New York State

Department of Health

AIDS INSTITUTE

Uninsured Care Programs

Pre- Exposure Prophylaxis Assistance Program

(PrEP-AP)

SPECIALTY PROVIDER MANUAL

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NEW YORK STATE DEPARTMENT OF HEALTH/AIDS INSTITUTE

UNINSURED CARE PROGRAMS

Provider Manual to support the use of HIV Pre-exposure Prophylaxis (PrEP) through participation in the Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)

BACKGROUND

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which people who do not have HIV take a daily pill to reduce their risk of becoming infected. Based on studies showing significant reduction in HIV acquisition among HIV-negative persons who use PrEP and receive a package of prevention, care and support services, the U.S. FDA approved combination anti-retroviral therapy (ART) for use as PrEP among sexually active adults at risk for HIV infection. A detailed description of the guidelines for the use of Pre-Exposure Prophylaxis (PrEP) to prevent HIV transmission can be found at: **http://www.hivguidelines.org**

POPULATION TO BE SERVED

PrEP-AP serves HIV-negative persons who are residents of New York State who are uninsured or underinsured.

CLIENT ELIGIBILITY

1) Residency - New York State
2) Medical - HIV-negative
3) Financial - Financial eligibility is based on 435% of the Federal Poverty Level (FPL). FPL varies based on household size and is updated annually. Households cannot have liquid assets greater than $25,000. Liquid assets are cash, savings, stocks, bonds, etc. Liquid assets do not include car, home or federally recognized retirement accounts

CLIENT ENROLLMENT PROCESS

Applicants apply to the Program, providing proof of residency and income. A Medical Application completed by a physician is required to verify that the applicant is HIV-negative. Once eligible, a PrEP-AP Identification Card is sent to the applicant which can be used to receive covered services from enrolled providers.

IDENTIFICATION OF PARTICIPANT ELIGIBILITY

An enrolled participant must present a PrEP-AP Identification Card whenever he/she requests medical services. In addition to the Identification Card, hospitals and participating clinics must verify participant eligibility via the Automated Eligibility Verification System at **1-800-832-5305** (available 24 hours a day) on the date the service is provided. (This phone number is listed on the participant's identification card.)

STANDARDS OF CARE

The New York State Department of Health's Office of the Medical Director directly oversees the

development, publication, dissemination, and implementation of clinical practice guidelines. A detailed description of the guidelines for a the use of Pre-Exposure Prophylaxis (PrEP) to prevent HIV transmission can be found at: **http://www.hivguidelines.org**

PROVIDER ELIGIBILITY AND REQUIREMENTS

Hospitals and Clinics that are enrolled in the New York State Medicaid Program are eligible to enroll in PrEP-AP.

In addition to meeting the requirements outlined in this manual, providers must meet the record-keeping requirements for their particular type of facility outlined in the regulations of the New York State Department of Health.

Please note that for PrEP-AP purposes, records must be maintained for six years from the date of payment.

REIMBURSABLE SERVICES UNDER PrEP-AP

The services reimbursable under PrEP-AP include the following medical services, provided on an out-patient ambulatory basis. PrEP medication will be provided to uninsured individuals through the manufacturer patient assistance program (PAP). Providers are responsible for assisting patients with the PAP application to receive Truvada as indicated for PrEP. PrEP-AP uses the established Medicaid rate schedules and coding for payment of covered service. No co-payment can be charged to participants. As a provider, you agree to provide your patients with the following services:

1. **Initial Pre-Prescription Education and Evaluation** – Must include the following elements; evaluation and education for the patient regarding the risks, benefits, and options of PrEP. This education includes:

   - How PrEP works as part of a comprehensive prevention plan;
   - The limitations of PrEP;
   - PrEP use, including dosing and adherence;
   - Information regarding prevention of the transmission of HCV infection;
   - Common side effects;
   - The long-term safety of PrEP;
   - Baseline tests and the schedule for monitoring;
   - The criteria for discontinuing PrEP;
   - The possible symptoms of seroconversion;
   - For women, the potential benefits/risks if pregnancy occurs during use of PrEP;

