HIV Pre-Exposure Prophylaxis (PrEP) Policy
Provider Driven

I. Statement of Need

At year-end 2021, an estimated 1.2 million people in the United States aged 13 and older had Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) in the United States with an estimated 32,100 new HIV infections, according to the Centers for Disease Control and Prevention (CDC). Between 2017 and 2021, new HIV diagnoses among American Indian and Alaska Native (AI/AN) persons increased by 16%; the only group other than Native Hawaiian/Other Pacific Islanders to see an increase, as shown by the CDC graphic.

Other sexually transmitted infections (STIs), such as syphilis, also occur at higher incidence rates amongst AI/AN people compared to the United States average. These STIs, specifically syphilis, have been shown to increase the risk of HIV transmission. Substance use, particularly methamphetamine use, is prevalent throughout Indian Country. This, paired with shared injection equipment, increases the risk of HIV transmission. The need for low-barrier access to HIV prevention care is apparent.

II. Purpose and Goals

For individuals at risk of acquiring HIV, Pre-Exposure Prophylaxis (PrEP) is a highly effective biomedical prevention tool that when taken as prescribed, can greatly reduce the chance of getting HIV from sex or injection drug use. HIV PrEP, has the potential to decrease not only the burden of HIV, but also decrease the prevalence of other STIs through frequent testing and treating new infections promptly. PrEP visits will also allow the opportunity to link individuals to other healthcare services, such as immunizations and harm reduction counseling.

Access to PrEP should be available on-demand, with immediate access to medications. Increasing access to preventive measures meets one of the pillars of the Ending the HIV Epidemic initiative (EHE) in reducing new HIV cases by 90% by 2030.

III. Policy and Procedure

A. Indications for PrEP (include but are not limited to):

1. Sexually-Active Adults and Adolescents (weighing over 77 pounds/35 kg)
    a. Sexual partner(s) is living with HIV with a detectable or unknown viral load
    b. Sexual partner(s) unaware of their HIV status
    c. Bacterial STI in past 12 months
    d. History of inconsistent or no condom use with sexual partner(s)

2. Persons Who Inject Drugs
    a. Injecting partner(s) is living with HIV with a detectable or unknown viral load

b. Injecting partner(s) unaware of their HIV status
c. History of sharing injection equipment with injecting partner(s)

B. Inclusion Criteria:

1. HIV Ag/Ab test negative in the past 7 days OR HIV Ag/Ab test pending at the time patient is picking up medication
2. If HIV exposure exists in the last 72 hours, offer HIV post-exposure prophylaxis (PEP) and then bridge to HIV PrEP upon completion of PEP if risk remains. CDC HIV PEP Policy
3. No signs/symptoms of acute HIV Infection in the past 4 weeks (flu-like symptoms: fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, mouth ulcers, diarrhea, etc.) If present, test for acute HIV (viral RNA) and consider deferring HIV PrEP until test results are back
4. For tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and tenofovir alafenamide/emtricitabine (TAF/FTC)
    a. eGFR> 60 ml/min for TDF/FTC or >30 for TAF/FTC, or renal function test pending at the time patient is picking up medication
    b. Documented HBV infection/vaccination status or pending HBV labs
5. Assess for any history of renal disease, liver disease, osteopenia/osteomalacia osteoporosis; presence may impact PrEP agent selected
6. Additional testing to be drawn for same day PrEP Initiation:
    a. STI screening (at all anatomical sites of exposure – pharyngeal, rectal, vaginal, urine): Gonorrhea, Chlamydia, Syphilis, Trichomonas
    b. Hepatitis B serology (if not known to be hepatitis B immune)
    c. Hepatitis C screening
    d. Lipid panel (for FTC/TAF initiation)
    e. CMP for eGFR (oral PrEP)
    f. Pregnancy test (if indicated)
7. Willingness and ability to take a medication on a schedule AND return for regular appointments and labs while taking PrEP

