

## ENVIRONMENTAL SCAN

# HIV Pre-Exposure Prophylaxis with Emtricitabine/Tenofovir Disoproxil Fumarate – Regulatory and Reimbursement Policies

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## Context

Infection with the HIV continues to be a public health concern in Canada. Despite the wide availability and effectiveness of condoms in reducing sexual transmission, new HIV infections occur annually. The Public Health Agency of Canada estimated that 2,570 new infections (range: 1,940 to 3,200) occurred in Canada in 2014;<sup>1</sup> of these, 54.3% were in sexually active men who have sex with other men (MSMs).<sup>2</sup>

HIV infection can be effectively treated with a range of antiretroviral drugs as part of antiretroviral therapy (ART) to suppress the virus and halt its progression. ART also reduces the transmission of the virus.<sup>3</sup> However, at this time a permanent cure remains elusive and much focus is given to prevention. Until recently, the main approaches to HIV infection prevention consisted of promoting the use of physical barriers during sex (condoms) or behavioural changes such as needle exchange when injecting drugs and avoidance of high-risk sexual encounters – precautions that may not be accepted by some individuals. This situation changed in 2012 with the FDA approval and availability of the fixed-dose antiviral combination emtricitabine and tenofovir disoproxil fumarate (FTC/TDF) Truvada, manufactured by Gilead, for HIV pre-exposure prophylaxis (PrEP) in the US. Taking the antivirals once daily lowers the likelihood of HIV establishing a productive infection in the human host.<sup>4</sup> Clinical trials have shown this treatment could allow a 44% to 75% relative risk reduction in sexually transmitted HIV infections in individuals at risk overall, and up to 86% in individuals at high risk of infection.<sup>5,6</sup> This regimen for the indication of PrEP was approved by the FDA in 2012,<sup>7</sup> and in early 2016 by Health Canada.<sup>8</sup>

In August 2016, the CADTH Canadian Drug Expert Committee (CDEC) recommended reimbursement of FTC/TDF for use as PrEP of HIV type 1 (HIV-1) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults at high risk of infection.<sup>1</sup> FTC/TDF was previously recommended for reimbursement by CDEC for treatment of HIV in combination with another antiretroviral<sup>9</sup> and is listed in all Canadian public drug plan formularies. However, while use of FTC/TDF for PrEP has shown clinical efficacy in the indicated populations, the cost of preventive treatment may have a significant impact on public drug budgets and is likely cost-effective only in certain high-risk groups.<sup>5,10,11</sup> Hence, the need for further understanding of national and international established criteria or policies to promote the optimal use of the drug in selected high-risk groups as well as national and international provision models for HIV PrEP is warranted to support decision-making.

## Objectives

The objectives of the Environmental Scan are to:

- describe national and international regulations, policies and patient selection criteria for the public provision of HIV PrEP with FTC/TDF
- identify patient eligibility criteria for the public funding of HIV PrEP with FTC/TDF.

The Environmental Scan provides an overview of such policies and criteria in Canada and six reference countries (the US, UK, Australia, France, Ireland, and New Zealand). It neither provides a comprehensive review or appraisal of the effectiveness of these criteria or policies nor does it recommend one policy option over another.

**Table 1: Regulatory Approval and Public Coverage of FTC/TDF for PrEP**

Country	Regulatory Approval of FTC/TDF for PrEP	Year of Regulatory Approval	Open Benefit Public Drug Plan Coverage <sup>a</sup> for FTC/TDF	Public Payer Reimbursement of FTC/TDF for PrEP Indication	Public Distribution of FTC/TDF for PrEP <sup>b</sup>
Canada	Yes (Health Canada)	2016	In some provinces – see Appendix 2	Yes (Quebec)	No
US	Yes (FDA)	2012	Yes (US Medicaid/Medicare)	Yes (US Veterans Affairs)	Yes (the State of New York, the State of Washington, and the City of Philadelphia)
UK	Yes (EMA)	2016	No	Yes (NHS Scotland)	No
France	Yes (EMA)	2016	No	Yes (French Social Security)	No
Ireland	Yes (EMA)	2016	No	No	No
Australia	Yes (TGA)	2016	No	No	No
New Zealand	No	NA	No	No	No

EMA = European Medicines Agency; FDA = US Food and Drug Administration; NA = not applicable; NHS = National Health Service; TGA = Therapeutic Goods Administration.

