

FAQ ABOUT PREP IN FRANCE

**ADVOCACY, RESEARCH, ADMINISTRATIVE PROCESS,
EXPERT RECOMMENDATIONS AND ACCESS**



How did PrEP get started in France?

AIDES submitted a request for a temporary recommendation for use (RTU) to the Agence nationale de sécurité du médicament (ANSM; the French National Agency for Drug and Health Product Safety) in 2013. The request led to an RTU, which was published in December 2015. PrEP has been accessible in France since January 2016.

What is the current legal framework for PrEP access?

RTUs regulate the prescribing of drugs pending their marketing authorisation (AMM). For an RTU to be issued, the following two conditions must be met:

- there is an unmet therapeutic need; and
- the drug's risk/benefit ratio is assumed to be favourable, in particular, based on published scientific efficacy and tolerance data.

RTUs are valid for a maximum of three years and are renewable. Their purpose is to ensure safe drug use through the implementation of patient monitoring, organised by the pharmaceutical companies concerned in conjunction with the prescribing physicians.

The RTU defines the practical prescribing conditions: by whom, for whom, how, etc.

How was the RTU obtained?

Authorisation of PrEP was made possible by the confluence of several aligned factors over the previous three years:

1. Recognising that there was a problem. Given:
 - the incidence of HIV in MSM;
 - the steady decline in systematic condom use in HIV-negative MSM; and
 - the still-insufficient participation in early screening, it became apparent that PrEP had to be added to the array of prevention tools, since TasP effect was insufficient in curtailing the epidemic (see 2014 projections in this regard).



2. With a paradigm shift, PrEP became an acceptable strategy:

- AIDES participated in the ANRS-Ipergay trial by recruiting participants and supporting them throughout the trial;
- PrEP was authorised in the U.S.;
- Informing those people potentially interested in PrEP ;
- Discussions held with all the stakeholders in the fight against AIDS;
- Strong interorganisational networking;
- Serious involvement by AIDES in the national expert recommendations;
- Knowledge and desirability of this new prevention tool in the main populations for AIDS transmission determined by an AIDES survey, FlashPrEP.

3. Putting the issue on the agenda, thanks to several seized opportunities:

- Organising of the ANRS Ipergay trial;
- A January 12, 2012 notice from the Conseil National du Sida (the French National AIDS Council), an independent national authority, in support of PrEP.
- A 2013 request from AIDES for an RTU to force a government body to take up the issue;
- Mobilisation for PrEP in the public health legislation that was being debated in the last part of 2015;
- AIDES also used reforms in screening to make PrEP available at new screening centres (CeGIDDs) in 2016.

4. Involvement in opportunities for positive discussions and influence:

- Regional HIV consultation bodies (called COREVIHs);
- The habit of working together with the Ministry of Health's office and departments;
- Direct, long-standing ties with political leaders;
- The involvement and influence of leaders in the scientific community with policymakers;
- The presence of structures for supporting public policies specifically dealing with HIV; and
- A large community social base at AIDES that's conducive to mobilisation.

How many people are likely to receive PrEP?

Based on the Morlat report, close to 40,000 people could receive PrEP. The rollout should be done gradually over the next few years.

As of March 18, 2016, 355 people had accessed PrEP under the RTU.

Edit : As of June, 2016, more than 1000 people had accessed PrEP under the RTU.

Who can prescribe PrEP within the legal framework?

Under the RTU, hospital physicians with HIV management experience may prescribe PrEP.

However, it is also stipulated and recommended by experts that PrEP be accessible at CeGIDDs, which the health-care legislation passed at the end of 2015 also provides for. This access should become a reality in the course of 2016 through an amendment to the RTU.

What does community support consist of?

What does the training involve, and who provides it?

AIDES proposes to physicians who set up PrEP consultations that trained activist supporters be allowed to offer community support within the context of these consultations.

The support model in the Ipergay trial, which served as a basis for support in the context of the RTU, calls for a global approach to health. It proposed:

- Personalised support (new questions about recently experienced situations, risk perception, and information about how the trial is going and about the individual's knowledge of STIs);
- Long-term support (for gradual empowerment); and
- Support that lays the foundation for a multidisciplinary care trajectory centred on clearly identified needs (referrals to other health professionals).

The supporters are trained to work both permissively and non-judgementally in regard to sexual practices, substance use, lifestyle, etc. and to foster close empathy. The supporters use a number of tools on a confidential basis: brief counselling (inspired by motivational interviewing) offered to participants at each visit and when they are given unfavourable results; intensified counselling sessions on request (at a hospital or elsewhere); and the facilitation of monthly meetings for PrEP users. The supporters remain available and reachable by e-mail, text message or telephone.

This joint work with physicians as part of a preventive sexual health approach adds to the framework required for a global approach to health, and participants are pleased with it.

The Agence nationale du médicament (ANSM) does not recommend the use of support in the RTU notice because this is outside its purview. However, an ANSM commission, the Initial Benefit/Risk Commission, which drafted the notice, explicitly mentions community support. The Minister of Health's speech, in which PrEP was announced, explicitly mentions it as well.



