PrEP/PEP
Provider Starter Packet

Pre- & Post-Exposure Prophylaxis: Starter Packet for Providers

LOUISIANA DEPARTMENT OF HEALTH

Dear Prescriber,

Enclosed you will find information regarding the identification of patients at-risk of HIV and the prescription of Pre- and Post-Exposure Prophylaxis (PrEP and PEP). We have also included material on billing and payment methods for these regimens, as well where to seek additional training for physicians, nurses and front desk staff.

This packet includes:

- An easy-to-follow check list for the Prescription of PrEP
- A single-page prescription guide for PrEP
- A single-page prescription guide for PEP
- A risk assessment worksheet for HIV for the use of PrEP and PEP
- A guideline for recognizing symptoms of Acute HIV Infection
- Available Online and In Person Training Sessions for PEP and PrEP
- Payment Options for PrEP and PEP for
    - Medicaid patients,
    - Medicare, Part D patients,
    - Commercially Insured patients,
    - Uninsured patients (see: “Advancing Access: the Gilead Patient Assistance Program”)
- ICD-10 and CPT Codes for PrEP and PEP
- Guidelines for State-Mandated Reporting of STIs, including copies of relevant state forms:
    - Syphilis and HIV during Pregnancy (see “HIV/Syphilis During Pregnancy”),
    - HIV Reporting in non-pregnant patients (see “Confidential Reporting Worksheet”),
    - All other Reportable STIs (see “STD-43”)

Please also consider being part of our state provider directory. Register online at:
https://goo.gl/forms/eXle5vm12Z1BVkps2

Please do not hesitate to contact us with the information if you need further assistance.

Louisiana Dept. of Health, Office of Public Health
STD/HIV Program
1450 Poydras Ave., Suite 2136
New Orleans, LA 70112

Pre-Exposure Prophylaxis Check List

LOUISIANA DEPARTMENT OF HEALTH

Initial Visit

Before Starting

☐ **The patient is at risk of contracting HIV** (see "Risk Assessment" sheet)

☐ **The patient is capable of adhering to a once-daily pill** and returning to the office for refills and lab work every three months

☐ **The patient has no symptoms of acute HIV infection** or recent (<1 mo) exposures to HIV (*see "Acute Retroviral Syndrome Symptom List*)

- ☐ IF YES: **Perform both an HIV test and an HIV qualitative RNA/NAAT**

☐ **The patient does not have known renal impairment** (eGFR of < 60 mL/min, Cockcraft-Gault)

☐ **The patient was counseled that PrEP does not protect against other sexually transmitted infections**; thus, risk-reduction strategies, such as avoiding intercourse with partners of unknown STI status and the usage of condoms remains necessary.

☐ **Discuss paying for PrEP** (see "Payment Assistance") and consider completing Advancing Access or Co-Pay Assistance Coupon forms. If the patient will have difficulty paying for labs or office visits, consider referring patient to a community health center or federally qualified health center (FQHC) with an established PrEP program.

Lab Tests

☐ **HIV: 4th generation dual antibody/antigen test** is preferred. A 3rd generation test or *finger-stick* Point of Care test is acceptable, but oral swab rapid tests are not approved for HIV testing in the context of PrEP. Consider adding a qualitative HIV NAAT to the HIV test if suspected acute infection.

☐ **3-site STI screening:**

- ☐ **Oropharyngeal and urine Gc/Ct NAAT** for all patients
- ☐ **Self-administered rectal swab Gc/Ct NAAT** for patients who participate in receptive anal sex
- ☐ **Syphilis screening**

- [ ] **Hepatitis B surface antigen** (HBsAg); consider a full hepatitis panel; vaccination recommended for those non-immune to hepatitis B or hepatitis A, especially MSM.

- [ ] **Serum Creatine or Basic Metabolic Panel (preferred)** for all patients; consider a *comprehensive metabolic panel* for patients taking hepatically metabolized medications, who have a history of alcoholism, or who have other conditions concerning for underlying liver disease.

- [ ] **Baseline urinalysis** for all patients to screen for proteinuria

- [ ] **Pregnancy test** for women of child-bearing potential. Truvada is a Pregnancy B medication; it is often used in HIV+ pregnant women. There is limited data on the safety of Truvada during breastfeeding. Discuss the risks and benefits of Truvada with the patient if she is pregnant.

Counseling Patients on Truvada for the first time

- [ ] **Emphasize adherence to Truvada**,

- [ ] **Discuss risk reduction strategies** independent of Truvada

- [ ] **Emphasize condoms** are needed to prevent other STIs

- [ ] **Discuss start-up syndrome** (gastric pain, nausea, gas) that usually subsides in 1 or 2 mo.

Prescribing Truvada as PrEP for the first time

- [ ] **Prescribe Truvada, once daily PO, disp #30 tablets, without refills.** It is preferable to wait for lab results; however, do not delay PrEP if the patient may be exposed to HIV subsequently. You may call the prescription into the patient's pharmacy after his or her labs return.