<sup>a</sup> Public drug plan coverage is independent of the indication of use (treatment or prevention) and without criteria.

<sup>b</sup> Public HIV care programs that are not administered as general drug benefit programs.

## Methods

A limited literature search was conducted on key resources including PubMed, MEDLINE, Embase, the Cochrane Library, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by study type. Grey literature (literature that is not commercially published) was identified by searching relevant sections of the Grey Matters checklist ([www.cadth.ca/grey-matters](http://www.cadth.ca/grey-matters)). Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011, and December 16, 2016.

The review of the grey literature was performed by consulting websites of national and international Health Technology Assessment agencies, drug and device regulatory agencies, health economics repositories, clinical guideline repositories, systematic review repositories, professional associations, and other relevant public repositories. Google and other Internet search engines were used to search for additional Web-based materials, including government resources. These searches were supplemented by reviewing the bibliographies of key papers and by information obtained from consultation with Canadian clinicians and researchers in HIV PrEP.

## Findings

A summary of the international regulatory approval and public payer coverage status of FTC/TDF for PrEP in countries included in the scan is provided in the Table 1. Country-specific details on patient selection criteria set by regulators and public payers is subsequently outlined in Appendix 1.

## Canada

In February 2016, FTC/TDF received approval from Health Canada for the indication of HIV PrEP in combination with safer sex practices. The Health Canada authorized product monograph<sup>8</sup> for Truvada (FTC/TDF) describes the high-risk population for HIV infection as follows:

- has partner(s) known to be HIV-1 infected
- engages in sexual activity within a high-prevalence area or social network and one or more of the following:
  - inconsistent or no condom use
  - diagnosis of sexually transmitted infections (STIs)
  - exchange of sex for commodities (such as money, food, shelter, or drugs)
  - use of illicit drugs or alcohol dependence
  - incarceration
  - partner(s) of unknown HIV-1 status with any of the factors listed above.

In August 2016, CDEC recommended reimbursement of FTC/TDF for use as PrEP of human HIV-1 in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 infection in adults at high risk for infection if the following conditions are met:

- provided in the context of a sexual health program by a prescriber experienced in the treatment and prevention of HIV-1 infection
- reduced price for Truvada.

CDEC discussed the definition of “high risk,” noting that the risk of HIV-1 infection in adults is dependent on both individual factors and the prevalence of HIV-1 infection in a given setting.<sup>1</sup>

Currently in Canada, public drug plans reimburse FTC/TDF for the treatment of HIV (see Appendix 2) and a number of jurisdictions including Nova Scotia, Ontario, Quebec, Veterans Affairs, and the federal Non-Insured Health Benefits Program list the drug combination as a general benefit (i.e., its reimbursement not being tied to specific criteria or indications).<sup>12-15</sup> In Alberta, British Columbia, and Prince Edward Island, FTC/TDF is provided without specified restrictions through special drug programs. Of note, these programs are focused on HIV treatment and do not consider antiviral use for PrEP.<sup>16-18</sup> Other provincial drug plans impose eligibility criteria for reimbursing FTC/TDF for HIV treatment (see Appendix 2).

Excluding the guidance in the Truvada (FTC/TDF) product monograph, there are currently no pan-Canadian policies or guidelines addressing the selection of candidates at high risk for PrEP. In addition, no pan-Canadian initiative or program incorporating FTC/TDF for HIV prevention was identified.

While FTC/TDF for PrEP is currently not routinely covered in British Columbia, the British Columbia Centre for Excellence in HIV/AIDS provides general practice guidelines on HIV PrEP.<sup>19</sup> These guidelines give information to physicians who may choose to prescribe these medications for patients covered by private insurance or willing to cover the drug costs.

Guidance on the use of FTC/TDF for PrEP was developed by the Quebec Ministry of Health before the product receiving marketing approval in Canada for that indication. In 2013, the *Ministère de la santé et des services sociaux* released a temporary notice on HIV PrEP addressing the lack of clear directives regarding prescribing FTC/TDF for this indication.<sup>20</sup> The notice recognized the potential use of FTC/TDF in individuals at high risk of acquiring HIV,

while advising against its widespread and unselected use. FTC/TDF is listed as an unrestricted benefit in the *régime public d'assurance médicaments* formulary.<sup>13</sup> Thus, Quebec is currently the only Canadian public administration to both acknowledge and fund pharmacologic HIV PrEP. The Quebec Ministry of Health's notice recommended the use of FTC/TDF for PrEP as follows:

- Use of FTC/TDF for PrEP is acceptable by MSMs who are HIV-negative and exhibiting high-risk behaviours (unprotected anal sex with individuals of positive or unknown HIV status), or serodiscordant couples with one partner showing detectable HIV loads.
- Physicians should follow patients and screen for HIV and other STIs every three months.
- Counselling should be provided to support compliance and address potential health issues, such as FTC/TDF side effects, and prevention and treatment of STIs.