   - Perform laboratory tests (reporting of the test results to the patient):

     - Baseline HIV Test
       - Third-generation and fourth-generation HIV test
       - Nucleic acid amplification test (NAAT, viral load) for HIV for:
         - Patient with symptoms of acute infection
         - Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month

- Basic Metabolic Panel
- Urinalysis
- Serology for Viral Hepatitis A, B, C
- Screening for Sexually Transmitted Infections (NAAT for gonococcal and chlamydia infection-3 site screening (genital, rectal, pharyngeal)
- Pregnancy Test

2. Prescribing and Monitoring PrEP

- Lab report and Prescription visit:
  - Review lab results
  - A prescription for Truvada (TDF/FTC), one tablet daily to begin when patient has a confirmed negative HIV test result
- 30-day visit:
  - Assess side effects
  - Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
  - Discuss risk reduction and provide condoms
- 3-month visit:
  - HIV test
  - Ask about STI symptoms
  - Discuss risk reduction and provide condoms
  - Serum creatinine and calculated creatinine clearance
  - Pregnancy test
- 6-month visit:
  - HIV test
  - Obtain STI screening tests
  - Pregnancy test
  - Discuss risk reduction and provide condoms
- 9-month visit:
  - HIV test
  - Ask about STI symptoms
  - Discuss risk reduction and provide condoms
  - Serum creatinine and calculated creatinine clearance
  - Pregnancy test
- 12-month visit:
  - HIV test
  - Obtain STI screening tests
  - HCV serology for MSM, IDUs and those with multiple sexual partners
  - Pregnancy test
  - Urinalysis
  - Discuss risk reduction and provide condoms

3. Discontinuation of PrEP Regimen

PrEP should be discontinued and the participant terminated from PrEP-AP if the patient:

- Receives a positive HIV test result
- Develops renal disease
- Is non-adherent to medication or appointments after attempts to improve adherence

- Is using medication for purposes other than intended
- Reduced risk behaviors to the extent that PrEP is no longer needed
- Requests discontinuation with referral to risk reduction support services and documentation of referral
  Note: For women who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether there are ongoing risks for HIV during pregnancy.

UTILIZATION REVIEW, RECORD KEEPING, AUDIT AND CLAIM REVIEW

I. Record-Keeping Requirements

Federal Law and State Regulations require providers to maintain financial and health records necessary to fully disclose the extent of services, care, and supplies provided to participants. Providers must furnish information regarding any payment claimed to authorized officials upon request of the State Department of Health.

For medical facilities subject to inspection and licensing requirements provided in Article 28 of the Public Health Law, the State Hospital Code contains specific details concerning content and maintenance of medical records. Practitioners providing diagnostic and treatment services must keep medical records on each participant to whom care is rendered.

The minimum content of the participant record **MUST** include:

- Participant identification (name, sex, age, etc.);
- Conditions or reasons for which care is provided;
- Nature and full description of services provided;
- The dates of service provided and ordered.

The maintenance and furnishing of information relative to care included on a claim is a basic condition for participation. For audit purposes, records on participants must be maintained and be available to authorized officials for six years following the date of payment. Failure to conform with these requirements may affect payment and may jeopardize a Provider's eligibility participate in the Program.

II. Medical Review

The Department of Health's Utilization Review Agent will, based on the data supplied in the billing process or through chart review at the site, generate the following types of information:

- Statistical profiles, by individual Provider, of medical activity and frequency of service;
- Errors in billing or patterns of poor billing procedures;
- Indications of unacceptable practices, e.g., abusive or fraudulent activity;
- Generalized data on quality of care.

Information will be shared with the provider either directly through Program staff or in writing. Once aware of any errors in billing, the provider will be able to expedite payment by correcting his/her billing procedures.