  Truvada likely requires up to 3 weeks to be fully effective in vaginal mucosa, and at least a week to be effective in rectal mucosa; there is limited data on urethral tissue. Patients should be counseled that it will likely take about 3 weeks for the medication to be fully protective.

- [ ] **Schedule patient's first follow-up visit in 30 days** to discuss access, adherence, and side-effects

Follow-Up Visits (At 30 days, then every 90 days)

Before Re-Prescribing (note: these steps may be performed by any trained healthcare worker)

- ☐ **Determine continued risk for HIV infection**
- ☐ **Assess adherence** and ask if the patient had difficulty filling his or her prescription
- ☐ **Discuss sexual activities** and how the patient has reduced his or her risk
- ☐ **Discuss side-effects** ask if the patient had difficulty filling his or her prescription

Lab Tests

- ☐ **Every 3 months: 4th generation dual antibody/antigen HIV test** (preferred) or 3rd generation test; *finger-stick* Point of Care test acceptable, but oral swap rapid tests are not approved for HIV testing in the context of PrEP. Consider a qualitative HIV NAAT if suspected acute infection.
- ☐ **Every 3 months: 3-site STI screening:**
  - ☐ **Oropharyngeal and urine Gc/Ct NAAT** for all patients
  - ☐ **Self-administered rectal swab Gc/Ct NAAT** for patients who participate in receptive anal sex
  - ☐ **Syphilis screening**
- ☐ **Every 3 months: Pregnancy test** for women of child-bearing potential. Discuss the risks and benefits of Truvada, a category B drug, with the patient if she is pregnant.
- ☐ **First 6 mo and then annually: SCr or Basic or Comprehensive Metabolic Panel**. Consider more frequent monitoring if clinical concern warrants testing.
- ☐ **Annually: urinalysis** for proteinuria for all patients
- ☐ **Annually:** Hepatitis C screening if indicated

Prescribing PrEP for further Follow-up Visits

- ☐ Prescribe **Truvada, once daily PO, disp #30 tablets, with 2 to 3 refills (max). Follow-up in no more than 3 months. Some patients may require more frequent monitoring.**

Pre-Exposure Prophylaxis (PrEP): Risk Assessment Form

LOUISIANA DEPARTMENT OF HEALTH

Gay, Bisexual, and other Men who have Sex with Men (MSM), and Transgendered Persons

In the past 6 months, has the patient had receptive or insertive anal intercourse?

1.) Did the patient report inconsistent condom use outside of a monogamous relationship with a partner of documented HIV status?
2.) Has the patient had a high number of sex partners?
3.) Has the patient exchanged sex for money or drugs?
4.) Does the patient have a history of substance abuse, including alcohol or amphetamine abuse, that could lead to unprotected sex with partners of unknown status?
5.) Has the patient had a recent (6 mo) history of a bacterial STI?

IF YES TO ANY ITEMS, *PATIENT IS A PrEP CANDIDATE*

Females and Heterosexual Males

Risk Factors Predictive of HIV in Heterosexuals (1 of each)

1.) **High Prevalence Networks:** Does the patient live or socialize in a high-prevalence group:
    a. Does the patient live in a zip code with high HIV prevalence (see AIDSVu.org)?
    b. Does the patient belong to or socialize within high-prevalence communities, examples of which include, but are not limited to:
        i. The homeless community;
        ii. Incarcerated or recently incarcerated persons;
        iii. Sex workers;
    c. Has the patient had past partners with a history of HIV or who were at substantial risk of HIV (MSM, incarceration, or intravenous drug use)?
2.) **Behavioral Risk Factors:** In the past 6 months, has the patient:
    a. Participated in unprotected sex with one or more partners of unknown status?
    b. Been diagnosed with an STI in the past 6 months?

IF YES TO ANY OF ITEM (1) AND ANY OF ITEM (2), *PATIENT IS A PrEP CANDIDATE*

Independent Predictors of HIV infection in Heterosexuals (any)

1.) Has the patient contracted syphilis in the past 12 months?
2.) Has the patient contracted a rectal STI in the past 6 months?
3.) Does the patient exchange sex for money or drugs?
4.) Is the patient's partner at risk of contracting HIV?

IF YES TO ANY ITEM *THE PATIENT IS A PrEP CANDIDATE*

Special Populations

HIV+/HIV- couples:

1.) Does the patient have sexual contact with HIV+ persons, male or female?
2.) Does the patient use condoms inconsistently or not at all?
3.) Does the patient's partner have an unreliable or non-suppressed/detectable HIV viral load?