## United States

The FDA became the first regulatory agency to approve the use of FTC/TDF for PrEP in 2012. The considerations for suitable selection of patients in the FDA-approved monograph<sup>7</sup> are the same as in the Health Canada-approved monograph.<sup>8</sup> In 2013, the US Centers for Disease Control and Prevention (CDC) and US Public Health Service produced joint HIV PrEP clinical practice guidelines to help patient selection, care, and follow-up.<sup>21</sup> These guidelines recommend that FTC/TDF for PrEP be considered for individuals who engage in behaviours that lead to increased risk of HIV-1 transmission, including:

- MSMs who are at substantial risk of HIV acquisition
- heterosexually active men and women who at substantial risk of HIV acquisition
- adult injection drug users who are at substantial risk of HIV acquisition
- heterosexually active men and women whose partners are known to have HIV infection.

Behaviours or conditions that place an individual at substantial risk of HIV acquisition include:

- commercial sex work
- having a sexual partner who is HIV-positive
- STI diagnosed or reported in the last six months
- high number of sex partners
- history of inconsistent condom use
- injecting partner who is HIV-positive.

These guidelines have been adopted by a number of national and local organizations.<sup>22-26</sup> Notably, the US Department of Veterans Affairs covers FTC/TDF for PrEP, albeit with restrictions (see Appendix 1).<sup>26,27</sup> The department recommends clinicians use CDC guidelines for selecting patients for PrEP.<sup>26</sup>

While federal guidelines are in place, FTC/TDF is not covered by the US government for the general population. The US Medicare and Medicaid programs provide FTC/TDF with no restrictions only to their target populations, namely people with disabilities, people with low income, and the elderly (65 and above).<sup>28</sup> A majority of US PrEP beneficiaries pay for FTC/TDF out of pocket or with some assistance from private insurance.<sup>29</sup> For people without access to health coverage, a medication assistance program is available from the Truvada (FTC/TDF) manufacturer.<sup>30</sup> Some local and regional public health programs in the US do support HIV PrEP access for individuals who do not benefit from coverage by private or federal plans. For example, the city of Philadelphia provides PrEP free of charge to all of its residents regardless

of insurance status and without explicit restrictions.<sup>31</sup> The State of Washington covers drug costs only for HIV-negative individuals enrolled in a health insurance plan.<sup>32</sup> Candidates must meet the following risk factors:

- is male or transgender, has sex with men, and has one or more of the following risks:
  - diagnosis of rectal or urethral gonorrhea, rectal chlamydia, or early syphilis in the prior 12 months
  - methamphetamine or popper use in the prior 12 months
  - history of providing sex for money, drugs, food, shelter, or transportation in the prior 12 months
  - unprotected anal sex outside of a long-term, mutually monogamous relationship.
- is in an ongoing sexual relationship with an HIV-infected person who:
  - is not on ART
  - is on ART but is not virologically suppressed
  - is within six months of initiating ART
  - is on ART and is virologically suppressed.
- is in an ongoing sexual relationship in which the female partner is trying to get pregnant
- is a woman who provides sex for money, drugs, food, shelter, or transportation
- injects drugs that are not prescribed by a medical provider.

In the State of New York, a special PrEP assistance program provides reimbursement for necessary primary care services (including drugs) for patients under the care of clinicians experienced in providing services to patients who are HIV-negative and at high risk,<sup>25</sup> in accordance with the guidelines by the Medical Care Criteria Committee.<sup>33</sup> These guidelines recommend that clinicians should discuss PrEP with the following individuals who are not infected with HIV and who have substantial and ongoing risk:

- MSMs who engage in unprotected anal intercourse
- individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner
- male-to-female and female-to-male transgender individuals engaging in high-risk sexual behaviours
- individuals engaging in transactional sex, such as sex for money, drugs, or housing
- individuals who use injection drugs and who report any of the following behaviours:
  - sharing injection equipment (including to inject hormones among transgender individuals)
  - injecting one or more times per day
  - injecting cocaine or methamphetamine
  - engaging in high-risk sexual behaviours.
- individuals who use stimulant drugs associated with high-risk behaviours, such as methamphetamine
- individuals diagnosed with at least one anogenital STI in the last year
- individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who demonstrate continued high-risk behaviour or have used multiple courses of nPEP.

