

PrEP Access and Future Horizons: Changes in the Drug Market and Coverage

November 19, 2020



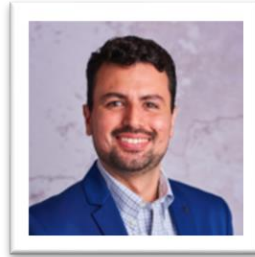
NASTAD's PrEP Team



Tim Horn

Director, Medication Access and Pricing

- 340B program income
- Generic drug market
- Self-testing purchasing collective



Edwin Corbin-Gutierrez

Associate Director, Health Systems Integration

- EHE coordination



Kendrell Taylor

Manager, Prevention

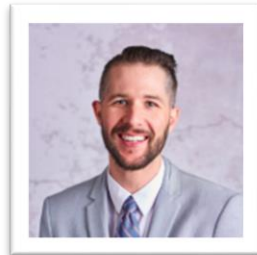
- PrEP program implementation
- Self-testing for PrEP monitoring



Amy Killelea

Senior Director, Health Systems & Policy

- Implementation of the USPSTF recommendation
- Health plan coverage



Mike Weir

Senior Manager, Policy & Legislative Affairs

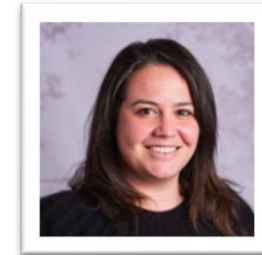
- Federal and state policy and regulatory framework



Nicole Elinoff

Manager, Prevention

- PrEP program implementation
- TelePrEP learning collaborative



Dori Molozanov

Manager, Health Systems Integration

- Telehealth regulations
- Health plan coverage
- PrEPcost.org

Agenda

- ✓ Introduction of generic PrEP drugs to the US market
- ✓ New ACA coverage protections for patients (through USPSTF)
- ✓ Potential changes in health plan coverage
- ✓ Accelerating the scale-up of telePrEP
- ✓ Scaling up self-testing services for PrEP uptake and monitoring

What drugs are available for PrEP?

- Tenofovir disoproxil fumarate and emtricitabine (TDF/FTC)
 - Brand name: Truvada by Gilead Sciences
 - Generic TDF/FTC is now available from Teva Pharmaceuticals USA
- Tenofovir alafenamide fumarate and emtricitabine (TAF/FTC)
 - Brand name: Descovy by Gilead Sciences
 - TAF/FTC was approved with limitations and is indicated only for gay, bisexual, and other men who have sex with men (GBM) as well as transgender women

When will generic PrEP become available?

- It's already here! On October 2, 2020, Teva Pharmaceuticals USA began selling generic TDF/FTC in the US.
- Three other generic manufacturers have received FDA approval to market TDF/FTC as of October 21, 2020:
 - Amneal Pharmaceuticals
 - Aurobindo Pharma
 - Zydus Pharmaceuticals
- All four have AB bioequivalence
 - AB bioequivalence indicates that pharmacies can switch patients from the brand-name drug to the generic therapeutic equivalent.

