PART 5a:
PRE-EXPOSURE PROPHYLAXIS (PrEP)
PrEP AS HIV PREVENTION FOR ELIGIBLE HIV NEGATIVE PATIENTS

What is PrEP?

▶ Pre-exposure prophylaxis (PrEP) is a form of HIV prevention for people who are at substantial risk of getting HIV. Research shows that consistent use of PrEP reduces the risk of HIV transmission through sex or injection drug use by up to 92%. It is less effective without consistent use.

▶ PrEP involves taking a daily tablet that combines two antiretroviral drugs, tenofovir and emtricitabine.

▶ The common side effects of PrEP are headache, abdominal pain, nausea and weight loss. Side effects are likely to resolve or improve after the first month.

▶ PrEP does not provide protection against other sexually transmitted infections or pregnancy.

Who is NOT eligible for PrEP?

▶ People living with HIV or with signs of acute HIV infection - All individuals must have a confirmed negative HIV test before initiating PrEP.

▶ People with renal insufficiency (i.e. CrCl < 60 mL/minute)

▶ People who are not ready to adhere to a daily PrEP regimen and regular STI testing and follow-up care.

Before initiating PrEP, obtain the following:

▶ HIV test ideally with a 4th generation antigen/antibody test conducted by a laboratory within seven days of PrEP prescription. “HIV testing can be accomplished by 1) drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test or and antibody-only test or 2) performing a rapid, point-of-care, FDA-approved, fingerstick blood test. Rapid tests that use oral fluid should not be used to screen for HIV infection because they can be less sensitive than blood tests”.

▶ Viral load if you suspect acute HIV infection.

▶ Basic metabolic panel. If CrCl < 60mL/min, do not start PrEP.

▶ Urinalysis. If patient has significant proteinuria, consult an expert before starting PrEP.

▶ Serology for Hepatitis A, B and C.

▶ STI screen: Syphilis screening and gonorrhea/chlamydia screening at 3-sites (genital, rectal, pharyngeal).

▶ Pregnancy Test: If positive, discuss risks and benefits of initiating PrEP.
PrEP AS HIV PREVENTION FOR ELIGIBLE HIV NEGATIVE PATIENTS CONT.

For more information on PrEP guidance:
▶ 888-788-PREP,
▶ www.prepmaryland.org,

For patients interested in learning the estimated copays and annual cost of PrEP for their specific insurance:
▶ prepcost.org

After initiating PrEP, conduct the following tests and monitoring:
▶ Every 3 months – 1) HIV test (as listed on page 64): Confirm negative result and no acute HIV infection before writing a refill; 2) Pregnancy test; 3) Ask about STI symptoms and exposure risk (e.g. number of partners, use of protection); 4) 2 Creatinine + CrCl: at 3 month visit, then every 6 months, more frequently if at risk for renal insufficiency.
▶ Every 6 months – 1) STI screen: Gonorrhea, chlamydia and syphilis screening at 3-sites (genital, rectal, pharyngeal), perform even if patients are asymptomatic; and 2) Creatinine + CrCl (as above).
▶ Annually – 1) Urinalysis; and 2) Hepatitis C Ab (for high risk patients).

Speak with a clinician experienced in managing PrEP, if patient:
▶ Has chronic active hepatitis B.
▶ Is pregnant or attempting to conceive
▶ Is taking nephrotoxic drug, or is at risk for bone loss.
Access

In order to access HIV Pre-Exposure Prophylaxis (PrEP), you need a prescription for Truvada written by a health care provider and a means to cover the cost of the drug as well as the cost of medical visits and lab work that are part of a comprehensive PrEP program.

Types of Insurance Coverage

Private Insurance via the Marketplace:

- Maryland Health Connection is Maryland’s official health insurance marketplace, offering a range of health coverage options from health insurance carriers and public health care programs. You can get the coverage you need online, over the phone, or in person. Go to: https://www.marylandhealthconnection.gov for more information.

- Financial assistance is available to help reduce the cost of health care for individuals and families who enroll in a marketplace health insurance plan and meet certain income requirements.

  - For premium assistance, your household income is between 100% and 400% of the federal poverty level (for an individual, between $12,060 and $47,520; for a family of four, between $24,600 and $97,200, in 2017). Consumers may use their premium assistance for any plan under any metal tier in the Marketplace (Bronze, Silver, Gold or Platinum) and may choose to receive it in advance each month or at the end of the year when they file their taxes.

