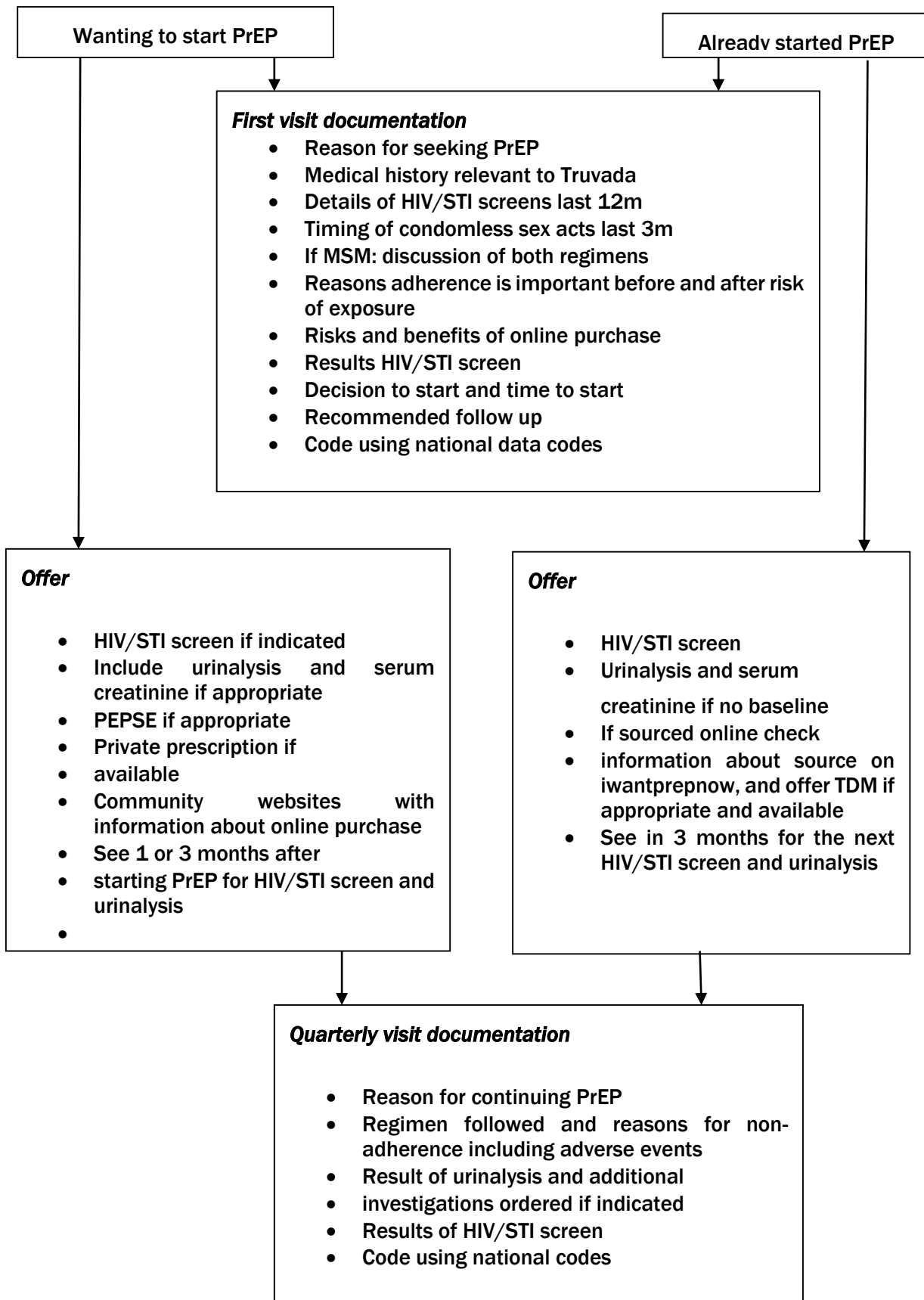
Funding has been agreed for the extra tests that are required to monitor individuals taking PrEP (associated additional tests are bone (blood profile), renal and liver function and (from October) point of care test at the clinics) along with the drug cost. Health boards will be re-imbursed by submitting the itemised costs to [healthprotection@wales.gsi.gov.uk](mailto:healthprotection@wales.gsi.gov.uk)