IF YES TO ALL QUESTIONS, *THE PATIENT IS A PrEP CANDIDATE*
(IF YES TO ALL ITEMS, EXCEPT (3), *CONSIDER RISK V. BENEFITS OF* PrEP)

IV Drug Use: If the patient injects IV drugs with shared equipment, *THE PATIENT IS A PrEP CANDIDATE*

Pre-Exposure Prophylaxis QuickStart Guide

LOUISIANA DEPARTMENT OF HEALTH

1 Establish Risk:
See "Risk Assessment" sheet for details

Gay, Bisexual, and other men who have sex with men (MSM) and transgendered persons:

- Sex without condoms in the past 6 mo with one or more partners of unknown status
- STI within the past 6 months

Heterosexual Men and Women:

- Residence in a high prevalence zip code or social group AND either or both:
  - Inconsistent condom usage with multiple partners
  - STI in the past 6 mo
- OR diagnosis of a rectal STI within 12 mo.
- OR diagnosis of syphilis in the past 12 mo.

Consider PrEP for all patients who

- Inject IV drugs with shared needles
- Have an HIV+ partner with detectable viral load, or further protection is desired.

2 Establish Candidacy

A. Is this patient willing to take a tablet a day with office visits every three months?
IF NO: Do not prescribe PrEP

B. Does the patient have significant co-morbidities (osteoporosis, Stage 3 or greater chronic kidney disease, or hepatitis B)
IF YES: consult a specialist first.

C. Is there reasonable suspicion that the patient may be acutely infected with HIV?
IF YES: Add a viral load to the HIV test before starting PrEP or delay PrEP

3 Baseline Tests and Counseling

Labs:

1. **Lab-based or finger-stick rapid HIV test: do not prescribe PrEP if HIV+**
2. CrCl or BMP (CMP if medical concerns)
3. Urinalysis for proteinuria desirable
4. Pregnancy Test for women
5. Hepatitis panel (HBsAg at minimum; vaccinate for HAV and HBV if needed)
6. Syphilis + Urine Gc/Ct at minimum
7. Syphilis + 3-site Gc/Ct (urine, oral, and self-performed rectal if history of anal sex) NAAT recommended

Counsel patients:

1. That condoms should still be used
2. That PrEP cannot prevent other STIs
3. That adherence to PrEP is vital for optimal HIV protection
4. Start Up Syndrome (see "Side Effects")

4 Initial PrEP Prescription

Prescribe a 30 day supply of Truvada (1 tab PO daily)
Schedule a follow-up visit in 30 days
Discuss Insurance:

- Fill out Advancing Access/ co-pay assistance card if patient qualifies
- If patient cannot afford labs or office visits, refer to community health center (contact OPH representative if referral center needed)

5 Follow-Up Prescription

Labs:

- Repeat CrCl at 6 mo then yearly
- Yearly Urinalysis and Hep C as needed
- Repeat **HIV,** syphilis, 3-site STI test **q 3 mo**.
- For women, pregnancy test q 3 mo.

Counsel Patients:

- Discuss ways to reduce risk during sex
- Stress Adherence and Condom use

Prescribe Truvada for no more than 90 days
Schedule Follow-up visits every 90 days

Side Effects: Abdominal pain, bloating, nausea, and headaches which usually go away in a month

Contraindications: HIV infection, kidney disease (eGFR <60), HIV exposure <72 hrs (see "PEP")

Caution: osteoporosis, liver disease, mild renal impairment, hepatitis B infection (which may be exacerbated by abrupt withdrawal of Truvada)

Special considerations: Pregnancy (category B), Adolescents (Truvada is approved for ages >12)

NOTE: Descovy (TAF/FTC) and other ARVs should not be used for PrEP until further study is complete.

CALL 855-HIV-PREP FOR HELP

Monday - Friday
10am – 5 pm (CST)

CLINICIAN CONSULTATION CENTER

Post-Exposure Prophylaxis (PEP): Risk Assessment Form

LOUISIANA DEPARTMENT OF HEALTH

Occupational Post-Exposure Prophylaxis (oPEP)

1.) Was the patient injured with a needle, blade/scalpel, bone fragment, contaminated with blood, semen, or vaginal fluid, or other infectious fluid?
2.) Was the patient bitten by another patient, resulting in broken skin and bleeding?
3.) Was the exposure less than 36 hours from assessment?

IF YES TO ALL OF THESE QUESTIONS:
INITIATE PEP AS SOON AS POSSIBLE
IF EXPOSURE OCCURRED BETWEEN 36 to 72 HOURS:
CONSIDER RISKS v. BENEFITS TO PEP

Non-Occupational Post-Exposure Prophylaxis (nPEP)

1.) Did the patient have anal or vaginal sex without protection in the past 36 hours?
2.) Was the partner of unknown HIV status?
3.) Is the patient concerned about HIV and willing to take 28 days of medication to reduce that risk?

IF YES TO ALL OF THESE QUESTIONS:
INITIATE PEP AS SOON AS POSSIBLE
IF EXPOSURE OCCURRED BETWEEN 36 to 72 HOURS:
CONSIDER RISKS v. BENEFITS TO PEP
IF EXPOSURE OCCURRED AFTER 72 HOURS:
CONSIDER PrEP (see "PrEP Quick Start" sheet)

Non-Occupational PEP for Sexual Assault

1.) Is there reason to believe that the assault resulted in exposure to seminal or vaginal fluids in a mucous membrane or broken skin?
2.) Is significant anogenital trauma present?
3.) Is the patient concerned or worried about contracting HIV?