Is the hospital network going to be able to meet the demand? Does it have sufficient resources for this?

Presently, hospital outpatient departments are able to keep up with the gradual implementation. In some locations, getting an appointment might take longer, given the increasing demand. Establishing the right to prescribe at facilities like CeGIDDs will result in an expanded offer. The implementation of PrEP is also going to involve a gradual increase in the offer of and need for support provided by organizations.

What coverage is provided for the medications?



PrEP is covered, 100% by health insurance (mandatory public health insurance for all residents of France, whether or not they are working, on the sole condition that they have lived in France for more than three months, and for documented foreigners).

This coverage should extend to undocumented foreigners whose financial resources are below a certain threshold, under a specific mechanism providing health care coverage: aide médicale d'État (State Medical Assistance).

What coverage is provided for the medical visits and laboratory tests?

Medical visits and lab tests are partially (70%) covered by health insurance. The remainder is covered by the patient's supplementary health insurance or out-of-pocket by the patient if he/she does not have supplementary insurance.

Certain necessary tests may not be covered at all. For example, for the chlamydia and gonorrhea screening tests, three sites might be tested during a given visit: oral, anal and genital. Often, only one of these test sites is covered by health insurance.

AIDES therefore plans to review the coverage conditions and the portion of the costs borne by patients in the context of providing PrEP.

What is the cost of PrEP to the public health insurance program?

At the moment, AIDES does not have the information to answer this question.

What about physicians who aren't "for" PrEP? Can they choose not to prescribe it?

Under the freedom of prescription, a physician can also choose not to prescribe PrEP. The physicians' code of ethics states that "Except in emergency situations and situations where he [the physician] would fail to meet his humanitarian responsibilities, a physician has the right to refuse to provide care for professional or personal reasons. If he withholds his services, he must inform the patient and provide the physician specified by the patient with information useful for the continuation of care."

This clause applies to individual physicians and does not apply to hospital departments. Therefore, it would seem that hospital departments have to organise and create the conditions for permitting access to PrEP.

Is PrEP also used informally?

Enacting the RTU does not prevent the persistence of informal PrEP practices. The issue is, as much as possible, to support and guide these people toward a formal PrEP consultation.

Is there a black market?

AIDES's studies have not found any reports of a possible black market. There may have been a black market before the RTU because of greater information about this new prevention tool, about a demand with no supply.

Has there been any protest against the government's decision?

PrEP authorisation and coverage have not been the subject of any particular public protest. The intensive, but targeted, media strategy has made it possible to prevent this tool from becoming subject to delay due to political divisions. The government announcement was made around December 1st, but at a time when there was another event.

AIDES's negotiations directly with the minister's office but with very little involvement of the ministry's departments made it possible to move quickly on the decision. Some of the ministry's departments working on financial management were not involved upstream, which contributed to the occurrence of problems downstream.

Some opposition was, however, voiced within the LGBT communities. Nonetheless, explanation and education around the Ipergay trial up to the present time, has made it easier to adopt this tool and made it possible, little by little, to reach a near-consensus.

How to mobilise the community?

Research (Ipergay, Flash PrEP and Flash PrEP EU) play a mobilising role in involving communities, raising people's awareness, assessing the need for this tool and its desirability, and enabling people outside organisations fighting against AIDS to advocate for this tool.

Social networks have been an important vector in this mobilisation. A dedicated Facebook page was created. It is used to share information on the informal or wild use of PrEP, as well as to promote and coordinate action supporting the authorisation of PrEP. In March 2016, six months after its creation, it had more than 1,500 members.

A group of PrEP activists, Free PrEP Now!, has been formed from and alongside the Facebook group, with support from AIDES, to request PrEP and its coverage from the Ministry of Health. Visibility, posterings and tagging actions have been organised. The group remains mobilised on PrEP implementation.

How to talk about PrEP to communities?

Overall, the pharmacological prevention of HIV is new (PrEP is still largely unknown). It's important to communicate in a very clear manner, since the current characterisation by people who aren't familiar with PrEP is that the drugs are intended solely for people who already have HIV/AIDS. One should therefore opt for very simple and straightforward messages: "PrEP is intended for people who do not have HIV/AIDS" or "PrEP is a drug that keeps one from getting HIV/AIDS".

Are the mobilized communities only MSM, or have you also worked with DU, trans, SW, migrant or other organisations?

The trans community was mobilised and taken into consideration by AIDES and certain Parisian hospitals before PrEP was authorized. A trans PrEP office has been set up.

The network of Afro-Caribbean organisations for the fight against AIDS is also starting to get mobilised around this issue in strong cooperation with AIDES.

The fact remains that, both in terms of mobilisation and access, MSM are at present particularly well represented.

Are all the populations exposed to HIV being informed about PrEP? Is there a good level of coverage?

The results of the Flash PrEP survey carried out by AIDES in 2014 show that this is not the case. The new European edition of Flash PrEP in 2016 will provide an opportunity to obtain a new assessment of the level of knowledge in France and in 10 other European countries.

In 2014, there was better uptake of this tool among MSM and in the cities that participated in the ANRS Ipergay trial.

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