Funding will be allocated retrospectively on the basis of actual costs incurred for the provision of PrEP and additional associated tests (associated additional tests are bone (blood profile), renal and liver function and (from October) point of care test at the clinics), through an uplift to health board resource allocations. Health boards should submit itemised costs at the end of each quarter detailing the total number of supplies and total patient numbers in the relevant quarter. The exception being quarter four where details to the end of February should be submitted during March, these will be used to estimate the payment for quarter four. Funding is conditional on health boards providing the required service data to Public Health Wales. The activity itemised will be checked against the monitoring data before Welsh Government Finance is authorised to pay any invoices.

## REFERENCES

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APPENDIX 1- FLOW CHART



**SHOULD I MONITOR INDIVIDUALS WHO ARE ACCESSING PREP OUTSIDE OF THE NHS?**

Yes – the guidelines mentioned in response to the above question will provide further guidance on this.

**HAS TRUVADA® BEEN APPROVED FOR PREP PROVISION IN WALES?**

Yes – Truvada® is licensed for use as PrEP in the UK and the Cabinet Secretary for Health, Well-being and Sport has announced that it will be provided to all those in whom it is clinically indicated for three years from July 2017.

**HOW DO WE RECORD PREP USAGE BY AN INDIVIDUAL THROUGH OUR DATA SYSTEMS?**

When an individual is seen in the sexual health clinics the use of PrEP will be coded on the main data systems using the codes outlined in this document.

**ARE INFORMATION MATERIALS AVAILABLE TO SHARE WITH MY CLIENTS?**

A range of information materials are available online regarding PrEP. A selection of the key publications is available below.

Resource	Provider	Overview
<a href="#">PrEP: A UK Guide</a>	i-base	An A7-sized leaflet on PrEP in the UK. This is an introduction to how PrEP works and buying PrEP online. <a href="#">Print copies can be ordered online.</a>
<a href="#">PrEP for women</a>	i-base	An A7-sized leaflet on PrEP for women including trans women. <a href="#">Print copies can be ordered online.</a>
<a href="#">How to get PrEP in the UK</a>	Aidsmap	Factsheet outlining the different approaches to PrEP within the UK
<a href="#">PrEPARED in Wales</a>	Frisky Wales	The webpage for service users, outlining key FAQs on the PrEPARED in Wales project. Also in <a href="#">Welsh</a> .
<a href="#">PrEP (Pre-Exposure Prophylaxis)</a>	Terrence Higgins Trust	Webpage outlining details about PrEP.
<a href="#">Women and PrEP</a>	Sophia Forum	Website outlining benefits of PrEP for women.

**HOW EFFECTIVE IS PREP AT PREVENTING HIV INFECTION?**

Since 2010, the efficacy of oral PrEP, commonly ‘Truvada®’, has been demonstrated in four key studies, iPrEx, PROUD, IPERGAY and Partner (see chapter 6 of the ‘Preparing for PrEP’ main report for full details of clinical trials). These studies, and others, have shown that PrEP can reduce the risk of getting HIV from sex by more than 90% **when used consistently**. It is highly effective for preventing HIV if used as prescribed, but it is much less effective when not taken consistently.

**ARE THERE ANY PARTICULAR SIDE EFFECTS FROM TAKING PREP TO PREVENT HIV INFECTION?**

PrEP can cause side effects like nausea in some people, but these generally subside over time. No serious side effects have been observed, and these side effects aren’t life threatening. 1 in 10 people experience mild side effects like nausea, tiredness, indigestion and headache.

Nevertheless, one of the substances that make up Truvada®, tenofovir, can impact upon kidney function and/or bone density – as such, our recommendations, and the clinical management guidelines, highlight the need for possible renal function and bone density tests according to clinical need, to monitor any possible changes.



**WHAT INTERVAL SHOULD BE GIVEN FOR FOLLOW UP OF PATIENTS ON PREP?**

Follow-up should be planned according to clinical judgement and may be for 3 months, or for 4 weeks after initiation if indicated – via phone or email is sufficient – to review side effects, adherence and that daily and on-demand based regimes are being taken appropriately.