IF YES TO ANY OF THESE QUESTIONS AND EXPOSURE OCCURRED IN <36 HRS:
INITIATE PEP AS SOON AS POSSIBLE
IF EXPOSURE WAS BETWEEN 36 and 72 HRS:
CONSIDER RISK v BENEFITS OF PEP

Post-Exposure Prophylaxis (PEP) QuickStart Guide

LOUISIANA DEPARTMENT OF HEALTH

1 Establish the Need for PEP

Occupational Exposure: oPEP

- Needle stick injury
- Human bite resulting in blood
- Other exposure resulting in blood-to-blood, semen, or vaginal fluid contact

Non-occupational Exposure (nPEP):

- Unprotected sexual intercourse (vaginal or anal)
- Use of shared needles or needle stick injury
- Human bites resulting in blood

Sexual Assault (nPEP):

- Potential exposure to blood or semen from the assailant in open wound or through intercourse

2 Establish Candidacy

Occupational Exposure: oPEP

- Recommended within 2 hours
- **ASAP and < 36 hours is ideal**
- **36 – 72 hours: case-by-case**
- **>72 hours: Not Recommended**

Non-occupational Exposure (nPEP):

- Discuss risk of HIV with patient
- **ASAP and < 36 hours is ideal**
- **36 – 72 hours: case-by-case**
- **>72 hours: Consider PrEP**

Sexual Assault (nPEP):

- **Time limits as above**
- Offer to all patients
- Offer Emergency Contraception

3 Baseline Tests

Labs:

1. Baseline HIV test (for all)
2. Baseline CMP (Truvada + Isentress or Tivicay)

oPEP: no further tests needed

nPEP (other than potential assault):

3. STI panel: RPR + 3-site (urine, oral, and if applicable, self-swabbed rectal) Gc/Ct
4. Urine pregnancy test
5. Emergency contraception if needed

nPEP (if potential sexual assault):

2. **Empiric** treatment of gonorrhea and chlamydia (**baseline STI testing is not recommended)**
3. Urine pregnancy test
4. Emergency contraception

4 Prescribing PEP

Prescribe

Prescribe 30‡ days of

PO Daily Truvada*
(Tenofovir 300 mg/Emtricitabine 200 mg)

AND

Option 1 (preferred): Integrase Inhibitor

PO BID Raltegravir 400 mg (Isentress)

OR

PO Daily Dolutegravir 50 mg (Tivicay)

Call Pharmacy to ensure Medications Stocked

Additional Options:
http://www.hivguidelines.org/pep-for-hiv-prevention

5 Follow-Up

3 days:

- Check Side-effects, adherence, and toxicity

Weekly:

- Monitor patients for adherence and emotional well-being

28 days (nPEP):

- **After completed, for sexual exposure other than assault, strongly consider PrEP (Truvada only)**

4 weeks and 12 wks:

- Retest for HIV

Side Effects: Abdominal pain, bloating, nausea, diarrhea; medication-dependent.

Contraindications: HIV exposure >72 hrs (see "PrEP");

Drug-Specific Toxicities: Pregnancy, Renal (ClCr <60 mL/min) and Hepatic impairment require special considerations and monitoring
http://www.hivguidelines.org/

*Lamivudine 150 mg PO bid may be substituted for Emtricitabine

‡Guidelines are for 28 days; however, pharmacies may have difficulty filling prescriptions for fewer than 30 pills.

CALL 888-448-4911 FOR HELP

CLINICIAN CONSULTATION CENTER

Seven days a week
8am – 11 pm (CST)

Acute Retroviral Syndrome (ARS)

LOUISIANA DEPARTMENT OF HEALTH

Clinical Signs and Symptoms of Acute (Primary) HIV Infection

		Gender		Transmission	
	%Overall (n=375)	%Male (n=355)	%Female (n=23)	%Sex (n=324)	%IV Drug Use (n=34)
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin Rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical Lymphadenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night Sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

Reproduced from the CDC Guidelines for Pre-Exposure Prophylaxis (2014).
https://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. Curr Opin HIV AIDS. 2008;3(1):10-15.

Paying for Pre- and Post-Exposure Prophylaxis: Assistance Programs

LOUISIANA DEPARTMENT OF HEALTH

Commercial Insurance (Copay Assistance)	• Private insurance usually covers PrEP.
	• Deductibles and co-pays for medication may still require significant out-of-pocket cost (see "Advancing Access" below).
	• If out of pocket costs are prohibitive for lab tests, office visits, and other associated costs may be mitigated by referring patients to a community health center or Federally Qualified Health Center that can reduce or eliminate these out-of-pocket costs.
	