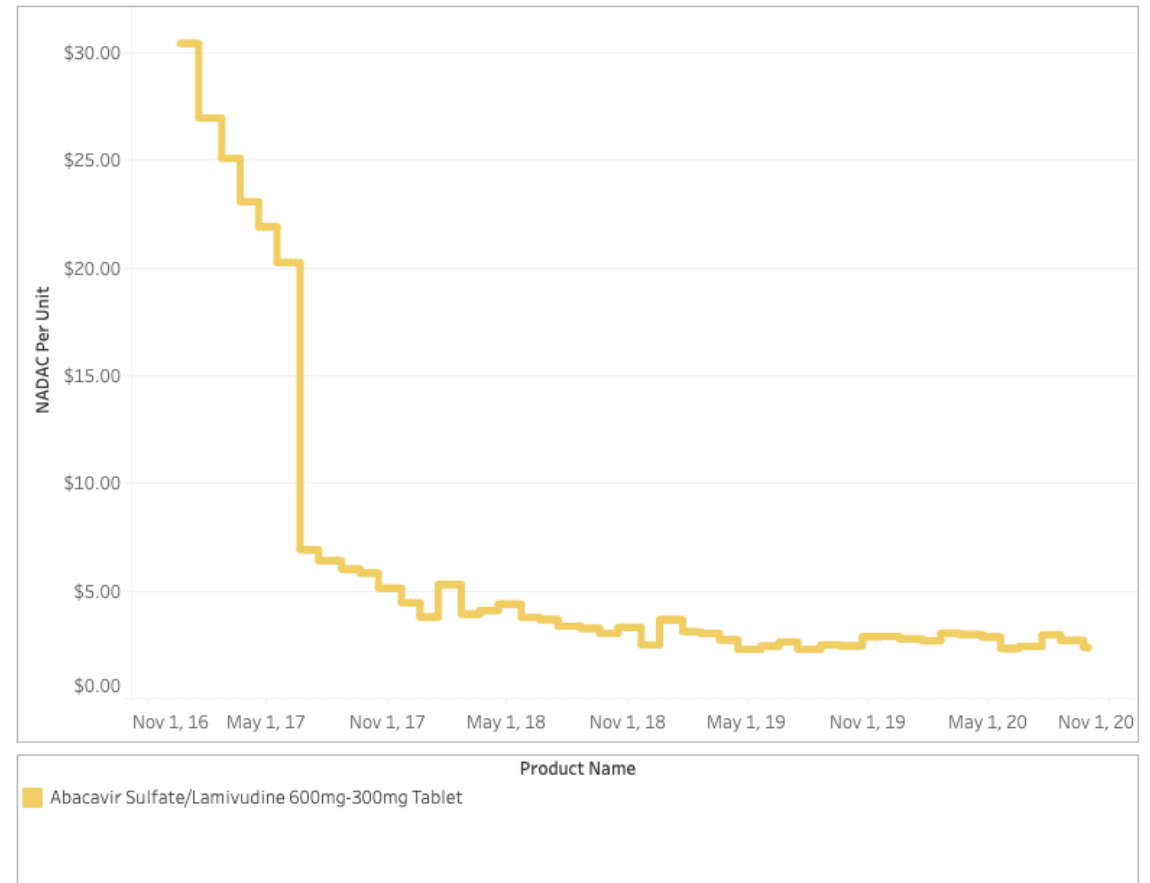
How much does generic TDF/FTC cost?

- As of October 14, 2020, the wholesale acquisition cost (WAC) price per pill of Teva's generic TDF/FTC is **\$48.51**, which is approximately **21 percent lower** than the brand-name version.
- NASTAD does not anticipate that Teva's TDF/FTC's list price will go down during its exclusivity period. The most significant price decreases typically come about once multiple generic manufacturers compete in the same market.

Does competition drive prices down?

Competition in the drug market helps manage costs to support sustainability, expansion, and affordability through our public and private payer systems. It will also ensure that public health programs, community programs, educational systems, prisons/jails, and people vulnerable to HIV who are underinsured or struggle with high cost-sharing have access to PrEP.

Competition and Drug Prices



Will copay assistance programs be available for generic PrEP?

- Teva has made available a copay savings card/coupon for TDF/FTC providing up to \$600 per month for six months.
- Gilead Sciences has not announced any changes to its Advancing Access Copay Relief for Truvada or Descovy program at this time.

Is PrEP becoming a preventive service in 2021?

