

# Groupe : référentiel méthodologique pour l'organisation de la consultation PrEP

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## **interCOREVIH**

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# Base de travail

## Recommandations existantes :

- Prise en charge du VIH – Recommandations du groupe d’experts MORLAT  
[https://cns.sante.fr/wp-content/uploads/2018/04/experts-vih\\_prevention-depistage.pdf](https://cns.sante.fr/wp-content/uploads/2018/04/experts-vih_prevention-depistage.pdf)
- HAS –Bon usage du médicament PrEP par ténofovir/emtricitabine (MaJ Avril 2019)
- IDSA. US Guideline Criteria for Human Immunodeficiency Virus Preexposure Prophylaxis: Clinical Considerations and Caveats , Calabrese September 2019
- OMS : July 2019  
<https://www.who.int/hiv/pub/prep/211/en/>
- Recommandation Australian – septembre 2019

# Plan (qui, quoi, comment, où ...)

1. Introduction
2. Indications de la PrEP en France ?
3. Que faut 'il savoir avant de commencer le PrEP ?
4. Les modes de prises et le suivi des patients sous PrEP ?
5. Les situations complexes
6. Quand considérer le TPE ?

# 1/ Introduction ( 10 lignes)

- Définition de la PrEP
- Prévention combinée
- Les études clés (Prévenir)
- Un peu d'épidémiologie avec les chiffres clés

## 2/ Indications de la PrEP en France

**En finir avec les sempiternels critères d'inclusion et d'exclusions**

**Ne pas freiner l'objectif principal des guidelines**

**⇒ Soutenir l'utilisation de la PrEP dans la prévention du VIH**

**⇒ pas de critères trop restrictifs**

# US Guideline Criteria for Human Immunodeficiency Virus Preexposure Prophylaxis: Clinical Considerations and Caveats

Sarah K. Calabrese,<sup>1</sup> Douglas S. Krakower,<sup>2,3,4</sup> Tiara C. Willie,<sup>5,6</sup> Trace S. Kershaw,<sup>7</sup> and Kenneth H. Mayer<sup>2,3,8</sup>

**Table 1. Overview of 2 Versions of Criteria Contained Within the US Centers for Disease Control and Prevention Guidelines**

Version of Criteria	Population		
	MSM	Heterosexual Women and Men <sup>a</sup>	PWID
Summary of guidance	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI (gonorrhea, chlamydia, or syphilis)</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI (gonorrhea or syphilis)</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> <li>• In high-prevalence area or network</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive injecting partner</li> <li>• Sharing injection equipment</li> <li>• ...</li> <li>• ...</li> <li>• ...</li> <li>• ...</li> </ul>
Recommended indications	<p>Adult man Without acute or established HIV infection Any male sex partners in past 6 months (if also has sex with women, see recommended indications for heterosexually active men and women) Not in a monogamous partnership with a recently tested, HIV-negative man AND 1+ of the following:</p> <ul style="list-style-type: none"> <li>• Any anal sex without condoms (receptive or insertive) in past 6 months</li> <li>• A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months</li> </ul>	<p>Adult person Without acute or established HIV infection Any sex with opposite sex partners in past 6 months Not in a monogamous partnership with a recently tested, HIV-negative partner AND 1+ of the following:</p> <ul style="list-style-type: none"> <li>• Is a man who has sex with both women and men (behaviorally bisexual; see also recommended indications for MSM)</li> <li>• Infrequently uses condoms during sex with 1+ partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)</li> <li>• Is in an ongoing sexual relationship with an HIV-positive partner</li> <li>• A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months</li> </ul>	<p>Adult person Without acute or established HIV infection Any injection of drugs not prescribed by a clinician in past 6 months AND 1+ of the following:</p> <ul style="list-style-type: none"> <li>• Any sharing of injection or drug preparation equipment in past 6 months</li> <li>• Risk of sexual acquisition (see also recommended indications for MSM and heterosexually active men and women)</li> <li>• ...</li> <li>• ...</li> <li>• ...</li> </ul>

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**Table 2. Recommended Alternative to US Centers for Disease Control and Prevention Preexposure Prophylaxis Eligibility Criteria**

