

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

December 9, 2020



NASTAD's PrEP Team



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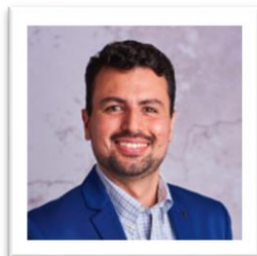
- USPSTF implementation
- Health plan coverage



Dori Molozanov

Manager, Health Systems Integration

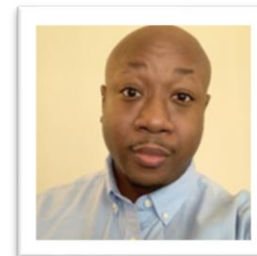
- Telehealth regulations
- Health plan coverage



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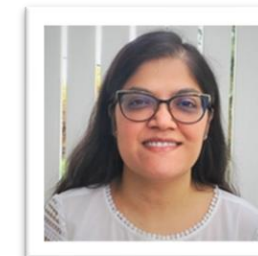
- EHE systems coordination



Kendrell Taylor

Manager, Prevention

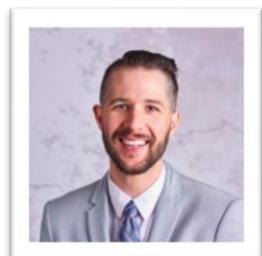
- PrEP implementation
- Take Me Home



Krupa Mehta

Manager, Prevention

- PrEP program implementation
- TelePrEP learning collaborative



Mike Weir

Senior Manager, Policy & Legislative Affairs

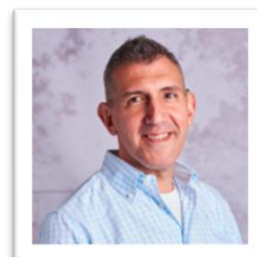
- Federal and state policy
- Regulatory framework



Nicole Elinoff

Manager, Prevention

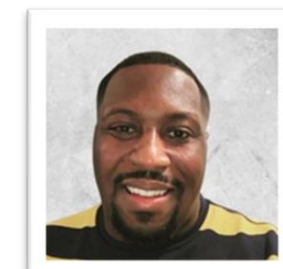
- PrEP implementation
- TelePrEP learning collaborative



Tim Horn

Director, Medication Access and Pricing

- 340B program income
- Generic drug market



Will Lee

Legal Fellow, Health Systems Integration

- PrEP policy research

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 currently approved 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?

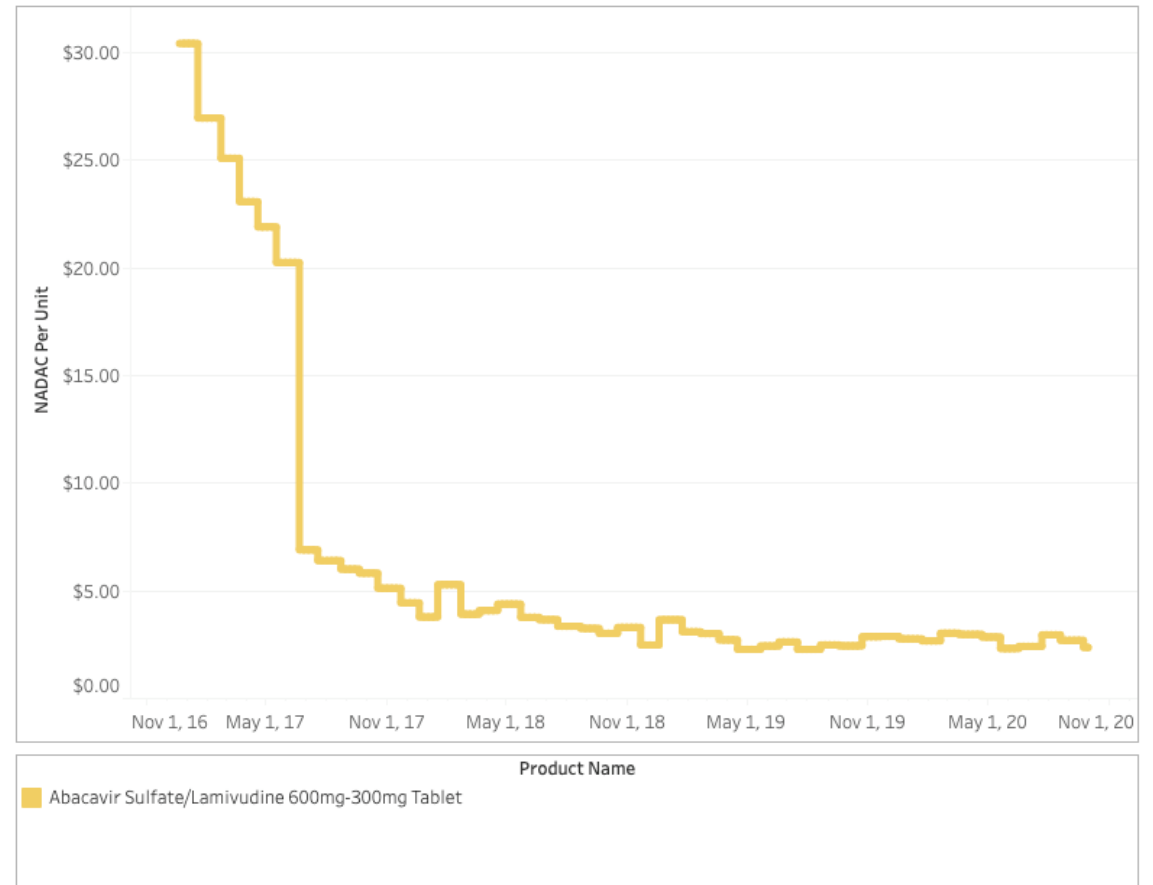
- As of October 14, 2020, the wholesale acquisition cost (WAC) price per pill of Teva's generic TDF/FTC is **\$48.51 per pill**, which is approximately **21 percent lower** than the brand-name version. This translates to a monthly cost of **\$1455.00 for generic TDF/FTC**.
- NASTAD does not anticipate 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.

