Minor Consent	Amendments to New York's health regulations allow minors to consent to their own HIV treatment and HIV preventive services such as pre-exposure prophylaxis (Prep) and post-exposure prophylaxis (Pep) without parental/guardian involvement (10 NYCRR Part 23).
Long- Acting Injectable PrEP	In December 2021, the FDA approved long-acting injectable cabotegravir (CAB LA; brand name Apretude) for PrEP. This document has been updated with current available information on CAB LA. Insurance coverage and payment options are still in development; for the latest updates on how to access CAB LA and other helpful topics, see the NASTAD resource <u>Long-Acting Injectable PrEP is Here: Frequently Asked Questions (FAQs) for Implementation</u> (May 2022).

Health Coverage and New York State Department of Health Sponsored Programs				
N.Y. Insurance Law §§ 3216(i)(17)(E), 3221(I)(8)(E) and (F), and 4303(j)(3)	Effective January 1, 2020, all issuers, except for grandfathered health plans*, must provide coverage for PrEP for the prevention of HIV infection at no cost sharing and cover screening for HIV infection at no cost-sharing. See the NYS Department of Financial Services Circular Letter (October 2020) for more information.			
Affordable Care Act Implementation Part 47	<ul> <li>In June 2019, and again in August 2023 to include Descovy and Apretude in addition to Truvada, the U.S. Preventive Services Task Force (USPSTF) gave PrEP an "A" grade recommendation. The Affordable Care Act (ACA) requires commercial health plans and Medicaid expansion programs to cover select preventive services-including any service with a Grade A from the USPSTF-without cost sharing, which means that these services must be covered before any deductible and without coinsurance or a copayment. In addition to medication, PrEP services to be covered without cost sharing include medication, visit, testing and adherence counseling.</li> <li>NASTAD PrEP coverage fact sheet (July 2021)</li> <li>Federal Guidance (July 2021)</li> </ul>			
Fee-for-Service Medicaid	Medicaid covers PrEP for adults and adolescents, including PrEP medical appointments, and lab tests. (NYRx covers medications)  Medicaid does not increase. Further time of Paraelite description (FORs). Addressed.			
Helpline: 1-800-541-2831	<ul> <li>Medicaid does not issue Explanation of Benefits document (EOBs). Adolescent confidentiality is protected.</li> </ul>			

<sup>\*</sup> Grandfathered Health Plan: An individual health insurance policy purchased on or before March 23, 2010. These plans were not sold through the Marketplace, but by insurance companies, agents, or brokers. They may not include some rights and protections provided under the Affordable Care Act. Plans may lose "grandfathered" status if they make certain significant changes that reduce benefits or increase costs to consumers. A health plan must disclose whether it considers itself a grandfathered plan. (Note: If you're in a group health plan, the date you joined may not reflect the date the plan was created. New employees and family members may be added to existing grandfathered group plans after March 23, 2010).

Medicaid Managed Care  Helpline: 1-800-541-2831	<ul> <li>Medicaid Managed Care Plans (MMCPs) cover PrEP for adults and adolescents, including PrEP medical appointments, and lab tests. (NYRx covers medications)</li> <li>MMCPs are required to send notice upon a service or claim denial, where: the denial was not based on medical necessity; the enrollee already received the service; and, the enrollee is not liable for the cost of the service, consistent with the Department of Health's Policy for the Protection of Confidential Health Information for Minors Enrolled in NYS Medicaid Managed Care Plans.</li> <li>An adolescent may work with their plan or provider to obtain consent to send notices to an alternate address.</li> </ul>
Medicaid Pharmacy Program, NYRx	<ul> <li>Effective April 1, 2023 all New York State Medicaid members have the NYS Medicaid Pharmacy Program (NYRx) as their pharmacy benefit.</li> <li>Truvada, Descovy or Apretude are on the NYRx formulary</li> <li>The initial prescription for a PrEP medication does not require prior authorization. For subsequent prescriptions the patient must have an HIV negative test documented in within the last 120 days. If testing can be confirmed, in the patients' medical history, claims should 'auto-bypass' (i.e., not require prior authorization). If testing cannot be identified in the patients' medical history prior authorization will be required to confirm the patient is HIV negative.</li> <li>To obtain prior authorization please call the NYRx Clinical Call Center at 877-309-9493 or fax the Standard Prior Authorization Form to 1-800-268-2990</li> </ul>
<u>Medicare</u>	<ul> <li>All Medicare prescription drug plans cover PrEP. However, plan premiums, copayments, and other out-of-pocket expenses may apply. Some medication assistance programs (listed below) may help reduce costs.</li> <li>Long-acting injectable PrEP/CAB LA is expected to be covered under Part B as a provider-administered drug. The beneficiary may be responsible for up to 20% of the medication cost after the deductible requirement has been met.</li> <li>Supplemental insurance coverage, Medicaid dual-eligibility, or enrollment in the Qualified Medicare Beneficiary (QMB) program may defray CAB LA cost-sharing requirements.</li> <li>Some Medicare Advantage plans that include prescription drug coverage (Part D) may opt to cover CAB LA as a pharmacy benefit.</li> </ul>
PrEP Assistance Program (PrEP-AP)  Hotline: 1-800-542-2437	<ul> <li>PrEP-AP serves adults and adolescents who are residents of New York State and are uninsured and prescribed PrEP.</li> <li>Financial eligibility is based on 500% of the Federal Poverty Level (FPL).</li> <li>Covers costs of clinical visits and lab testing for uninsured individuals. Services include HIV, STI/STD testing, counseling, and supportive primary care services consistent with clinical guidelines for PrEP.</li> <li>PrEP medication is not covered by PrEP-AP. Manufacturer's patient assistance programs (PAP) (listed below) should be contacted for uninsured individuals.</li> <li>Providers that are enrolled in the New York State Medicaid Program are eligible to enroll in PrEP-AP. To become a PrEP-AP provider contact the ADAP Provider Relations Unit at (518) 459-1641 or email damarys.feliciano@health.ny.gov for more information.</li> <li>Providers are responsible for assisting patients with the patient assistance program application to receive their PrEP medication.</li> </ul>