C. Selection of HIV PrEP Regimen and Prescribing

1. Preferred regimen:
   Tenofovir disoproxil fumarate 300 mg/Emtricitabine 200 mg (TDF/FTC) PO daily
    a. On national core formulary
    b. Indicated for adults and adolescents ≥35 kg
    c. Not recommended for CrCl <60 mL/minute

2. Alternative regimens:
    a. Tenofovir alafenamide 25 mg/Emtricitabine 200 mg (TAF/FTC) PO daily
        1. Not on national core formulary
        2. Indicated for adults and adolescents ≥35 kg. May be used for patients when TDF/FTC is deemed inappropriate defined as:
            - In the presence of bone disease
            - CKD stage 3 or greater (CrCl </=60 mL/min)
            - CKD stage 2 (CrCl 61-89 mL/min) with additional risk factors for worsening renal function such as DM, hypertension, and/or persistently elevated UACR (>30mg/g)
            - **Of note: TAF/FTC should not be used in severe renal impairment**

(CrCl <30mL/min)

3. Has not been adequately evaluated in cisgender females and will not be offered to those patients

b. Cabotegravir (Apretude) 600mg long-acting IM injection
   1. Not on national core formulary
   2. Indicated for adults and adolescents ≥35 kg

Due to high costs, approval for non-formulary medications (TAF/FTC or Cabotegravir IM injections) will be on a case-by-case basis. If applicable, patients will go through the drug company's patient assistance program (see appendix for guidance)

3. Potential drug interactions can be checked here: https://www.hiv-druginteractions.org/checker

3. Prescribing Instructions
   a. Prescriptions should not be written for more than 3 months at a time
   b. Refills should not be processed if HIV test >90 days ago and patient does not have a HIV test pending
   c. HIV labs (HIV Ag/Ab and HIV-1 RNA assay) required if a lapse of >7 days in PrEP therapy

D. Clinical Follow-up & Monitoring

1. If there has been a lapse of >7 days in PrEP or if it has been >90 days since last HIV testing, then new HIV testing (HIV Ag/Ab and HIV-1 RNA assay) is needed
2. At least every 3 months:
   - Repeat HIV testing (HIV Ag/Ab and HIV-1 RNA assay) and offer medication adherence and behavioral risk reduction support
   - Bacterial STI screening at all anatomical sites of exposure: oral, rectal, urine, vaginal
3. At least every 6 months:
   - Assess renal function for patients aged ≥50 years or who have an eCrCl <90ml/min at PrEP initiation
4. At least every 12 months:
   - Assess renal function for all patients
   - For patients on TAF/FTC: assess weight, triglyceride and cholesterol levels
5. For patients on CAB:
   - Documented negative HIV-1 RNA assay (≤1 week before initiating or reinitiating PrEP, at 1-month post-initiation, then every 2 months while taking PrEP, and following discontinuation of PrEP)

See appendix for telePrEP guidance

E. Patient education

1. PrEP should be taken exactly as prescribed by the healthcare provider
2. Avoid changing your dose or stop taking PrEP without first talking with your healthcare provider
3. Store medications at room temperature

4. Most common side effects for oral PrEP: headache, abdominal pain, changes in weight
5. Most common side effect for injectable PrEP: injection site reaction

F. DoxyPEP (STI prevention)

1. Anyone taking HIV PrEP should be considered for DoxyPEP
2. Refer to IHS DoxyPEP guidelines

G. Discontinuation of PrEP

1. Patients will be discontinued from PrEP by provider for any of the following reasons:
   a. Confirmed HIV infection
   b. Decline in renal function: CrCl <30 mL/min (for TAF/FTC), CrCl <60 mL/min (for TDF/FTC)
   c. Intolerance or allergy to PrEP regimen
   d. HIV risk behavior no longer present and patient wishes to discontinue PrEP

2. When discontinuing PrEP provider should document:
   a. HIV status at the time of discontinuation
   b. Reason for discontinuation
   c. Recent medication adherence and reported sexual risk behavior
   d. Education provided: continue to take PrEP for 28 days since last exposure
   e. Patient informed regarding ability to restart PrEP in future

3. Restarting PrEP instructions
   a. Requires same initial evaluation, minus the Hep B serology (if vaccinated)