In summary, there is no single program or set of criteria for providing HIV PrEP in the US. All US programs identified in this report mention serodiscordant couples, MSMs, transgender individuals, sex workers and injection drug users as eligible HIV PrEP beneficiaries. Parameters defining high-risk sexual behaviour are provided by the CDC and the State of Washington but not by the State of New York or the City of Philadelphia. The State of New York program is the only public payer that recommends HIV PrEP for prior nPEP users.

## Europe

In July 2016, the European Medicines Agency Committee for Medicinal Products for Human Use recommended granting Truvada (FTC/TDF) a marketing authorization in the European Union for PrEP.<sup>34</sup> The committee recommended educational material be prepared for prescribers and patients, but did not provide criteria or definitions for identifying individuals at high risk.

In England, FTC/TDF is not covered by NHS England for the prevention of HIV infection. In early 2016, NHS England contended that it did not have the legal authority to commission a service providing access to drugs for HIV PrEP and that local public health authorities were responsible for this type of care. After assessing the case, the court of justice reaffirmed the NHS England authority on the matter.<sup>35</sup> NHS England is appealing on the judgment, but will also consider PrEP coverage in its prioritization process for new interventions and may use the opportunity to negotiate a lower medication price with the manufacturer.<sup>36</sup>

More recently, the National Health Service and Public Health England have announced their plan to provide FTC/TDF for PrEP to 10,000 users in 2017, and to continue providing it over three years. This will be conducted in the context of a clinical trial aiming to answer outstanding questions concerning implementation and sustainability before a wider availability of the program in England.<sup>37</sup> The selection criteria for enrolling in this trial are currently unknown.

To support program and policy development, consultations and clinical reviews were conducted<sup>38</sup> and an impact assessment report was produced.<sup>39</sup> A draft policy proposition outlining a proposed patient care pathway and funding model is available for consultation.<sup>40</sup> According to this proposal, PrEP is projected to be made available by NHS England for individuals meeting any of the following three criteria:<sup>40</sup>

- MSMs, trans women or trans men who are currently HIV-negative and who are clinically assessed to be at high risk of HIV acquisition through fulfilling the following criteria:
  - have a documented confirmed HIV-negative test during an earlier episode of care in the preceding year (i.e., 42 days ago to 365 days ago)
  - report condomless intercourse in the previous three months, and this is documented in the clinical notes
  - affirm their likelihood of repeated condomless intercourse in the next three months, and this is documented in the clinical notes.
- The partner who is HIV-negative (confirmed by a current documented HIV-negative test) of a person diagnosed with HIV who is not known to be virally suppressed and with whom condomless intercourse is anticipated and so is clinically assessed and considered to be at high risk of HIV acquisition. PrEP should be recommended where the treating clinician recommends and monitors treatment as part of an active risk-reduction intervention including health education, safer sex promotion, and exploration of treatment as prevention for the HIV-positive partner.



- heterosexual men and women who are HIV-negative, clinically assessed and known to have had condomless sex with a person with HIV (who is not known to be virally suppressed) within the past three months and for whom it is anticipated that this will occur again, either with the same person or another person with similar status, and so is clinically assessed and considered to be at high risk of HIV acquisition. PrEP should be recommended where the treating clinician recommends and monitors as part of an active risk-reduction intervention including health education and safer sex promotion.

The NHS England draft policy also mentions the following exclusions:

- individuals in monogamous relationships with a partner who is known to be diagnosed with HIV and whose viral load is undetectable
- individuals without a current confirmed negative HIV test result (to minimize the risk of patients with undiagnosed HIV starting PrEP and developing a drug-resistant virus)
- individuals who do not or no longer meet the criteria for high risk of HIV acquisition
- individuals whose only risk of HIV acquisition is due to injecting drug use (as the current HIV incidence in this group in the UK is too low for PrEP to be cost-effective)
- people known to be diagnosed with HIV
- individuals under 16 years of age
- treatment outside of Level 3 genitourinary medicine services.