  - For cost-sharing subsidies, an individual’s annual household income must be 250% of the federal poverty level (or $29,425 for a single person) or less. **Individuals may only receive cost-sharing subsidies if they choose to enroll in a Silver-level plan.**

- You can stay on your parent’s health insurance until you turn 26.

- Open enrollment for this year is November 1, 2019 to December 15, 2019.

- The amount you pay to access PrEP will vary depending on the metal level you choose and the corresponding premium, deductible, copay and coinsurance amount.

Medicaid:

- Maryland has chosen to implement the Affordable Care Act’s Medicaid expansion. To find out if you are eligible for Medicaid or the Maryland Children’s Health Program (MCHP), and for information on how to apply, go to https://www.marylandhealthconnection.gov/medicaid-basics-benefits. Enrollment in Medicaid and MCHP is year-round. If eligible, coverage will be effective back to the first day of the month in which you applied.

If You Are Insured

Medicaid and most private insurance covers PrEP, however, several barriers can still make accessing PrEP difficult. These barriers may include **high out of pocket costs** (e.g., premiums, co-pays, etc.); **prior authorization** (when the pharmacy and doctor need to submit documentation to the insurance company to get the drug approved), and **quantity limits** (when the plan will only pay for a few pills instead of a full month supply). The CDC publishes a helpful brochure (http://www.cdc.gov/hiv/pdf/risk_Prep_TalkingtoDr.pdf) on how to talk to your doctor about PrEP.

**PrEP-Related Resources in Baltimore (partial list)**

**Chase Brexton – Mount Vernon** 1111 North Charles Street Baltimore, MD 21201
Telephone: **410-837-2050**; http://chasebrexton.org

**Johns Hopkins John G. Bartlett Specialty Practice**
1717 E Monument St
Baltimore, MD 21287
Telephone: **410-955-1725**
Free and Low Cost Clinics
Free and low cost clinics in Baltimore, including community clinics and federally qualified health centers, generally accept most types of health insurance and provide services for people who don’t have insurance at a sliding scale payment rate (including, possibly free). These clinics generally serve individuals from the county where the clinic is located and surrounding areas. To find a list of clinics in your area visit: http://findahealthcenter.hrsa.gov/SearchHCC.aspx

Medication Assistance and Copay Programs

Gilead’s Medication Assistance Program: provides Truvada for PrEP at no cost for those without health insurance or prescription drug coverage. To be eligible for Gilead’s Medication Assistance Program for Truvada, you must:

- Be HIV-negative
- Have an income below 500% of the FPL ($58,850 for one person)
- Not have any other source for health insurance or prescription coverage (re-evaluated on a regular basis)
- Have a prescription for Truvada
- Show proof of U.S. residency. In other words, you must live in the US but you don’t have to be a “legal resident.”
- Medication (30 day supply) will be shipped to provider's office—may take up to two weeks. Gilead will check your status every 90 days and requires that you reapply after 6 months.

Contact Gilead: 1-855-330-5479

Gilead’s Co-pay Program provides assistance (up to $7,200 per year) for out of pocket costs (including co-pays, co-insurance and deductibles) for people who have private insurance, regardless of income. It does not cover out-of-pocket costs for clinical visits or labs. To be eligible for Gilead’s co-pay program for Truvada, you must:

- Have private insurance
- Reside in the US or US territories
- Not have Medicaid or Medicare

If eligible, Gilead will issue a co-pay card for use at pharmacies. They will also reimburse when pharmacies don’t accept the card. Need to re-apply every 6 months. Contact Gilead at 1-877-505-6986 (www.gileadcopay.com)

Patient Access Network (PAN) Co-pay Program: Through the Patient Access Network, you may receive a grant for up to $3,600 per year. Patients may apply for a second grant during their eligibility period subject to availability of funding, which covers deductibles and co-insurance and is designed for those whose out-of-pocket costs are not fully covered by the Gilead program. Most pharmacies should be able to bill PAN directly. To qualify for co-payment assistance with Patient Access Network, you must:

1. The patient must be getting treatment for HIV treatment and prevention.
2. The patient must have Medicare health insurance that covers his or her qualifying medication or product.
3. The patient's income must fall at or below 500% of the Federal Poverty Level.
4. The patient must reside and receive treatment in the United States or U.S. territories. (U.S. citizenship is not a requirement.)

Contact: www.panfoundation.org/fundingapplication/welcome.php or 1-866-316-PANF