Medication Assistan	Medication Assistance Programs				
New York City	In New York City, there are other options available for low-cost access to PrEP. Visit the NYC Health Map. Select "Sexual Health Services" from the services menu. Then select "PrEP and PEP" and "Sliding Scale for Uninsured" under "Cost" to find locations offering this service.				
U.S. Department of Health and Human Services – "Ready, Set, PrEP"  855-447-8410 GetYourPrEP.com	<ul> <li>"Ready, Set, PrEP", is a national program that makes PrEP medications available at no cost to people without prescription drug insurance coverage. GetYourPrEP.com or 855-447-8410. (9:00am – 8:00pm EST Monday – Friday)</li> <li>To qualify, patients must: <ul> <li>lack prescription drug coverage,</li> <li>be tested for HIV with a negative result,</li> <li>have a prescription for PrEP, and</li> <li>live in the U.S. including tribal lands and territories.</li> </ul> </li> <li>There is no income eligibility requirement for this program. At time of publication, longacting injectable PrEP/CAB LA is not expected to be available through this initiative.</li> </ul>				
Gilead Co-Pay Coupon Program	<ul> <li>Covers up to \$7,200 per year in prescription co-payments for Truvada (emtricitabine and tenofovir disoproxil fumarate) and Descovy (emtricitabine &amp; tenofovir alafenamide).</li> </ul>				
1-877-505-6986 Gileadadvancingac cess.com/copay- coupon-card	<ul> <li>Patient must have commercial insurance.</li> <li>Patient must NOT be enrolled in Medicare or Medicaid.</li> <li>No income eligibility requirement.</li> <li>For individuals under the age of 18, a patient representative will need to attest/sign on the minor's behalf.</li> </ul>				
Gilead Advancing Access Patient Assistance Program  1-800-226-2056 Gileadadvancing access.com	<ul> <li>Covers prescription costs for Truvada and Descovy.</li> <li>Patient must be uninsured, or their insurance does not cover any prescription cost.</li> <li>Patient must have annual income less than 500% of the FPL based on household size.</li> <li>For individuals under the age of 18, a patient representative will need to attest/sign on the minor's behalf.</li> </ul>				
ViiVConnect  1-844-588-3288  Monday – Friday  8AM – 11PM (ET)	ViiVConnect can help match patients to a program that best meets their financial needs based on their circumstances, insurance situation and the eligibility criteria for the programs:  • The Apretude Savings Program helps eligible, enrolled patients with their out-of-pocket costs for long-acting injectable PrEP (CAB LA; brand name Apretude).  Patients may be eligible if:  • They have a commercial insurance plan that provides coverage for Apretude under either the medical or pharmacy benefit, and  • They are a resident of the US (including the District of Columbia and Puerto Rico).  Patients are not eligible if they are enrolled in Medicare, Medicaid (or Mi Salud, Puerto Rico's government-funded health plan), VA or TRICARE.  Verify patient eligibility and get immediate access to savings card numbers for eligible patients. Go to APRETUDECopayProgram.com to enroll a patient.				