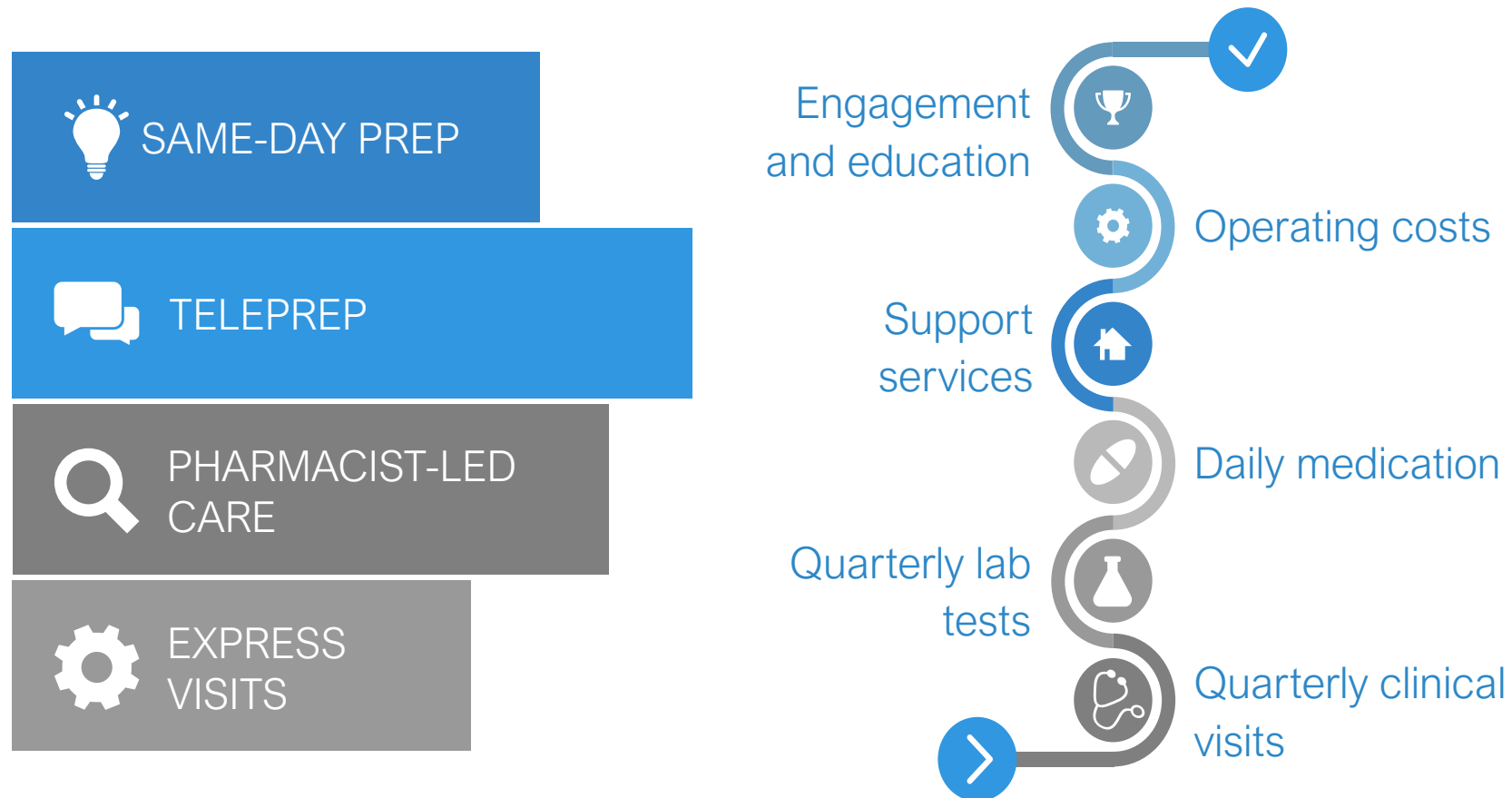
Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition	A

- Starting in January 2021 (and earlier for some employer and student health plans), most private insurance plans must provide \$0 cost-sharing for at least one PrEP product, so most patients should not need copay assistance programs.

Will the coverage of PrEP change because of these market dynamics?

- As generics enter the TDF/FTC market, commercial insurers will have an additional incentive to prefer generic TDF/FTC to contain their costs.
- Many will use prior authorization requirements (PA) to control the use of high-cost medications and services.
 - PAs are never recommended—burdensome on providers and patients
 - PA implementation approach is essential in minimizing barriers
 - Clinically sound
 - Adherent to federal guidelines
 - Does not restrict access to clinically indicated regimens
 - Is not discriminatory or stigmatizing

Innovative Delivery Models: TelePrEP



TelePrEP Learning Collaborative

Goal:

NASTAD will provide high-intensity technical assistance to participating jurisdictions with the goal of launching operational telePrEP programs by December 2021.