Indicators of PrEP Candidacy	
Individual level	<ul style="list-style-type: none"> <li>Recent or anticipated condomless oral, anal, or vaginal sex</li> <li>Recent or anticipated sharing of injection equipment</li> <li>Biomarkers of recent condomless sex (eg, sexually transmitted infection<sup>a</sup> or pregnancy)</li> <li>Reported desire to use PrEP</li> </ul>
Partner <sup>b</sup> level	<ul style="list-style-type: none"> <li>Sexual or injecting partner with unknown HIV status and/or perceived to be at risk for acquiring HIV</li> <li>Sexual partner living with HIV who has a clinically detectable viral load or unknown viral suppression status<sup>c</sup></li> <li>Injecting partner living with HIV</li> <li>Partner-related barriers to using other forms of protection (eg, intimate partner violence, economic incentive)</li> </ul>
Network/Community level	<ul style="list-style-type: none"> <li>Multiple partners</li> <li>Partner concurrency</li> <li>Partner network known to have high HIV prevalence</li> <li>Neighborhood/community known to have high HIV prevalence</li> </ul>

### Key Considerations for Applying Indicators

These indicators of PrEP candidacy are intended to guide conversations about PrEP with patients and to support patients in making informed decisions about whether to use PrEP.

- The indicators are *not* intended to be used as screening criteria to determine whether a patient should be educated about or offered PrEP.
- The indicators listed may not identify all individuals at risk for HIV or all HIV risk factors affecting a single individual.
- All patients should be educated about PrEP as part of routine sexual healthcare, irrespective of sexual orientation, gender identity, or self-disclosed risk behaviors.
- The indicators vary in their strength of association with population-level HIV incidence, and the magnitude of risk posed by any single indicator will vary according to individual-level circumstances.
- Patients who express a desire for PrEP but do not report specific HIV risk factors should still be offered PrEP. Patients may choose not to disclose private and potentially stigmatizing sexual behavior or injection practices but wish to mitigate the risk associated with these activities.

PrEP can be used alone or in combination with other methods (eg, condoms) to protect against HIV.

# Model australien

## A discuter

### Box 4.1 PrEP suitability criteria for men who have sex with men

#### HIV risk in the previous 3 months and the future 3 months

The clinician should prescribe PrEP if the patient describes a history of any of the following HIV acquisition risks in the previous 3 months and if the patient foresees that there are likely to be similar acquisition risks in the next 3 months:

- At least one episode of condomless anal intercourse (insertive or receptive) with a regular HIV-positive partner who is either not on treatment, or who is on treatment but has a detectable HIV viral load
- At least one episode of receptive condomless anal intercourse with any casual male partner
- One or more episodes of engaging in sexualised drug use, sometimes referred to as 'chemsex'. In the Australian context this typically involves the use of crystal methamphetamine (Ice), but can also include the use of gamma hydroxybutyrate (GHB)
- One or more episodes of rectal gonorrhoea, rectal chlamydia or infectious syphilis, including any STIs diagnosed at screening for PrEP
- More than one episode of anal intercourse where a condom slipped off or broke where the HIV serostatus of the partner was not known, or where the partner was HIV positive and not on treatment or had a detectable viral load on treatment.

#### HIV risk in the future 3 months

The clinician should prescribe PrEP if the patient foresees that they will have HIV acquisition risk in the upcoming 3 months, despite not having had HIV acquisition risk in the previous 3 months.

Note: The following list is not exhaustive and there are likely to be many other scenarios where PrEP could be suitably offered for people whose HIV risk acquisition is exclusively in the future:

- When a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners
- When a person plans to return home to an overseas country which has a high HIV prevalence during which time they anticipate that they will be having condomless sex with casual partners
- When a person reports that they have recently left a monogamous relationship and will be having condomless sex with casual partners in the future
- When a person reports that they will be entering or leaving institutional or correctional facilities in the near future where they may have condomless sex with casual partners in the future
- When a person presents with concerns of deteriorating mental health and a history of having previously increased their HIV acquisition risk behaviour in this setting
- When a person presents with a history of intermittent binge drinking of alcohol or recreational drug use and a history of having had increased their HIV acquisition risk behaviour in this setting.