<https://www.tevapharm.com/news-and-media/latest-news/teva-launches-first-generic-versions-of-hiv-1-treatments-truvada-emtricitabine-200-mgtenofovir-disopro/>

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 still be available?

- 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 PrEP coverage change?

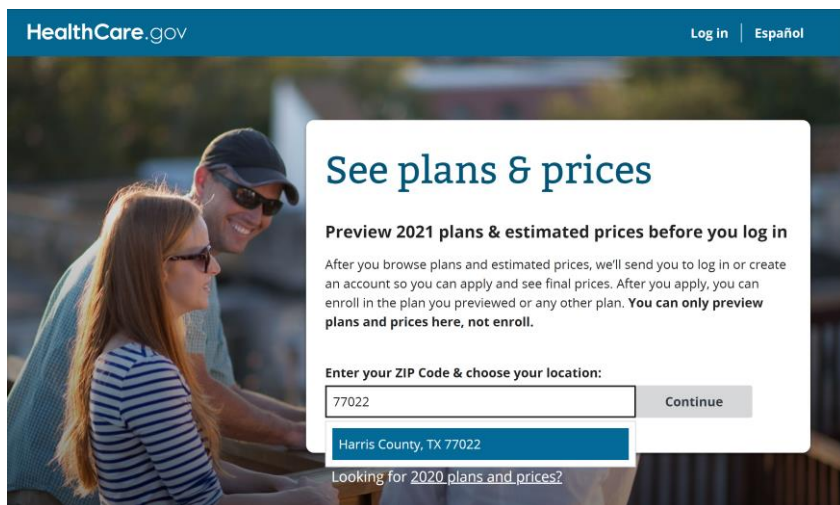
- As generics enter the TDF/FTC market, commercial insurers will have an additional incentive to use generic TDF/FTC to contain their costs.
- Many are expected to use prior authorization requirements (PA) to control the use of high-cost medications and services.
 - PAs are never recommended—burdensome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

How do you verify preventive service coverage?

1 Go to healthcare.gov/see-plans and enter your zip code

2 After finding a health plan, select “**list of covered drugs**” under “plan documents”

3 Search “**Truvada**” or “**emtricitabine-tenofovir disoproxil fumarate**” (or Descovy if indicated)



Plan documents

[PDF Summary of Benefits](#)

[PDF Plan brochure](#)

[PDF Provider directory](#)

[PDF List of covered drugs](#)



Drug Name Search

Enter a drug name to begin
emtricitabine-tenofovir disoproxil fumarate

How do you verify preventive service coverage?

