Updated Pre-Exposure Prophylaxis Recommendations for the Prevention of HIV Infection

Background
This Bulletin is an update to the previously published 2014 Pre-Exposure Prophylaxis (PrEP) recommendations, including new information on medications and resources. PrEP is an HIV prevention strategy in which HIV-negative individuals take a daily antiretroviral (ARV) prescription medication to reduce their risk of acquiring HIV. PrEP reduces the risk of getting HIV from sex by about 99% and from injection drug use by 74%-84%, when taken as prescribed.1,2 Alaskans can access PrEP through their medical providers. Although some retail pharmacies may not have PrEP medications available for immediate dispensing, they are usually able to obtain the drugs within 1–2 days.

Update on Medications Approved for PrEP
In October 2019, the U.S. Food and Drug Administration (FDA) approved Descovy® (FTC/TAF), a fixed-dose combination tablet comprised of 200 mg of emtricitabine (FTC) and 25 mg of tenofovir alafenamide (TAF). In October 2020, a generic version of Truvada® (FTC/TDF) became available. This is a fixed-dose combination tablet of 200 mg of emtricitabine (FTC) and 300 mg of tenofovir disoproxil fumarate (TDF).

Expanded PrEP Access
Beginning January 2021, PrEP medications and services will be covered by applicable health plans without cost sharing, including co-pays. In June 2019, the U.S. Preventive Services Task Force (USPSTF) made a Grade A recommendation that clinicians offer PrEP to persons at high risk of HIV acquisition.3 Affordable Care Act (ACA) provisions require most private insurance plans and Medicaid expansion departments to cover PrEP medications and services will be covered by applicable health plans without cost sharing, including co-pays. In June 2019, the U.S. Preventive Services Task Force (USPSTF) made a Grade A recommendation that clinicians offer PrEP to persons at high risk of HIV acquisition.3 Affordable Care Act (ACA) provisions require most private insurance plans and Medicaid expansion programs to cover PrEP medications and services will be covered by applicable health plans without cost sharing, including co-pays.

Table. Updated Summary of PrEP Guidance

<table>
<thead>
<tr>
<th>Men Who Have Sex with Men</th>
<th>Persons Who Inject Drugs</th>
<th>Other Men and Women</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factors which Correlate to Risk of HIV Acquisition</strong></td>
<td><strong>HIV-positive sexual partner</strong></td>
<td><strong>HIV-positive sexual partner</strong></td>
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<tr>
<td>• HIV-positive sexual partner</td>
<td>• Recent bacterial sexually transmitted infection (STI)</td>
<td>• Recent bacterial STI</td>
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<tr>
<td>• Recent bacterial sexually transmitted infection (STI)</td>
<td>• High number of sex partners</td>
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</tr>
<tr>
<td>• History of inconsistent or no condom use</td>
<td>• Commercial or transactional sex work</td>
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<tr>
<td>• Commercial or transactional sex work</td>
<td>• Documented negative HIV test result (ideally with a 4th generation antigen/antibody test conducted by a laboratory) within the week prior to PrEP prescription</td>
<td>• Commercial or transactional sex work</td>
</tr>
<tr>
<td>• Normal renal function and no contraindicated medications</td>
<td>• No signs or symptoms of acute HIV infection, including fever, fatigue, myalgia, skin rash, and headache</td>
<td>• Male-to-female and female-to-male transgender individuals engaging in high-risk sexual behaviors</td>
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<tr>
<td>• Documented hepatitis B virus infection status and vaccination status, hepatitis C virus infection status for those at increased risk</td>
<td>• Normal renal function and no contraindicated medications</td>
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</tbody>
</table>

**Clinical Eligibility Criteria**
- A daily, oral fixed-dose combination tablet of: 200 mg emtricitabine (FTC) and 300 mg tenofovir disoproxil fumarate (TDF) (Brand name Truvada®), OR 200 mg emtricitabine (FTC) and 25 mg tenofovir alafenamide (TAF) (Brand name Descovy®).
- At least every 3 months provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment
- At least once a year (as opposed to every 6 months as previously recommended) for those who have been consistently taking PrEP and who are otherwise healthy and compliant.

**Clinical Monitoring**
- **HIV-positive sexual partner**
- **Recent bacterial STI**
- **High number of sex partners**
- **History of inconsistent or no condom use**
- **Commercial or transactional sex work**
- **Male-to-female and female-to-male transgender individuals engaging in high-risk sexual behaviors**
- **Current and previous exposure to tenofovir disoproxil fumarate (TDF)**
- **Current and previous exposure to emtricitabine (FTC)**
- **Current and previous exposure to tenofovir alafenamide (TAF)**
- **Current and previous exposure to lamivudine (3TC)**
- **Current and previous exposure to tenofovir disoproxil fumarate and emtricitabine (TDF/FTC)**
- **Current and previous exposure to emtricitabine and rilpivirine (ERI)**
- **Current and previous exposure to emtricitabine and dolutegravir (ETD)**
- **Current and previous exposure to emtricitabine and rilpivirine and dolutegravir (ETR/ERD)**
- **Current and previous exposure to emtricitabine and rilpivirine and dolutegravir and lamivudine (ETR/ERD/3TC)**

**References**
2. CDC. Pre-Exposure Prophylaxis (PrEP). Available at: https://www.cdc.gov/hiv/pdf/prevention/prep.html

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