To mitigate financial risks of commissioning HIV PrEP, the impact assessment proposed “ensuring eligibility criteria are enforced so only those at demonstrably high risk of HIV acquisition have access to PrEP, in line with the evidence for clinical and cost-effectiveness. If those not at risk have access to PrEP, cost-effectiveness is undermined.”<sup>41</sup>

In Scotland, reimbursement of FTC/TDF for PrEP was recommended by the Scottish Medicines Consortium in March 2017.<sup>42</sup> NHS Scotland endorsed this recommendation and accepted providing FTC/TDF for PrEP to eligible individuals.<sup>43,44</sup> The recommendation mentions that, “PrEP should be available to people with greatest risk of acquiring HIV if aged 16 or over, tested HIV-negative, able to attend the clinic for regular three monthly review including for monitoring, sexual health care and support, and to collect prescriptions, willing to stop NHS-funded PrEP if the eligibility criteria no longer apply and resident in Scotland.”<sup>42</sup> In addition, one of the following criteria should be met before offering HIV PrEP:<sup>42</sup>

- current sexual partners, irrespective of gender, of people who are HIV-positive with a detectable viral load
- MSMs and transgender women with a documented bacterial rectal STI in the last 12 months
- MSMs and 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 three months
- individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.

In France, evaluations were undertaken in 2015 (before the European Medicines Agency’s review of FTC/TDF for PrEP) to assess the value of HIV PrEP, its implementation and its associated public health benefits. An expert panel led by Professor Philippe Morlat produced a series of recommendations as the basis of national guidelines on HIV PrEP.<sup>45</sup> As a result, the *Haute Autorité de Santé* provided positive advice for the exceptional use of FTC/TDF for PrEP in the context of a temporary use recommendation (*recommandation temporaire d’utilisation*) that approved the “off-label” use of FTC/TDF for PrEP in France for a period of three years, beginning in January 2016.<sup>46</sup>

The recommendation targets the use of FTC/TDF for PrEP in the following populations:<sup>46</sup>

- MSMs or transgender persons at high risk of acquiring HIV who:
  - report unprotected anal relations with at least two partners over a period of six months
  - have experienced several STI episodes in the past year
  - have used post-exposure prophylaxis in the past year
  - usually consume psychoactive substances during sex.
- on a case-by-case basis for:
  - IV drug users who share syringes
  - sex workers exposed to unprotected sex
  - vulnerable individuals exposed to unprotected sex with a high risk of HIV transmission (with partners from a high-prevalence group, or with physical characteristics increasing the risk of HIV transmission such as ulcerations, bleeding or concomitant STI).

Identification of candidates and decisions regarding PrEP must be performed in the context of a confidential and non-judgmental conversation between the potential candidate and the physician to identify high-risk circumstances in the most objective manner.<sup>45</sup>

FTC/TDF for PrEP is now funded under the French social security umbrella (with 100% coverage) and can be dispensed at hospitals or local pharmacies. FTC/TDF for PrEP can only be prescribed by physicians in hospitals or infectious disease clinics experienced in the management of HIV infection.<sup>46</sup> Two HIV PrEP schemes are approved: continuous PrEP (one pill per day) and “on-demand” PrEP, with drug intake during the period surrounding a high-risk sexual encounter.<sup>45</sup>

In summary, Europe, France and Scotland have moved forward with national programs for the provision of HIV PrEP to their eligible populations. The UK is planning public provision of HIV PrEP and has proposed some criteria. These are shared in this report with the caveat that they may change along the development process. HIV PrEP is recommended for MSMs or transgender persons at high risk of acquiring HIV by all three jurisdictions. IV drug users, sex workers and other individuals at high risk of acquiring HIV are not formally recommended, but eligibility may be granted on a case-by-case basis. Partners of individuals with detectable HIV are deemed eligible in the UK but not in France, although interpretations may vary.

## Australia

FTC/TDF was approved by the Therapeutic Goods Administration for the indication of PrEP in May 2016.<sup>47</sup> The Therapeutic Goods Administration–approved product information document for Truvada (FTC/TDF) mentions that the product “is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 in adults at high risk.”<sup>48</sup> Proposed considerations for identifying suitable candidates are individuals:

- with partner(s) known to have HIV-1
- engaging in high-risk sexual behaviour or sexual activity within a high-prevalence area or social network or who have partners from high-prevalence areas.