III. Unacceptable Practice

An unacceptable practice is conduct by a person which conflicts with any of the policies, standards or procedures of the State of New York or Federal statute or regulation which relates to the quality of care, services and supplies or the fiscal integrity of the Program. Examples of

unacceptable practices include, but are not limited to the following:

- Knowingly making a claim for an improper amount or for unfurnished, inappropriate or unnecessary care, services or supplies;
- Practicing a profession fraudulently beyond its authorized scope, including the rendering of care, services or supplies while one's license to practice is suspended or revoked;
- Failing to maintain records necessary to fully disclose the extent of the care, services or supplies furnished;
- Submitting bills or accepting payment for care, services or supplies rendered by a person suspended or disqualified from participating;
- Soliciting, receiving, offering or agreeing to make any payment for the purpose of influencing a participant to either utilize or refrain from utilizing any particular source of care, services or supplies; and
- Knowingly demanding or collecting any compensation in addition to claims made under the Program.

IV. Audit and Claim Review

a) Providers shall be subject to audit by the Department of Health. With respect to such audits, the provider may be required:
   1. to reimburse the department for overpayments discovered by audits; and
   2. to pay restitution for any direct or indirect monetary damage to the Program resulting from their improperly or inappropriately furnishing covered services.

b) The Department of Health may conduct audits and claim reviews, and investigate potential fraud or abuse in a provider's conduct.

c) The Department of Health may pay or deny claims, or delay claims for audit review.

d) When audit findings indicate that a provider has provided covered services in a manner which may be inconsistent with regulations governing the Program, or with established standards for quality, or in an otherwise unauthorized manner, the Department of Health may summarily suspend a provider's participation in the Program and/or payment of all claims submitted and all future claims may be delayed or suspended. When claims are delayed or suspended, a notice of withholding payment or recoupment shall be sent to the provider by the Department. This notice shall inform the provider that within 30 days he/she may request in writing an administrative review of the audit determination before a designee of the Department of Health. The review must occur and a decision rendered within a reasonable time after a request for recoupment is warranted, or if no request for review is made by the provider within the 30 days provided, the department shall continue to recoup or withhold funds pursuant to the audit determination.

e) Where investigation indicates evidence of abuse by a provider, the provider may be fined, suspended, restricted or terminated from the Program.

V. Audits and Recovery of Overpayments

a) Recovery of overpayments shall be made only upon a determination by the Department of Health that such overpayments have been made, and recovery shall be made of all money paid to the provider to which it has no lawful right or entitlement.

b) Recovery of overpayments pursuant to this subject shall not preclude the Department of Health or any other authorized governmental body or agency from taking any other action with respect to the provider, including auditing or reviewing other payments, or claims for payment for the same or similar periods, imposing program sanctions, or

taking any other action authorized by law.

c) The Department of Health may utilize any lawful means to recover overpayments, including civil lawsuit, participation in a proceeding in bankruptcy, common law set-on, or such other actions or proceedings authorized or recognized by law.

d) All fiscal and statistical records and reports of providers and all covered services which are used for the purpose of establishing the provider's right to payment under the Program and any underlying books, records, and documentation which formed the basis for such fiscal and statistical records and reports shall be subject to audit. All underlying books, records and documentation, including all covered services provided, shall be kept and maintained by the provider for a period of not less than six years from the latest date of the following: the completion date of such reports, the date upon which the fiscal and statistical records were required to be filed, or the date the service was provided.

e) All claims made under the Program shall be subject to audit by the Department of Health, its agents or designees, for a period of six years from the latest of either the date of service or date of payment. This limitation shall not apply to situations in which fraud may be involved or where the provider or an agent thereof prevents or obstructs the performance of an audit pursuant to this part.