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**WHAT ADVICE SHOULD BE OFFERED TO THOSE WANTING TO STOP PREP?**

If the risk of HIV acquisition is through anal sex, the recommendation is that PrEP is continued daily until 48 hours after the last sexual risk.

If the risk of HIV acquisition is through vaginal sex, the recommendation is that PrEP should be continued daily for 7 days after the last sexual risk.

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## APPENDIX 3 - FREQUENTLY ASKED QUESTIONS – SERVICE USERS

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### WHAT IS PRE-EXPOSURE PROPHYLAXIS (PREP)?

PrEP is a process by which antiretroviral medications (ARVs) are used by HIV negative individuals before exposure to the HIV virus to reduce the risk of them becoming infected.

PrEP needs to be taken regularly to be effective, though there are two alternate approaches coming to the fore from the clinical trials – ‘daily PrEP’ and ‘PrEP on-demand’.

### HAS THERE BEEN AN INCREASE IN HIV TRANSMISSION IN WALES?

On average, over the past six years, there have been approximately 153 new cases of HIV infection diagnosed annually. The vast majority of infections diagnosed in Wales are sexually transmitted with 47.5% of new diagnoses since 2011 being attributed to men who have sex with men (MSM) whilst 31.6% of infections are recorded as acquired through heterosexual contact.

There is a steady increase in the number of people living with HIV in Wales, reflecting both an increase in survival and new diagnoses.

### SHOULD I CONSIDER TAKING PREP?

PrEP is for people without HIV who are at very high risk of getting it from their sexual behaviour or their potential exposure to HIV infection. Appendix 2 of the ‘Preparing for PrEP?’ main report provides proposed criteria for who could be eligible for PrEP. However, prior to starting PrEP, you **must** be certain that you are HIV negative. You can get a HIV test at your local Integrated Sexual Health Clinic.

### HOW DOES PREP WORK?

If you protect yourself with PrEP and you are exposed to HIV, PrEP prevents HIV from entering your cells and replicating. Therefore, you will remain HIV negative. PrEP is only effective when there is a sufficient amount of the active substances in your blood before you are exposed to HIV.

### HOW LONG DO I NEED TO TAKE PREP BEFORE IT IS EFFECTIVE?

When taken every day, PrEP is safe and highly effective in preventing HIV infection. PrEP reaches maximum protection from HIV for **receptive anal sex** at about **7 days** of daily use. For **all other activities**, including insertive anal sex and vaginal sex, PrEP reaches maximum protection at about **20 days** of daily use.

### CAN I USE PREP AFTER BEING EXPOSED TO HIV?

**PrEP** is only for people who are at ongoing very high risk of HIV infection but have had time to take the drug so that it reaches its protective levels before being exposed to HIV. **PEP (post-exposure prophylaxis)** is an option for someone who thinks they’ve recently been exposed to HIV. PEP is taken for up to **28 days** after someone has had sex if they think they’ve been exposed to HIV.

### WOULD IT BE REASONABLE TO EXPECT HIGHER RATES OF STIS IN THOSE TAKING PREP?

In all instances, clients will be advised on the need to use condoms to prevent STIs – **PrEP does not prevent against the transmission of other STIs**. PrEP trial participants and clients of PrEP programmes generally do have high rates of STIs, but as these participants and clients are inclined to risky sexual behaviour, this is true at the outset before they start on PrEP. Most studies indicate that men at highest risk for HIV – which includes those who already do not use condoms – are most likely to seek PrEP. In many cities where demonstration projects have taken place STI rates were on the rise well before PrEP became widely available.

**I LIVE OUTSIDE OF WALES – AM I ABLE TO ACCESS PREP AT SEXUAL HEALTH CLINICS IN WALES?**

Proof of Welsh residency will need to be provided in order to access the treatment from clinics in Wales. Monitoring of people using PrEP outside of the NHS (e.g. those who have purchased PrEP online for themselves) will be offered regardless of residence.

## APPENDIX 4 - SUMMARY OF PRODUCT CHARACTERISTICS

The datasheets for Truvada and generic tenofovir disoproxil fumarate/Emtricitabine (Teva brand) can be accessed via the links below:

Truvada - <https://www.medicines.org.uk/emc/product/3890>

Teva - <http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1516339374347.pdf>