	• Co-pay cards are available from the manufacturers:
	  ○ Gilead (Truvada): 1-877-505-6986 or www.gileadadvancingaccess.com
	  ○ Merck (Isentress): 1-800-850-3430 or www.isentress.com
	  ○ ViiV Healthcare (Tivicay): 1-866-747-1170 or www.mysupportcard.com

Medicaid and Medicare, Part D	• Medicaid: Office visits, lab tests, and prescription costs are covered. • Medicare Part D: Truvada and PEP are covered; however, co-pays may remain. Please see PAN below.

Un- or Underinsured Patient Assistance	• PrEP:
	  ○ Patients who cannot afford quarterly labs or office visits may seek assistance at a community health center or Federally Qualified Healthcare Center that provides PrEP services. Please see link at the bottom of the page.
	  ○ Uninsured Patients may apply for the Gilead Advancing Access program (below)
	• PEP:
	  ○ Patients/Providers may complete the Common PAP Application (HIV): http://hab.hrsa.gov/files/programassistform.pdf
	  ○ For Truvada, contact Advancing Access as above;
	  ○ For Isentress, contact Merk as above;
	  ○ For Tivicay, contact Merk as above;
	  ○ For all other medications, contact the manufacturer

Gilead Advancing Access Program: Co-Pay Assistance for Commercially Insured Patients	• **Co-pay Coupon Program**: patients **with commercial insurance,** including Affordable Care Act Marketplace Plans, may sign-up online for a medication co-pay waiver of up to $3,600 per year; there are no income restrictions, but patients with government health care insurance (e.g., TriCare, Medicaid, Medicare Part D) do not qualify. Other options for these patients are available.
	  ○ Apply at: www.gileadadvancingaccess.com
	  Or Call: 1-800-266-2056

Gilead Advancing Access Program for Uninsured Patients	• **Gilead Advancing Access Program**: medications are provided at up to no expense to individuals who meet the following criteria:
	  ○ No coverage for Truvada OR no insurance at all (commercial or government)
	  ○ incomes less than 500% of the federal poverty limit ($60,300 for a one-person household in 2017)
	  ○ A US address
	• The physician must:
	  ○ Complete the "Advancing Access" form (included) and fax it to: 1-800-216-6857
	  ○ Or call 1-800-226-2056
	  ○ Or complete online at www.gileadadvancingaccess.com

Patient Access Network (PAN) Foundation for Co-Pay assistance with Medicare, Part D	• Patient must have Medicare, Part D. • Covers prescription co-pays and deductibles of up to $8,000 per year • Patient must have an annual income less than 500% FPL (in 2016, 500% of FPL is $60,300 for a one-person household). • Contact: 1-866-316-7263 or visit www.panapply.org • Funding is allocated and offered on a regular basis; check back
Patient Advocate Foundation Copay Relief Proram (CPR) for patients with any insurance	• Covers prescription co-pays and deductibles for patients with insurance (including Medicare or commercial plans) • $8,000 maximum per year • Patient must have an annual income less than 400% FPL (in 2017, $47,550 for a one-person household). • Contact: 1-866-512-3861 or visit www.copays.org

INSTRUCTIONS

Complete all applicable sections of the Enrollment Form.

- **Section 1 (required)**: Check the box next to each service you are requesting from Advancing Access.
- **Section 2 (required)**: Write the name and dosage of the Gilead product you are requesting assistance with from Advancing Access.
- **Section 3 (required)**: Complete all fields with the patient's information.
- **Section 4 (required)**: Check the appropriate box to indicate if the patient is insured or uninsured.
  - If the patient is insured, fill in the patient's insurance information and fax a copy (front and back) of the patient's insurance card. If the patient has a secondary insurance, check the box to indicate this and fax a copy of the secondary insurance card.
  - If the patient is uninsured, complete Section 9 to apply to the Patient Assistance Program.
- **Section 5 (required)**: Complete all fields with the prescriber's information.
- **Section 6**: A healthcare provider must provide the patient's diagnosis and medical information.
- **Section 7 (required)**: The prescriber must sign and date this section for reimbursement support and the Patient Assistance Program.
- **Section 8 (required)**: The patient (or the patient's representative) must sign and date this section.
- **Section 9 (required only if applying to the Patient Assistance Program ("PAP"))**:
  - Provide the patient's annual household income and household size and complete the additional insurance information portion.
  - The patient must sign and date this section if applying to the PAP.
  - Attach documentation for all sources of income and proof of U.S. residency.

Mail or fax the completed Enrollment Form and all required documentation to the Advancing Access at the address or fax number below. Both sets of information are necessary to ensure timely application review.

An Advancing Access reimbursement counselor will notify the requestor about the patient's coverage and benefits, alternate funding options and/or qualification for the PAP, depending on the requested service(s).

Patients who meet the eligibility criteria for the PAP will be prequalified for the program.

- The program will notify the patient and the prescriber of the prequalified status.
- The prescriber's notification will also include a prescription form.
- The prescriber will have up to six months from the prequalified date to submit the completed prescription form to the dispensing pharmacy specified on the form.
- Once the dispensing pharmacy receives the completed prescription form, the patient will be enrolled in the PAP and will receive product free of charge from the pharmacy by mail. A toll-free telephone number is included if additional assistance is needed.