VI. Fraud

Examples of fraud include when a person knowingly:

- Makes a false statement or representation which enables any person to obtain medical services to which he/she is not entitled;
- Presents for payment any false claim for furnishing services or merchandise;
- Submits false information for the purpose of obtaining greater compensation than that to which he/she is legally entitled;
- Submits false information for the purpose of obtaining authorization for the provision of services or merchandise.

CIVIL RIGHTS

The Provider will not discriminate in its provision of services reimbursed under this Agreement based on any non-merit factor, including race, national origin, color, religion, sex, sexual orientation, gender identity, disability (physical or mental), age, status as a parent, or genetic information. The Provider has an affirmative duty to take prompt, effective, investigative and remedial action where it has actual or constructive notice of discrimination in the terms, conditions or privileges of provision of services to a member or potential member hereunder based on the factors listed above.

BILLING SECTION

PROGRAM IDENTIFICATION CARDS

Presentation of a Program Identification Card alone is not sufficient proof that a participant is eligible for services. You must verify the eligibility of each participant each time services are requested or you risk the possibility of nonpayment for services which you provide.

Other Health Care Coverage

If a PrEP-AP participant has other health care coverage, he/she is required to inform the Program of that coverage and assign all benefits associated with the use of that coverage to the Program. To mitigate participant out of pocket expenses the Program pays the fee for service Medicaid rate for covered services provided to eligible individuals. The program then bills the individuals other coverage. Acceptance of payment from PrEP-AP for covered services constitutes payment in full. Participants cannot be billed for services covered by the Program. **Do not bill third party payers or other insurance coverage for covered services.**

TIMELY CLAIM SUBMISSION

Claims must be submitted within 90 calendar days from the date of service. Claims denied for late claim submission by PrEP-AP cannot be billed to participants.

BILLING INSTRUCTIONS

The Program has an agreement with Emdeon to accept electronic claim submissions (837 Institutional or 837 Professional claims) on our behalf; if you are currently billing anyone via 837, you can submit claims to us. This is a Managed Gateway Agreement (MGA), allowing any clearing house to send claims to us at no cost to the billing provider; a copy of this MGA can be provided to your clearing house if needed.

You can start submitting claims electronically immediately using '**NYS DOH UCP**' as the Payer Name, and **14142** as the Payer ID. If your system requires a letter prefix, use the letter 'D' for government (Medicaid). Please note that we are **not** listed as "PrEP-AP", and will not receive claims sent to that Payer name.

You should note the following important information in order to successfully submit claims and receive prompt payment:

- Use the same specifications as Medicaid. Providers **must** have registered an NPI with us (the same one registered with Medicaid) in order to bill electronically. **Claims without an NPI match in our system will be rejected without adjudication.**
- Providers with multiple locations assigned to the same NPI **must** ensure that we have a valid ZIP+4 on file for each location in order to differentiate the service location. Again, **if we cannot match an NPI and ZIP+4 to a specific location, the claims will be rejected without adjudication**.
- Payment will continue to be issued to the location providing services, not the billing provider.
- We will provide both a 997 Functional Acknowledgement and a U277 Unsolicited Claim Status Report for each transaction received. The U277 will advise that we have either rejected the claim because we could not match the submitter to our provider database, or we have accepted and adjudicated the claim and it is pending our next payment cycle.

- Remittance information will continue to be provided on paper at this time. We will be providing 835 Electronic Remittance Advices (ERAs) in the near future. In order to receive ERAs when available, you must ensure your Federal Tax ID is on file with us. Please contact Ken White for more details.

Please contact Ken White at (518) 459-1641 or via email at krw03@health.state.ny.us if you have any questions regarding electronic claim submissions.

In certain circumstance paper claim forms will be accepted. Please contact the Claims Unit for more information:

UNINSURED CARE PROGRAMS
PrEP-AP
EMPIRE STATION
P.O. BOX 2052
ALBANY, NY 12220-0052

REMITTANCE STATEMENT

The Remittance Statement is the key control document which informs the provider of the status of submitted claims. Should further information be required on any detail on the Remittance Statement, Providers should contact the Program at **1-800-732-9503**.