In July 2016, Australia’s Pharmaceutical Benefits Advisory Committee did not recommend the reimbursement of FTC/TDF for HIV PrEP on the basis of unacceptable and uncertain cost-effectiveness in the proposed population (defined according to the Therapeutic Goods Administration’s indication) and at the proposed price.<sup>49</sup> Without public reimbursement of

FTC/TDF, PrEP as a publicly provided service in Australia is uncertain; alternative approaches such as state-sponsored public health programs and large-scale demonstration projects are being considered.<sup>50-52</sup>

## Other Jurisdictions

Based on the conducted scan, FTC/TDF for HIV PrEP is approved but not publicly reimbursed in Ireland.<sup>53</sup> The drug is not available in New Zealand.<sup>41</sup>

## Limitations

The findings of this review are not intended to provide a comprehensive review of the topic, but rather present current policy examples in Canada and comparable countries based on a limited literature review. Additionally, this report does not depict the full context of HIV care; rather, the findings presented reflect the perspective of public payers. Hence, it does not capture information about general practice guidelines, sexual health programs, demonstration projects or clinical trials. Guidelines were not searched in a systematic manner, but were identified and summarized when a public provider referred to selection criteria mentioned therein. Due to the unique context of each jurisdiction in regards to health system infrastructure, population composition, and societal values, it may be that provision models, programs, or policies are not directly transferable to other jurisdictions.

## Conclusions

The objective of this Environmental Scan was to gain an understanding of the characteristics of candidates that are linked to public provision of HIV PrEP with FTC/TDF in Canada and internationally. There is a patchwork of funding schemes for PrEP in Canada due to the recent approval and recommendations from national bodies. While PrEP has been used in the US for five years at the time of the publication of this report, there are no broad national programs for public provision of the therapy. Public support is limited to local initiatives or reimbursement by national programs covering people who are elderly, on a low income, have a disability, or are a veteran. In Europe, France has taken the lead with a nationwide provision of drugs for PrEP, and Scotland has recently followed suit. England has been more conservative and is now assessing the implementation and potential impact of such a program.

Overall, eligibility criteria do not vary significantly between jurisdictions. Most jurisdictions identify potential PrEP users as MSMs with recent STIs, multiple sex partners, use of drugs during sex, and inconsistent condom use. Sex workers, injection drug users, and users of nPEP are also prioritized by some jurisdictions. HIV-negative individuals in a serodiscordant sexual relationship are also generally identified as good PrEP candidates, but the level of HIV suppression in the positive partner is not always a consideration. Product monographs approved by regulators<sup>7,8,34</sup> suggest identification of high-risk candidates based on local HIV prevalence in the population or the candidate's social network; this consideration is not found in any public provider criteria or guidelines identified in the current report. In addition to selection criteria, guidelines from regulators mention the importance of clinician and patient education to maximize the effectiveness of PrEP and to mitigate any risks.

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## Appendix 1: Public Payer Eligibility Criteria for HIV PrEP

Public Payer or Public Health Program	Criteria or Considerations for Identification of Individuals at High Risk
Quebec Ministère de la santé et des services sociaux <sup>20</sup>	HIV-negative MSMs exhibiting high-risk behaviours (unprotected anal sex with individuals of positive or unknown HIV status), or serodiscordant couples with one partner showing detectable HIV loads
US Veterans Affairs <sup>26</sup>	<p>Populations for which PrEP should be considered include:</p> <ul style="list-style-type: none"> <li>• Sexually active MSMs at substantial risk of HIV acquisition</li> <li>• heterosexually active men and women at substantial risk of HIV acquisition</li> <li>• adult injection drug users at substantial risk of HIV acquisition</li> <li>• heterosexually active men and women whose partners are known to have HIV infection.</li> </ul> <p>Behaviours or conditions that place an individual at substantial risk of HIV acquisition include:</p> <ul style="list-style-type: none"> <li>• commercial sex work</li> <li>• having a sexual partner who is HIV-positive</li> <li>• STI diagnosed or reported in the last six months</li> <li>• high number of sex partners</li> <li>• history of inconsistent condom use</li> <li>• injecting partner who is HIV-positive.</li> </ul>
Washington State <sup>32</sup>	<p>Individuals considered to be at substantial risk of HIV acquisition include those who are:</p> <ul style="list-style-type: none"> <li>• male or transgender, have sex with men, and have one or more of the following risks: <ul style="list-style-type: none"> <li>◦ diagnosis of rectal or urethral gonorrhoea, rectal chlamydia or early syphilis in the prior 12 months</li> <li>◦ methamphetamine or popper use in the prior 12 months</li> <li>◦ history of providing sex for money, drugs, food, shelter or transportation in the prior 12 months</li> <li>◦ unprotected anal sex outside of a long-term, mutually monogamous relationship.</li> </ul> </li> <li>• in an ongoing sexual relationship with a person who is infected with HIV and who: <ul style="list-style-type: none"> <li>◦ is not on ART</li> <li>◦ is on ART but is not virologically suppressed</li> <li>◦ is within six months of initiating ART</li> <li>◦ is on ART and is virologically suppressed.</li> </ul> </li> <li>• in an ongoing sexual relationship in which the female partner is trying to get pregnant</li> <li>• a woman who provides sex for money, drugs, food, shelter or transportation</li> <li>• users of injection drugs who use drugs that are not prescribed by a medical provider.</li> </ul>