	Enrollment is required to verify eligibility. Once approved, Apretude will be shipped to the provider from TheraCom.
	The ViiV Healthcare Patient Assistance Program (PAP) may be able to help cover the cost of Apretude for patients who do not have insurance and are having trouble paying for prescribed Apretude.
	Eligible patients must:
	<ul> <li>Live in one of the 50 states, the District of Columbia, or Puerto Rico</li> <li>Have a household income less than or equal to 500% of the Federal Poverty Level based on household size</li> <li>Not be eligible for Medicaid or Puerto Rico's Government Health Plan, Mi Salud</li> </ul>
	And either:
	<ul> <li>Have no prescription drug coverage, or</li> <li>Have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan, and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year, or</li> <li>Have a private insurance plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of drug.</li> </ul>
	Provides financial assistance to financially and medically qualified patients for co- payments, co-insurance, and deductibles.
Patient Advances	Offers grant of up to \$7,500 per year.
Patient Advocate Foundation Co-Pay Relief	<ul> <li>Patients, their medical providers, or their pharmacists may submit applications 24 hours a day online or via phone Monday - Friday 8:30am – 5:30pm EST.</li> </ul>
Program	Patient must be currently insured and have coverage for the medication.
	Patient must have annual income less than 400% FPL.
1-866-512-3861 <u>Copays.org</u>	Once on the website's homepage, click "HIV, AIDS and Prevention" under "Find Your Fund" to navigate to additional details and instructions for how to apply.
	<ul> <li>Individuals under the age of 18 years may participate with parental/guardian consent.</li> </ul>
	Medical insurance premium assistance is available.
Helpful Resources	
New York State Department of Health, Office of Health Insurance Programs	Consumer handout outlining Medicaid benefits for accessing PrEP services:     What You Should Know About: HIV, PrEP, and You
Partnership for Prescription Assistance Program	<ul> <li>Online resource that helps uninsured and underinsured patients find programs that provide prescription medicines at low or no cost.</li> <li>Complete a brief questionnaire with basic information including prescription</li> </ul>
1-888-477-2669  Medication Assistance Tool	medicines, age, income, and current prescription coverage (if any). PPA searches its database for prescription assistance programs that might be able to help and displays the results.

Gilead Advancing Access  1-800-226-2056  Gilead Advancing Access  National Alliance of State & Territorial AIDS Directors	<ul> <li>Helps guide patients through the process of understanding the type of insurance they have and alternative coverage if needed.</li> <li>Can help match patients to a program that best meets their financial needs based on their circumstances, insurance situation and the eligibility criteria for the programs.</li> <li>How to verify if PrEP is a covered Preventive Service</li> <li>Long-Acting Injectable PrEP is Here: Frequently Asked Questions (FAQs) for Implementation</li> </ul>			
(NASTAD)				
Insufficient PrEP Coverage by a Health Plan: Contacts and Protocols for Filing a Complaint				
Commercial Insurance & HMOs	<ul> <li>File a complaint with the NYS Department of Financial Services (DFS) when encountering problems with PrEP coverage by using the DFS Secure Portal Link: Consumer Complaint - DFS Portal (ny.gov) and following these steps:</li> <li>The link for consumer complaints is first. A link for healthcare providers to file a complaint is further down the page.</li> <li>Click "File a complaint" and acknowledge twice that the filer is NOT a healthcare provider.</li> <li>Move through the menus and fill in information as directed.</li> <li>Complete the complaint within the 30-minute time limit once the complaint is started.</li> <li>Note: DFS handles complaints for commercial insurance and HMOs ONLY. It does not address complaints for Medicaid, Medicare, self-funded plans, or the Essential Plan.</li> </ul>			
Medicaid (Managed Care & Fee-For-Service) Helpline: 1-800-541-2831 Monday – Friday: 8:00am - 8:00pm Saturday: 9:00am - 1:00pm	Enrollees and providers can file a complaint with certain government agencies. Depending on the type of health care plan involved and the kind of complaint, there are different agencies that can help. See the NYSDOH List of government agency complaint contacts.			
<b>Medicare</b> 1–866–334–9866	Use the Medicare Complaint Form or follow the instructions from individual plan membership materials to submit a complaint about your Medicare health or prescription drug plan. To file a complaint:  • You must file it within 60 days from the date of the event that led to the complaint.  • You can file it with the plan over the phone or in writing.  • You must be notified of the decision generally no later than 30 days after the plan gets the complaint.  • If it relates to a plan's refusal to make a fast coverage determination or redetermination and you haven't purchased or received the drug, the plan must give you a decision no later than 24 hours after it gets the complaint.  See Medicare.gov: How to file a complaint (grievance) for more information.			