PrEP-AP produces a Remittance Statement for each payment cycle which contains all claims that have entered the computerized processing system. The Remittance Statement indicates status of the claims (paid/denied), and accompanies checks when they are mailed to providers.

DENIED CLAIMS

A claim will be denied if the service rendered is not covered by PrEP-AP, if it is a duplicate of a prior claim or if data is invalid or logically inconsistent.

The provider should review his/her copy of the denied claim, which is indicated on the Remittance Statement and, where appropriate, completely resubmit the claim with justification of reasons for approval. Providers should not resubmit claims which have been denied due to practices which contradict either good medical practice or Program policy. The Program will accept an annotated photocopy or duplicate copy of an original claim for the purpose of resubmission along with an annotated copy of the remittance statement.

DENIAL REASONS/COMMENTS

Use the following explanations to assist you when posting from the PrEP-AP remittance statement. **All resubmissions must be made within 60 days of receipt of the original denial in order to guarantee payment.**

Code 1: Participant is not eligible on the date of service in question. Contact the participant regarding this matter, do not keep resubmitting. Providers should be checking eligibility prior to the service being performed by calling the automated system at **1-800-832-5305**.

Code 2: Your facility was not eligible with PrEP-AP for the date of service in question. Contact the program before resubmitting this claim.

Code 3: The PrEP-AP ID is missing/invalid.

Code 4: The diagnosis code is either invalid or was not submitted. Review the record and resubmit with a corrected diagnosis code.

Code 5: This claim has either been paid on a previous batch or there is more than one clinic visit submitted for the same date of service. Unless a letter of appeal is sent in with the claim, it will continue to be denied for duplicate claim.

Code 6: Participant is not eligible because he/she is Medicaid eligible on the date of service.

Code 7: The procedure code is not recognized by the Program. Claims must be submitted using your facility's established Medicaid fee for service rate schedules or a valid CPT code (for ancillary services).

Code 8: The Program has a **90** day filing deadline. In order to guarantee payment, claims must be received within **90** days of the date of service. If funding is available, payment will be issued for claims submitted after this 90 day period, but there is

no guarantee. Participants are not responsible for provider billing errors. If you receive a denial and can correct the claim, you must send in the claim explaining that it is a resubmission within **60** days of the original denial.

Code 9: The date of service was not submitted or it was not a valid date.

Code 10, 11: The Program reimburses using established Medicaid fee for service rate schedules. If you do not know how to bill for PrEP-AP services, please contact the Claims Unit at **1-800-832-5305**. Our staff can assist you in the billing process. You will need to have your Medicaid provider number. These denial codes are also used if a service is not covered by PrEP-AP. Call the Claims Unit with any questions about covered services.

Code 12: The type of visit you have submitted is subject to an annual threshold (per treatment year). Treatment year is defined as the 364 days prior to the date of service in question.

Code 13: N/A

Code 14: The date of service was prior to the start of PrEP-AP. Verify the date of service.

Code 15: N/A

Code 16: Participant was never approved for PrEP-AP.

Code 17: Not covered under PrEP-AP.

Code 18: Your facility's rates and your cost-based clinic rate include all associated labs and ancillary services. If your facility cannot perform the necessary lab services, a contract needs to be established with a laboratory and your facility will be responsible for reimbursement. If your facility's cost-based rate has been built without the inclusion of lab and ancillary services, please notify the Program immediately.

Code 19: The participant has other insurance and is not eligible on the date of service in question. Contact the participant for additional information.

Code 20: N/A.

Note: All reimbursement is paid at the current Medicaid fee for service rates. Your facility is responsible for providing the Program with any rate changes. The rates will be updated the day we receive the update. There are no retroactive payments or adjustments because of a rate change.