The clinician should consider prescribing PrEP also in the following circumstances:

- When an HIV serodiscordant couple experience undue suffering and anxiety about inter-couple HIV transmission despite the positive partner being virologically suppressed on treatment
- When a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex
- When a person presents with a history of recurrent genital ulceration or dermatoses (e.g. psoriasis), as this may increase the risk of HIV transmission.



## 2/ Indications de la PrEP en France

- **« Chaque personne appartenant a un groupe à haute prévalence du VIH doit pouvoir bénéficier de la PrEP »**
    - TOUS LES HSH cis / toutes les personnes Trans
    - Pour les hommes cis / Femmes cis
      - ayant des rapports sexuels avec des personnes d'origine afro-caribéenne (ou autre zone à forte endémicité du VIH)
      - IST / TPE dans les 12 derniers mois
      - TDS
  - + au cas pas cas : toutes personnes se sentant exposée au risque d'infection par le VIH
- => A adresser en centre spécialisé ( CeGIDD, SMIT)

### 3/Que faut 'il savoir avant de commencer le PrEP ?

- Qui peut prescrire la PrEP ?
  - Médecin infectiologue dans les SMIT
  - CeGIDD / CPEF
  - MG ( bientôt)
- Quel bilan OBLIGATOIRE avant de commencer la PrEP ?
  - Testing ( Constance)
- Safety ? Risque lié a la PrEP ( quid IR, ostéoporose/ démonter les idées reçues)