4 The drug should be listed as “**Health Care Reform**” or “**ACA Preventive.**” There is no uniform format to list preventive drugs and the **preventive drug** tier number varies by insurance carrier.

Some plans mark the drug as ACA, without changing the drug tier used

TRUVADA TABLET 100-150 MG ORAL	2	
TRUVADA TABLET 133-200 MG ORAL	2	
TRUVADA TABLET 167-250 MG ORAL	2	
TRUVADA TABLET 200-300 MG ORAL	2	ACA NCDL, limitations may apply

- (\$0) [emtricitabine-tenofovir df oral tablet 200-300 mg](#)
- T2 [Truvada Oral Tablet 100-150 MG](#)
- T2 [Truvada Oral Tablet 133-200 MG](#)
- T2 [Truvada Oral Tablet 167-250 MG](#)
- (\$0) [Truvada Oral Tablet 200-300 MG](#)

TRUVADA 200-300 MG TAB
emtricitabine-tenofovir disoproxil fumarate

4

S
HCR Health Care Reform
PR Preventive Medication

ACA Preventive (ACA): Medicines marked in the ACA column are under the Affordable Care Act coverage of preventive services. These products have limited or \$0 member cost-sharing (copay or co-insurance), when meeting the conditions as outlined under the regulation. These are also indicated with an "A" in the drug tier column. To see what contraceptive products may be covered, visit www.bcbsil.com/PDF/rx/contraceptive-list-il.pdf

Drug Name	Drug Tier	Prior Authorization	Step Therapy	Dispensing Limits	ACA	Limited Distribution
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 100-150 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 133-200 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 167-250 mg	3			•		
TRUVADA - emtricitabine-tenofovir disoproxil fumarate tab 200-300 mg	3			•	•	

How do you verify preventive service coverage?

4 The drug should be listed as “**Health Care Reform**” or “**ACA Preventive.**” There is no uniform format to list preventive drugs and the **preventive drug** tier number varies by insurance carrier.

Some plans place preventive drugs as the lowest drug tier

- Tier 0 - No copayment for those drugs that are used for prevention and are mandated by the Affordable Care Act. Select oral contraceptives, vitamin D, folic acid for women of child bearing age, over-the-counter (OTC) aspirin, and smoking cessation products may be covered under this tier. Certain age or gender limits apply.
- - Tier 1: Preventative drugs with no member cost share under the Affordable Care Act
 - Tier 2: Generic Drugs
 - Tier 3: Preferred Brand Drugs
 - Tier 4: Non-Preferred Brand Drugs
 - Tier 5: Specialty Drugs

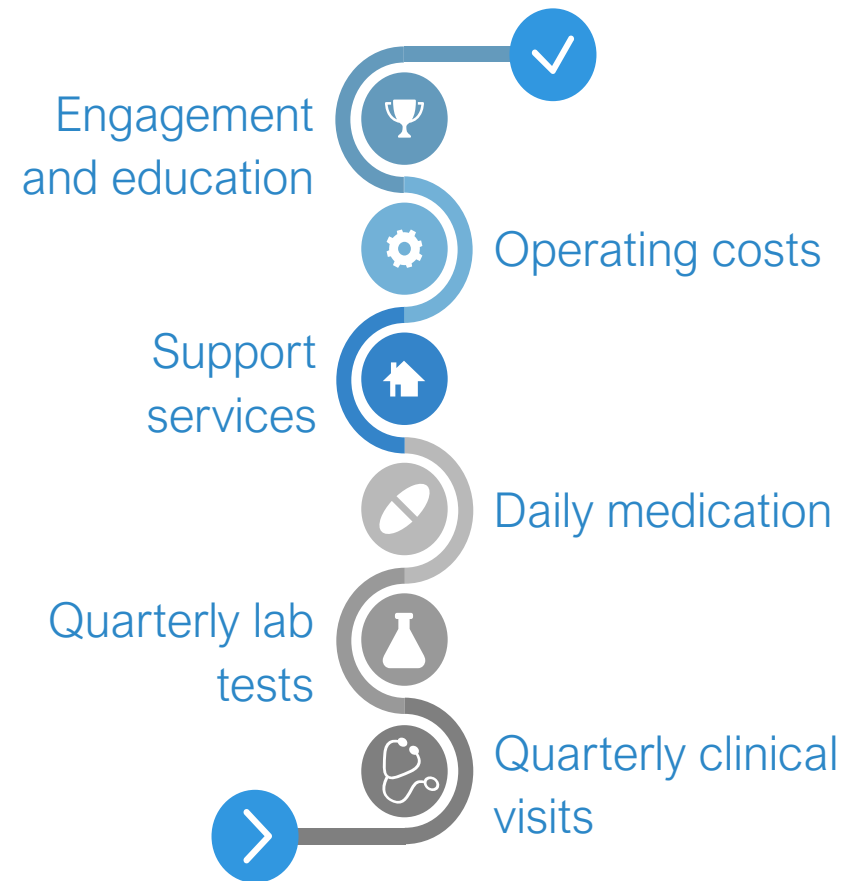
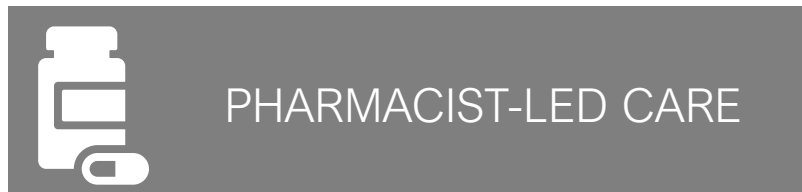
Others use the highest drug tier