Format:

- Virtual learning community
- Focus on 6-8 EHE jurisdictions
- Ongoing TA sessions with faculty
- Peer learning discussions peers
- Cohort one: October 1, 2020 - March 31, 2021

Topics covered in the learning collaborative:

- TelePrEP delivery models
- Promotion and education
- At home testing and lab contracts
- Service quality improvement and program evaluation
- Telemedicine regulations
- TelePrEP for youth
- Use of the 340B program
- Cost analysis, budgeting and scalability
- Contract pharmacy relationships and inter-agency partnerships
- Financial forecasting and program sustainability
- Operations review

Part of CDC PS19-1906 Component A

NASTAD's Self-Testing Request for Information

The RFI

- NASTAD surveyed its members to learn more about how health departments are providing access to at-home HIV, HCV, STI, and PrEP self-testing services.
- Of the 38 respondents, 21 jurisdictions currently offer HIV self-testing services. Almost all offer rapid at-home testing kits.

Findings

- Almost three fourths of health departments plan to expand self-testing services by the end of the year, including jurisdictions already offering self-testing.

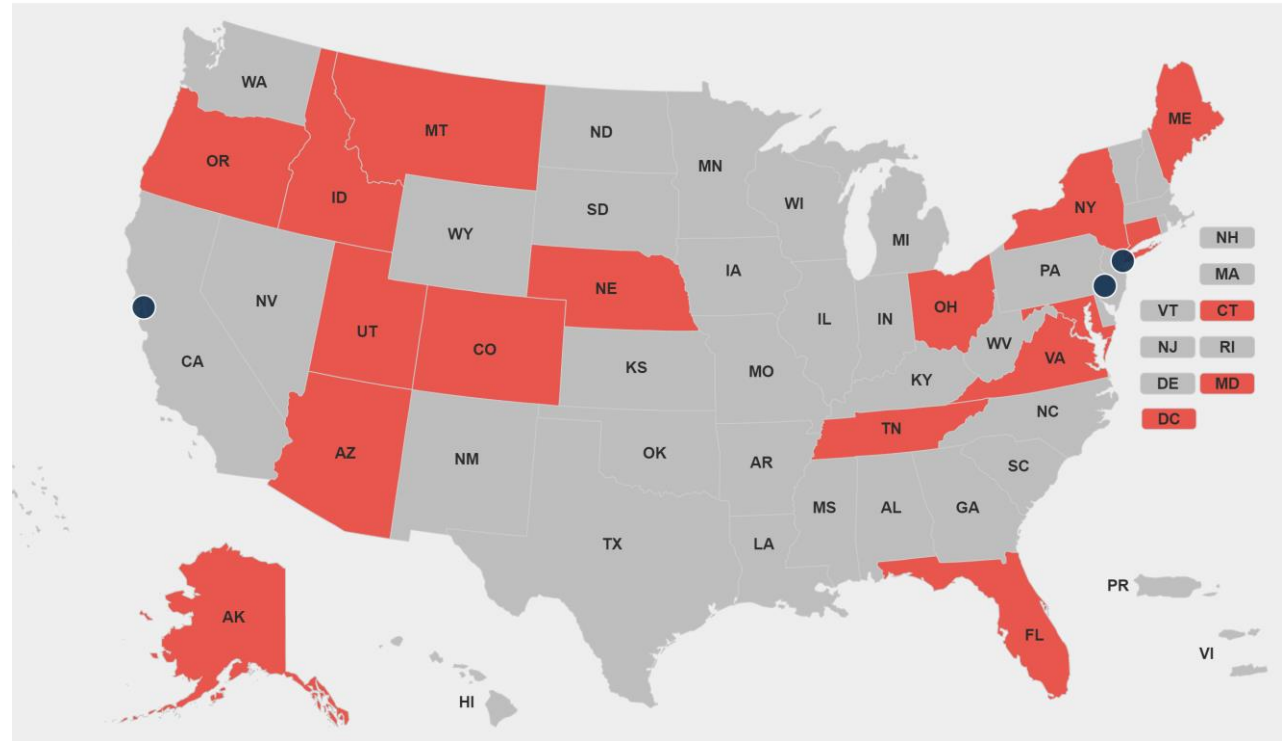
Top Five Potential Challenges

- Cost of the commercial self-testing services
- Integration of current care models and self-testing services
- Shipping costs and logistics
- Reporting and secured communication with providers and clients
- Laboratory validation of self-collection methods