<p><b>New York State</b><sup>33</sup></p>	<p>Individuals considered to be at substantial risk of HIV acquisition include those who are:</p> <ul style="list-style-type: none"> <li>• MSMs who engage in unprotected anal intercourse</li> <li>• in a serodiscordant sexual relationship with a partner who is known to be infected with HIV</li> <li>• male-to-female and female-to male transgender individuals engaging in high-risk sexual behaviours</li> <li>• engaging in transactional sex, such as sex for money, drugs, or housing</li> <li>• users of injection drugs who report any of the following behaviours:             <ul style="list-style-type: none"> <li>◦ sharing injection equipment (including to inject hormones among transgender individuals)</li> <li>◦ injecting one or more times per day</li> <li>◦ injecting cocaine or methamphetamine</li> <li>◦ engaging in high-risk sexual behaviours.</li> </ul> </li> <li>• individuals who use stimulant drugs associated with high-risk behaviours, such as methamphetamine</li> <li>• diagnosed with at least one anogenital STI in the last year</li> <li>• prescribed nPEP and who demonstrate continued high-risk behaviour or have used multiple courses of nPEP.</li> </ul>
<p><b>England (draft)</b><sup>40</sup></p>	<p>Individuals considered to be at substantial risk of HIV acquisition include those who are:</p> <ul style="list-style-type: none"> <li>• MSMs or transgender persons who are currently HIV-negative and who are clinically assessed to be at high risk of HIV acquisition through fulfilling the following criteria:             <ul style="list-style-type: none"> <li>◦ have a documented confirmed HIV-negative test during an earlier episode of care in the preceding year (i.e., 42 days to 365 days ago)</li> <li>◦ report condomless intercourse in the previous three months, and this is documented in the clinical notes</li> <li>◦ affirm their likelihood of repeated condomless intercourse in the next three months, and this is documented in the clinical notes.</li> </ul> </li> <li>• HIV-negative (confirmed by a current documented negative HIV test) and the partner of a diagnosed person with HIV who is not known to be virally suppressed and with whom condomless intercourse is anticipated and so is clinically assessed and considered to be at high risk of HIV acquisition</li> <li>• heterosexual men and women who are HIV-negative and clinically assessed and known to have had condomless sex with a person with HIV (who is not known to be virally suppressed) within the past three months and for whom it is anticipated that this will occur again, either with the same person or another person with similar status, and so is clinically assessed and considered to be at high risk of HIV acquisition.</li> </ul> <p>Excluding individuals who are:</p> <ul style="list-style-type: none"> <li>• in monogamous relationships with a partner who is known to be diagnosed with HIV and whose viral load is undetectable</li> <li>• without a current confirmed negative HIV test result (to minimize the risk of patients with undiagnosed HIV starting PrEP and developing a drug-resistant virus)</li> <li>• no longer considered at high risk of HIV acquisition, as they no longer meet the criteria</li> <li>• only at risk of HIV acquisition due to injecting drug use (as the current HIV incidence in this group in the UK is too low for PrEP to be cost-effective)</li> <li>• known to be diagnosed with HIV</li> <li>• under 16 years of age</li> <li>• in a treatment outside of level 3 genitourinary medicine services.</li> </ul>