FACILITER L'ACCES A LA PRIMO PRESCRIPTION

**Au J0 → SORTIR AVEC UNE ORDONNANCE DE  
PrEP**

# 4/ QUID des Schémas de Prise ( Chez les HSH)

**ET S'IL N'Y AVAIT QU'UN ?**

**SAVOIR COMMENCER ET SAVOIR S'ARRETER**

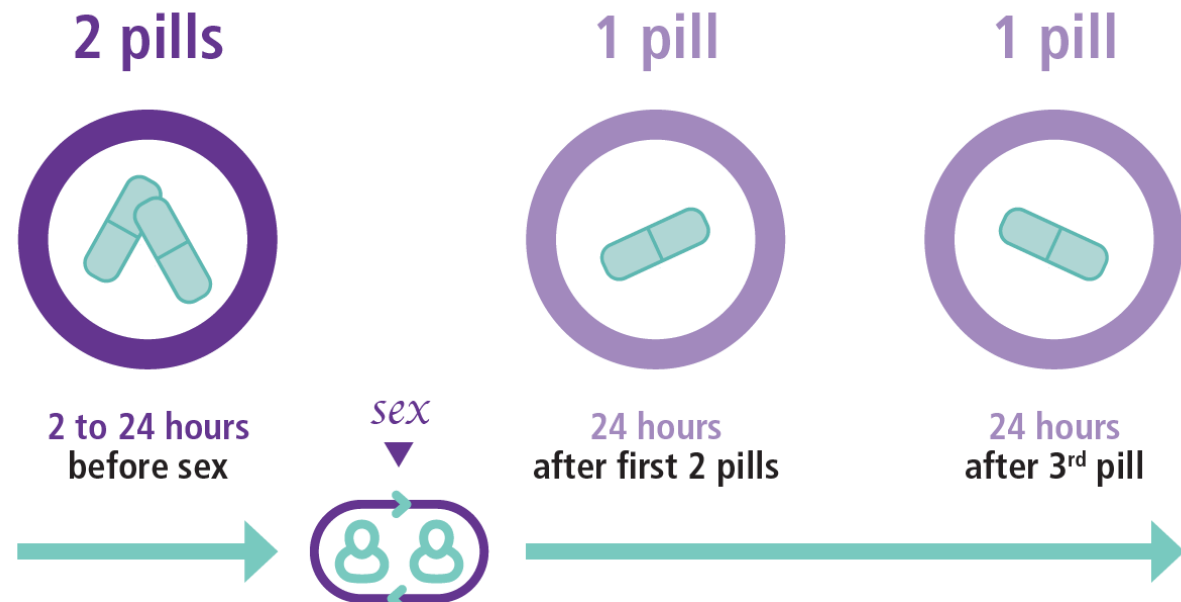
**2+1+1** OMS 2019 : EVENT-DRIVEN

# Prise discontinue

For whom is ED-PrEP appropriate?	For whom is ED-PrEP <b>NOT</b> appropriate?
<ul style="list-style-type: none"><li>• a man who has sex with another man:<ul style="list-style-type: none"><li>– who would find ED-PrEP more effective and convenient</li><li>– who has infrequent sex (for example, sex less than 2 times per week on average)</li><li>– who is able to plan for sex at least 2 hours in advance, or who can delay sex for at least 2 hours</li></ul></li></ul>	<ul style="list-style-type: none"><li>• cisgender women or transgender women</li><li>• transgender men having vaginal/frontal sex</li><li>• men having vaginal or anal sex with women</li><li>• people with chronic hepatitis B infection.</li></ul>