NASTAD Self-Testing RFI Themes: <https://www.nastad.org/resource/self-testing-rfi-themes>

NASTAD's State-Specific Service Maps

- Current maps showcase details on self-testing services and state-specific telePrEP services that are available at no cost to the patient.
- NASTAD is working on a third map of PrEP Assistance Programs.

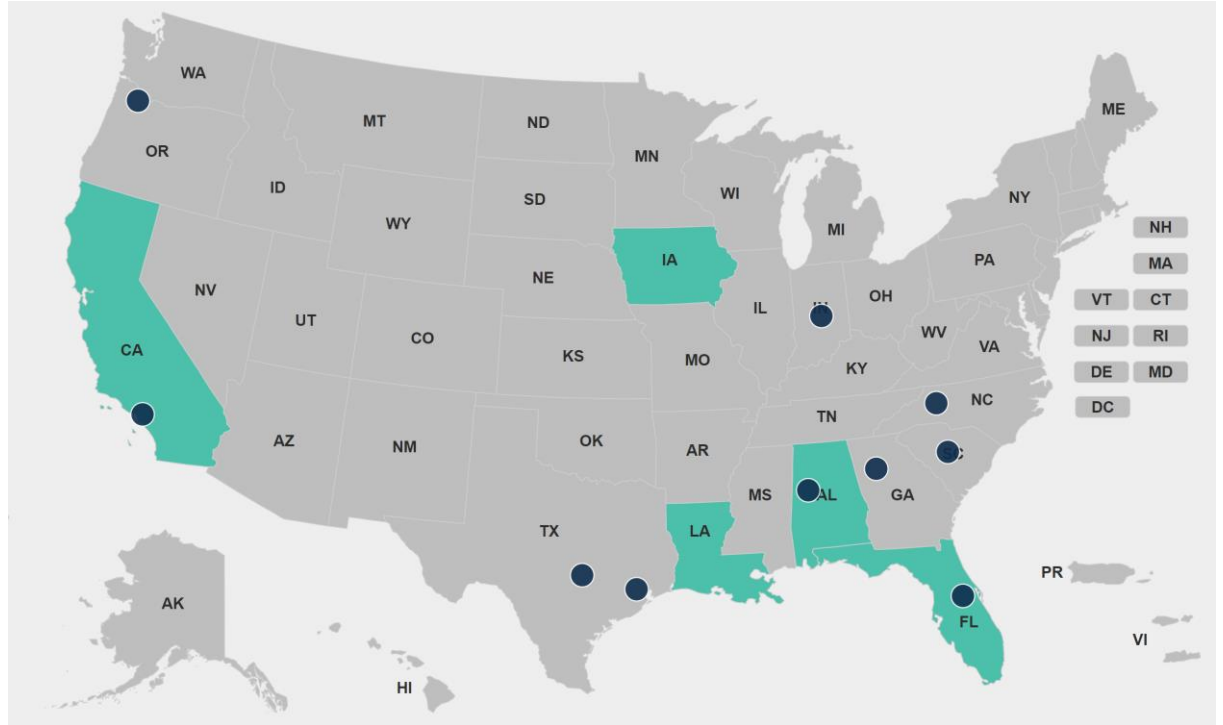


NASTAD's State-Specific-Self-Testing Map

NASTAD Self-Testing Services Map: <https://www.nastad.org/maps/state-specific-self-testing-services>

NASTAD's State-Specific Service Maps

- Information is gathered from various assessments disseminated through NASTAD's communication channels.
- Health department staff and providers are encouraged to submit updates about their programs.



NASTAD's State-Specific-TelePrEP Services Map

NASTAD TelePrEP Services Map: <https://www.nastad.org/maps/state-specific-tele-prep-services>

Contact Information

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