- • **Tier 7 – (Zero Cost Share Preventive Drug)**-The Patient Protection and Affordable Care Act of 2010 allows members to receive some preventive, evidence-based items and services at no cost to the member with certain stipulations.

Plans may also list preventive services on a **separate list**

- | | |
|---|---|
| Human Immunodeficiency Virus (HIV) prevention | |
| Medication for preexposure prevention of HIV in those at an increased risk. | |
| Truvada 200 mg/300 mg tablet | \$0 copay if utilizing for HIV prevention |

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:

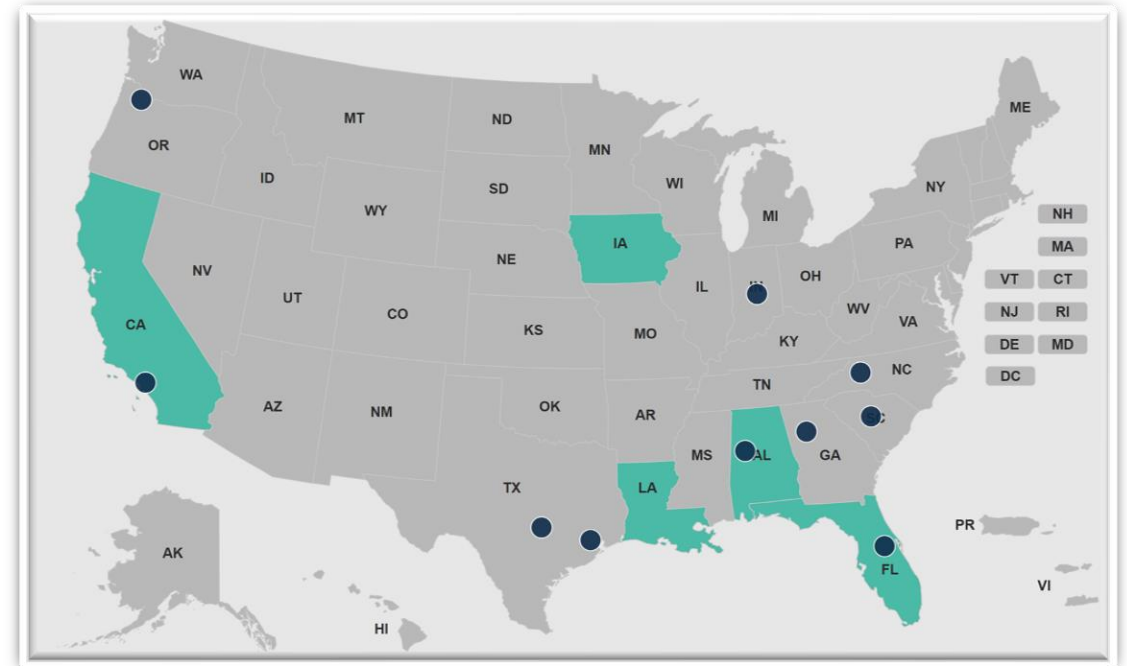
- TelePrEP delivery models
- Promotion and education
- At home testing and lab contracts
- Telemedicine regulations
- TelePrEP for youth
- Use of the 340B program
- Cost analysis, budgeting and scalability
- Contract pharmacy relationships and inter-agency partnerships
- Financial forecasting and program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

