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.1 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. Preventative 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 Grade A services with no cost sharing.

On December 3, 2019, the U.S. Department of Health and Human Services (HHS) launched Ready, Set, PrEP, a nationwide program that makes PrEP medications available at no cost to individuals who lack prescription drug coverage. Patients access the program through their health care provider. Health care providers can assist their patients in enrolling in the program by calling 855-447-8410 or visiting the following website: http://www.getyourprep.com.

Recommendations
1. Routinely screen all patients aged 13–64 years for HIV at least once. Screen patients with HIV risk factors at least annually and those at highest risk (including men who have sex with men and people who inject drugs) every 3–6 months in all health care settings, including emergency departments and correctional centers.
2. Offer PrEP to persons at increased risk for HIV acquisition, including partners of persons living with HIV (Table).

Resources
1. The National Clinical Consultation Center provides health care providers with clinically supported PrEP advice. Clinical consultation is available by calling (855) 448-7737 Monday-Friday 5:00 a.m. to 4:00 p.m. Alaska Time; voicemail is available 24-hours per day.

Table. Updated Summary of PrEP Guidance

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

Medications
- 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®). (Notes: (1) FTC/TAF or Descovy® for PrEP is not indicated in individuals at risk for HIV-1 through receptive vaginal sex; effectiveness in this population has not been evaluated. (2) Patient hepatitis B status, renal function, and bone health may impact medication decision making. See CDC’s complete clinical guidelines at the link below for additional information.)

Clinical Monitoring
- At least every 3 months provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment
- At 3 months and every 6 months thereafter, assess renal function
- Every 6 months, test for bacterial STIs, including chlamydia and gonorrhea at all sites (oral/rectal/genital) and syphilis

Complete and current clinical guidelines may be found online at: https://www.cdc.gov/hiv/guidelines/preventing.html

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