PATIENT CONFIDENTIALITY

Patient confidentiality is of primary importance to us. All patient information will remain confidential. Information may be provided to clinicians, social workers or family members when required to complete the enrollment process and coordinate patient assistance.

IMPORTANT REMINDER

Please be certain that all applicable pages of the Enrollment Form are completed and include all appropriate documentation when submitting the form. Incomplete forms slow the review process and, in some cases, may require a patient to reapply for the program.

Gilead Sciences, Inc. reserves the right to modify or discontinue the Advancing Access or terminate assistance at any time. Third-party reimbursement is affected by a range of factors; therefore, Gilead Sciences, Inc. cannot guarantee any coverage or reimbursement.

ADVANCING ACCESS®

ENROLLMENT FORM

PHONE: **1-800-226-2056** FAX: **1-800-216-6857**

1. REQUESTED PATIENT SERVICE(S) (REQUIRED)

CHECK ALL BOXES THAT APPLY

- ☐ Benefits Investigation
- ☐ Prior Authorization and Appeals Information
- ☐ Patient Assistance Program (PAP) Eligibility Screening
- ☐ Co-pay Coupon Program Enrollment
- ☐ Independent Co-pay Foundation Information

2. GILEAD MEDICATION PRESCRIBED (REQUIRED)

Product Name:	mg:
If requesting TRUVADA®, please indicate for: ☐ Treatment ☐ PrEP	

3. PATIENT INFORMATION (REQUIRED)

Patient Name:		Preferred Language:	
Address:		City:	
State:	Zip Code:	Phone #:	SSN (last 4 digits):
Email:		DOB:	Gender: ☐ M ☐ F
Alternate Contact Name:		Phone #:	Relationship:

CONTACT AUTHORIZATION

I authorize Advancing Access to leave a detailed message, including the name of my prescription, if I am unavailable when they call. ☐ Yes ☐ No

4. INSURANCE INFORMATION (REQUIRED)

PLEASE INCLUDE A COPY OF THE FRONT AND BACK OF INSURANCE CARD(S)

☐ Patient is insured (Please fill out all of the applicable insurance information below. Attach copy—front and back—of patient card.)		☐ Patient is uninsured (ie, no health insurance through any public or private payer) SEE OPTIONAL "PATIENT FINANCIAL INFORMATION" SECTION BELOW	
Primary Insurance:		Is this a Medicare Part D plan? ☐ Yes ☐ No	
Plan name:		Payer Phone Number:	
Subscriber Name:	Policy Holder Name:	Policy Holder Relationship to Patient:	
Policy #:	Group #:	Rx Bin #:	Rx PCN #:

☐ Check box if patient has secondary insurance coverage and fax a copy of insurance cards, if available.

5. PRESCRIBER INFORMATION (REQUIRED)

Prescriber Name:		Facility Name:	
Address:		City:	
State:	Zip Code:	Office Contact:	
Phone #:		Fax #:	NPI #:
Tax ID #:		State License #:	

6. DIAGNOSIS/MEDICAL INFORMATION

MUST BE COMPLETED BY HEALTHCARE PROVIDER

Diagnosis (Please include ICD-10 code):_____

7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY

By signing this form, I certify that I am prescribing Gilead medication for the patient identified in Section 3. I certify that this prescription medication is medically necessary for the patient and that it will be used as directed. I certify that I will be supervising the patient's treatments and verify that the information provided is complete and accurate to the best of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed to the patient through the Patient Assistance Program (PAP) or from any government program or third-party insurer.

If prescribing TRUVADA® for PrEP, I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

I certify that I have received the appropriate written authorization from the patient, in accordance with the Health Insurance Portability and Accountability Act of 1996, applicable state health information privacy law(s), and any other applicable requirements, in order to release the patient's personal and medical information to Gilead and its agents and contractors for the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking prior authorization if needed on the patient's behalf; 3) providing financial assistance, support, and referral services as needed; 4) facilitating the provision of the patient's prescription medication to the patient; 5) contacting the patient with educational materials about the patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program and/or the PAP; and 6) for Gilead's internal business purposes.

PRESCRIBER SIGNATURE (REQUIRED):	**DATE**:

PATIENT NAME: _____ DATE OF BIRTH: _____

8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQUIRED)

I understand that I must complete this enrollment form before I can receive assistance through Gilead Sciences, Inc.'s Advancing Access ("Program") and the Patient Assistance Program ("PAP"). As part of this process, Gilead and its agents and contractors (collectively, "Gilead") will need to obtain, review, use and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization.

Information to Be Disclosed: Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV-related status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form.

Persons Authorized to Disclose My Information: My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization.

Persons to Which My Information May Be Disclosed: Gilead, including the third party administrator responsible for the administration of the Program and the PAP.

Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made to Gilead so that Gilead may use and disclose the PHI for purposes of: 1) completing the enrollment process and verifying my enrollment form; 2) establishing my eligibility for benefits from my health plan or other programs; 3) providing financial assistance, support, and referral services, and communicating with my healthcare providers, including, but not limited to, facilitating the provision of my prescription medication to me; 4) contacting me to evaluate the effectiveness of the Program and/or the PAP; 5) for Gilead's internal business purposes, including quality control and service enhancing surveys; and 6) to send me marketing information, offers, and educational materials related to my treatment and/or my prescription medication, including the customer relationship marketing program (this use of my personal information is optional and by checking the box under the signatures below, I may opt in).

I understand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure. I understand further that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits or ability to obtain treatment from my healthcare providers will not change, but I will not have access to the services offered by Program and/or the PAP. I also understand that I may cancel this authorization at any time by notifying Gilead in writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gilead will stop using this authorization to obtain, use or disclose my PHI after the cancellation date, but the cancellation will not affect uses or disclosures of any PHI that have already been made pursuant to this authorization before the cancellation date. I am entitled to a copy of this signed authorization, which expires the earlier of two (2) years from the date it is signed by me or other time period required under the laws of the state in which I reside.

☐ By checking this box, I agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my prescription medication, including the customer relationship marketing program.

SIGNATURE of PATIENT or PATIENT'S REPRESENTATIVE (REQUIRED):	**DATE:**
Patient Representative's Name (if signing for the patient):	
Patient Representative's Relationship to Patient:	

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

PATIENT NAME: _____ DATE OF BIRTH: _____

9. PATIENT FINANCIAL INFORMATION (OPTIONAL)

REQUIRED ONLY IF APPLYING FOR THE PATIENT ASSISTANCE PROGRAM (PAP)

Current Annual Household Income: $

Number of People in Household: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other:

Please submit current documentation for all sources of income (eg, tax return, W2, last 2 pay stubs, etc.) and proof of U.S. residency (eg, utility bill, bank statement, etc.).

ADDITIONAL INSURANCE INFORMATION

Social Security Number:

Has the patient applied for ADAP?	☐ Yes	☐ No	If Yes, date of application:
Has the patient applied for Medicaid?	☐ Yes	☐ No	If Yes, date of application:
Is the patient eligible for Medicaid?	☐ Yes	☐ No	If No, state reason:
Is the patient eligible for VA benefits?	☐ Yes	☐ No	If Yes, has the patient tried to obtain the medication through the VA? ☐ Yes ☐ No
Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	☐ Yes	☐ No	If Yes, date of application:
Is the patient eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	☐ Yes	☐ No	If No, state reason:

TRUVADA® FOR PrEP MEDICATION ASSISTANCE PROGRAM

If enrolling in TRUVADA for PrEP Medication Assistance Program for uninsured patients, please select one:

☐ Ship medication to prescriber's office ☐ Patient will pick up medication from local pharmacy

APPLICANT DECLARATIONS AND AUTHORIZATIONS (REQUIRED ONLY IF APPLYING FOR THE PAP)

I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if Advancing Access becomes aware of any false or inaccurate information or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. If I receive free product through the PAP, I certify that I will not seek reimbursement or credit for this medication from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this medication or any cost for items associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that the PAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize the PAP and its administrator to forward my prescription to a dispensing pharmacy on my behalf.

SIGNATURE OF PATIENT/PATIENT REPRESENTATIVE: (REQUIRED ONLY IF APPLYING FOR PAP)	**DATE:**

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

Billing Codes for PrEP and PEP

Category	ICD-10	Description
Contact with and (suspected) exposure to communicable diseases	Z20.6	Contact with and (suspected) exposure to HIV *(recommended for prescriptions with Medicaid)*
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
	Z20.89	Contact with and (suspected) exposure to other communicable diseases
	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
High-risk sexual behavior	Z72.51	High-risk heterosexual behavior
	Z72.52	High-risk homosexual behavior
	Z72.53	High-risk bisexual behavior
Other hazardous exposures	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z77.9	Other contact with and (suspected) exposure hazardous to health
Contact with hypodermic needle	W46.0XXA	Contact with hypodermic needle (initial encounter)
	W46.0XXD	Contact with hypodermic needle (subsequent encounters)
	W46.1XXA	Contact with contaminated hypodermic needle (initial encounter)
	W46.1XXD	Contact with contaminated hypodermic needle (subsequent encounter)
Long-term prophylaxis	Z79.899	Other Long-Term (current) drug therapy

CPT	Description
99401	Prevention counseling (15 min)
99402	Prevention counseling (30 min)
99403	Prevention counseling (45 min)
99404	Prevention counseling (60 min)

Trainings for PEP and PrEP

LOUISIANA DEPARTMENT OF HEALTH

Online Trainings from the New York State Clinical Educational Initiative (CEI)