Part of CDC PS19-1906 Component A

TelePrEP Learning Collaborative

Applications for Cohort 2 open in
January 2021

Cohort 2: April 2021-October 2021

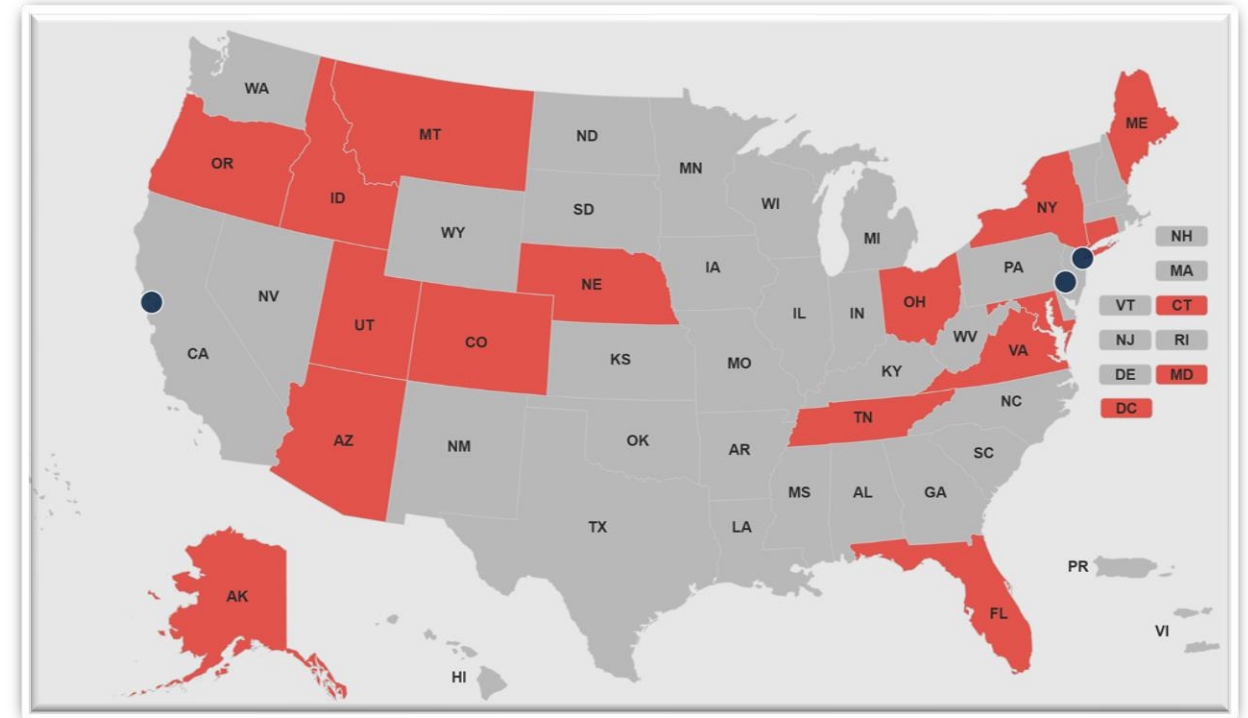


NASTAD's State-Specific-TelePrEP Services Map

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

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

CDC Self- Testing Services Resource: <https://www.cdc.gov/hiv/basics/hiv-testing/hiv-self-tests.html>

Reminder: Webinar Series

Self-Testing Strategies for HIV Testing and PrEP Access

Models

- Partnering with commercial vendors
- Maximizing current public health infrastructure

Format

- Feature models and innovations from health departments

For recordings of webinars, and to sign up for the series, visit NASTAD's End the HIV Epidemic website-
<https://www.nastad.org/ending-hiv-epidemics/resources>

Topics

- 1) Overview of self-testing initiatives and the Take Me Home program expansion
- 2) Integrating Self-Testing with Providers and Partners
- 3) Program Evaluation and Financing Strategies**
- 4) Innovative Strategies and Models**

Q&A

Contact Information

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