Source : OMS

**SANS JAMAIS DEPASSER 30  
COMPRIMES PAR MOIS**

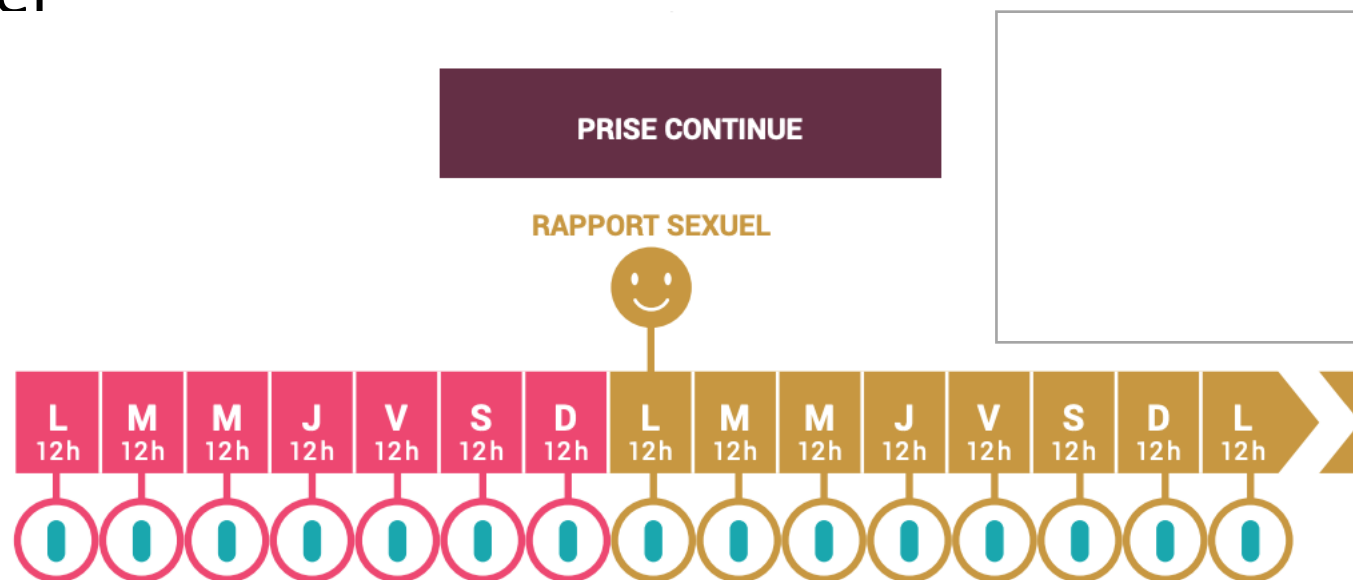


# 4/ les Schémas de Prise

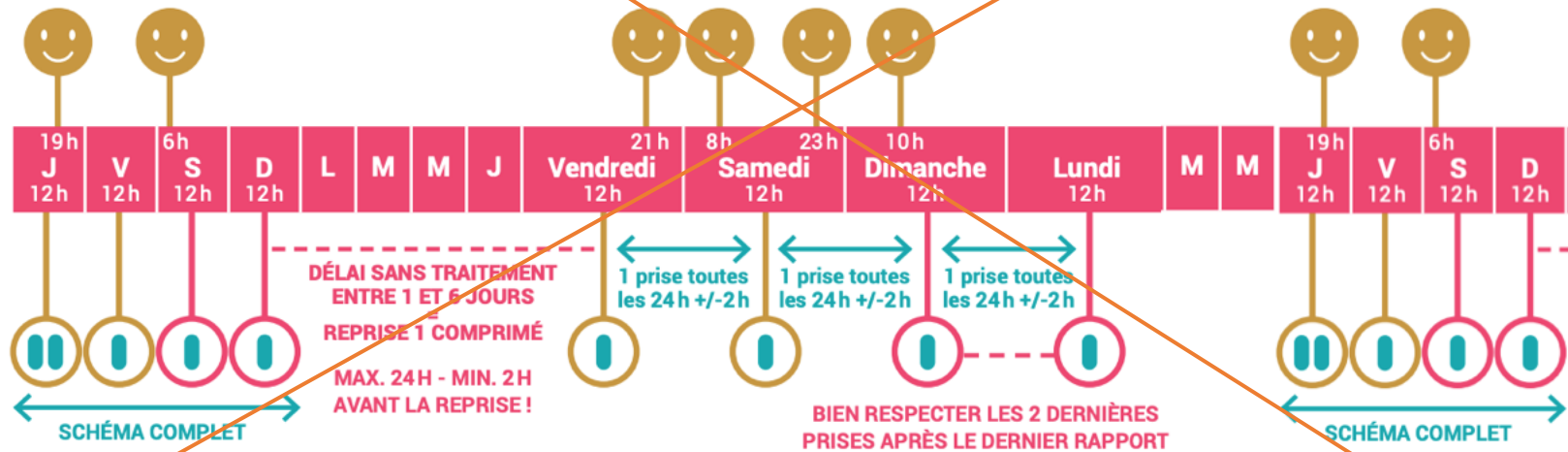
- Prise en continue

Commencer par 2 comprimés:

Chez les H et F hétéroS : Protection optimale si 7 jours avant et 7 jours après le rapport sexuel



Après une période sans PrEP de moins de sept jours, il n'est pas nécessaire de reprendre deux comprimés d'un coup pour la première prise, un seul suffit  
En revanche, lors de la prochaine prise un schéma complet ( 2 + 1 + 1 ) est nécessaire.



# 4/ Le suivi biologique

Examen clinique	Dans les 15 jours avant l'initiation de la PrEP	Au cours du suivi, après 1 mois	puis tous les 3 mois
Sérologie VIH (4ème génération)	X	X	X
Créatinine	X		X ( ou M6) <sup>1</sup>
Numération Formule Sanguine	X		
Sérologie VHA	X		
Sérologie VHB	X		
Sérologie VHC	X		x
TPHA – RPR/VDRL	X	?	x
PCR CT et NG 3 sites	X	?	x
B-HCG	X	X	x

Source : rapport Morlat 2018

1 : (eg, those >50 years, taking hypertension or diabetes medications, or with glomerular filtration rates. Source IAS 2019



# Le suivi ( 1 mois après l'initiation puis tous les 3 mois)

- Réalisation d'un dépistage du VIH et des autres IST
- Vérifier l'absence de signes en faveur d'une primo-infection VIH
- Vérifier les signes de bonne tolérance et l'observance au traitement
- Evaluer les conduites à risques d'acquisition du VIH dans les prochaines semaines
- Evaluer la consommation de substances psychoactives (notamment Chemsex avec 3 questions) et orienter le cas échéant
  - Date du dernier rapport sans produit
  - Nombre de rapport avec produit sur les 5 derniers rapports
    - Prise de drogue IV
- Parler contraception

## 5/ Les situations complexes ( Tableau)

1. Personne Transgenre
2. Femme enceinte
3. Allaitement
4. VHB chronique
5. Insuffisants rénaux
6. Ado/mineur
7. Les séroconversion ( vraies/ faux positif) ( Constance)
8. Sans prise en charge social ( => CeGIDD/ PASS)

## 6/ quand considérer le TPE ( A débattre)

- Prise Continue

Au moins prise de 4 comprimés dans le semaine => Pas de TPE

- Prise Discontinue

Si le Patient a pris correctement sa 1<sup>ère</sup> prise de 2 cp entre 2h et 24h avant le rapport sexuel

**ET**

Soit sa 2<sup>ème</sup> prise ( H24) soit sa 3<sup>ème</sup> prise (H48) = > pas de TPE

**DANS LES AUTRES CAS FAIRE TPE**