<p><b>Scotland</b><sup>42</sup></p>	<p>Individuals considered to be at substantial risk of HIV acquisition include those who are:</p> <ul style="list-style-type: none"> <li>• current sexual partners, irrespective of gender, of people who are HIV-positive and with a detectable viral load</li> <li>• MSMs and transgender women with a documented bacterial rectal STI in the last 12 months</li> <li>• MSMs and 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 three months</li> <li>• individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.</li> </ul>
<p><b>France</b><sup>46</sup></p>	<p>The use of FTC/TDF for PrEP has been recommended in the following populations</p> <ul style="list-style-type: none"> <li>• MSMs or transgender persons at high risk of acquiring HIV and who:             <ul style="list-style-type: none"> <li>◦ report unprotected anal relations with at least two partners over a period of six months</li> <li>◦ have experienced several STI episodes in the past year</li> <li>◦ have used post-exposure prophylaxis in the past year</li> <li>◦ usually consume psychoactive substances during sex.</li> </ul> </li> <li>• on a case-by-case basis for:             <ul style="list-style-type: none"> <li>◦ IV drug users who share syringes</li> <li>◦ sex workers exposed to unprotected sex</li> <li>◦ vulnerable individuals exposed to unprotected sex with a high risk of HIV transmission (with partners from a high-prevalence group, or with physical characteristics increasing the risk of HIV transmission such as ulcerations, bleeding or concomitant STI).</li> </ul> </li> </ul>

ART = antiretroviral therapy; MSMs = sexually active men who have sex with other men; nPEP = non-occupational post-exposure prophylaxis; PrEP = pre-exposure prophylaxis; STI = sexually transmitted infection.

## Appendix 2: Canadian Public Drug Plan Benefit Status for FTC/TDF

Jurisdiction	Full Benefit	Restricted Benefit	Restrictions or Other Notes
Alberta <sup>17</sup>	✓		Alberta Specialized High Cost Drug Program covers drugs (100% of costs) for the treatment of patients with HIV infection that are dispensed through the Southern and Northern Alberta clinics
British Columbia <sup>16</sup>	✓		Provided by the British Columbia Centre for Excellence in HIV/AIDS
Federal Non-Insured Health Benefits <sup>14</sup>	✓		
Manitoba <sup>54</sup>		✓	Exceptional Drug Status Program
New Brunswick <sup>55</sup>		✓	For treatment of HIV infection in patients requiring a dual nucleoside/nucleotide option and for whom efavirenz is not indicated Special authorization required if the prescriber is not an infectious disease specialist or medical microbiologist
Newfoundland and Labrador <sup>56</sup>		✓	Special authorization required Reserved for the treatment of patients with HIV where the virus is susceptible to both agents and efavirenz is not indicated due to adverse effects or antiretroviral resistance
Nova Scotia <sup>57</sup>	✓		Prescriber must be a medical doctor and pharmacist in HIV clinic only
Ontario <sup>12</sup>	✓		
Prince Edward Island <sup>58</sup>		✓	The Prince Edward Island AIDS/HIV drug program <sup>18</sup> is available to residents of the province who: <ul style="list-style-type: none"> <li>• test positive for HIV</li> <li>• are diagnosed with AIDS</li> <li>• have a needle-stick injury that is not work related and do not have private medical insurance.</li> </ul>
Quebec <sup>13</sup>	✓		Ministère de la santé et des services sociaux guidance for use in HIV PrEP <sup>20</sup>
Saskatchewan <sup>59</sup>		✓	Exceptional Drug Status For treatment of patients with HIV where: <ul style="list-style-type: none"> <li>• the virus is susceptible to tenofovir and emtricitabine</li> <li>• efavirenz is not indicated due to adverse effects or antiretroviral resistance.</li> </ul> When prescribed by, or on the advice of an infectious disease specialist familiar with HIV post-exposure prophylaxis (PEP); please refer to the HIV PEP treatment document on the formulary website Possible to perform online Exceptional Drug Status adjudication using a list of approved prescribers; antivirals for the treatment of HIV should be used under the direction of an infectious disease specialist
Veterans Affairs Canada <sup>15</sup>	✓		
Yukon <sup>60</sup>		✓	Exceptional Drug Status Covered by the Chronic Disease Program on a case-by-case basis on recommendation of specialist