- HIV Pre-Exposure Prophylaxis in the Real World (ONLINE)
  - Target Audience: All physicians, nurse practitioners (NPs) and physician assistants (PAs) involved or interested in HIV education
  - Continuing Medical Education (CME) available
  - Registration: https://www.ceitraining.org/courses/ ("HIV Prophylaxis")
- Post-Exposure Prophylaxis (ONLINE)
  - Target Audience: All physicians, NPs and PAs involved or interested in HIV education
  - Continuing Medical/ Nursing Education (CME/ CNE) available.
  - Registration: https://www.ceitraining.org/courses/ ("HIV Prophylaxis")
- Also visit www.ceitraining.org for: Free CME/CNE trainings on PrEP and/or PEP (online or in person) or additional online video learning modules about PrEP and PEP

AIDS Education and Training Centers (AETC)

Dana Gray, Program Manager
South Central AETC
LSU School of Public Health
2020 Gravier Street, 3rd Floor
New Orleans, LA 70112
phone: (504) 568-5647
dgray@lsuhsc.edu

Graham Patterson, Program Manager
Tulane University AETC
Tulane University
1430 Tulane Avenue SL-87
New Orleans, LA 70119
Phone (504) 988-9935
gpatters@tulane.edu

Louisiana Dept. of Health, Office of Public Health, STD/HIV Program

Erika Sugimori, Health Equity and Development Supervisor
Louisiana Department of Health—Office of Public Health
STD/HIV Program
1450 Poydras St., Suite 2136
New Orleans, LA 70112
phone: (504) 568-7474
erika.sugimori@la.gov

Reporting Guidelines for STIs and HIV

LOUISIANA DEPARTMENT OF HEALTH

Louisiana Sanitary Code, LAC: 51:11.105

*Per Louisiana Law, **all clinicians** must report the following infections to the Office of Public Health within the specified time, **regardless** of independent, automatic reporting by laboratories.*

Class B Diseases, Reportable within 1 business day

Note: The following is a Partial List of Reportable Diseases of Relevance to STI and HIV:

- HIV infection in pregnancy
- HIV infection, perinatal
- Syphilis

Class C Diseases, Reportable within 5 business days

Note: The following is a Partial List of Reportable Diseases of Relevance to STI and HIV:

- AIDS
- Chlamydia
- Gonorrhea (genital, oral, ophthalmic, rectal, PID)
- HIV infection (other than Class B)

Reporting Instructions:

- **HIV or Syphilis During Pregnancy:**
  - Complete and Fax Attached Form in 1 business day
- **HIV outside of Pregnancy:**
  - Complete and Fax Attached Form within 5 business days
- **Syphilis and STIs outside of Pregnancy**
  - Complete and Fax Attached STD-43 Form within 5 business days

Confidential OPH Fax: (504) 568-8384
Phone Line: (504) 568-7474

LOUISIANA CONFIDENTIAL REPORT OF SEXUALLY TRANSMITTED DISEASES (STDs)

PROVIDER INFORMATION

Name of Provider: | Phone: ( ) - | Fax Number: ( ) -

Facility Name: | Email:

Address: | City: | State: | Zip:

Name of Person Reporting: | Position:

PATIENT INFORMATION

Patient Medical Rec. #: | Insurance: ☐ Private ☐ Medicaid ☐ Unknown ☐ None

First Name: | Middle Initial: | Last Name:

Address: | City: | State: | Zip:

Patient Hm Ph: ( ) - | Patient Wk Ph: ( ) - | Patient Cell Ph: ( ) -

DOB (MM/DD/YYYY): / / | SSN: - - | Emergency Contact:

Sex at Birth: ☐ Male ☐ Female

Gender: ☐ Male ☐ Female ☐ Transgender Male-to-Female ☐ Transgender Female-to-Male

Pregnant: ☐ Yes, Expected Delivery Date: / / ☐ No ☐ Unknown

Race: ☐ White ☐ Black ☐ Asian/Pacific Islander ☐ American Indian/Alaskan Native ☐ Other/Unk

Ethnicity: ☐ Hispanic ☐ Non-Hispanic

Marital Status: ☐ Single ☐ Married ☐ Partner ☐ Divorced ☐ Widowed

Gender of Partner(s) **:** ☐ Male ☐ Female ☐ Transgender Male-to-Female ☐ Transgender Female-to-Male ☐ Unknown

CHLAMYDIA

☐ Uncomplicated
☐ Ophthalmia neonatorum
☐ Oral / Pharyngeal
☐ Rectal
☐ Pelvic Inflammatory Disease (PID)
☐ Pneumonia
☐ Other (specify): _____

Date of Specimen Collection:
_____/_____/_____

Test(s) Conducted:
☐ Culture
☐ NAATs
☐ Nucleic Acid Probe
☐ Point of Care Test
☐ Other (specify): _____

Date Treatment Administered:
_____/_____/_____

Date prescription given:
_____/_____/_____

Recommended Treatment:

☐ Azithromycin 1g orally in a single dose
☐ Doxycycline 100 orally twice a day for 7 days
☐ Erythromycin base 500 mg orally 4 times a day for 7days
☐ Amoxicillin 500 mg PO 3 times a day for 7 days **(if pregnant)**
☐ Other (specify): _____

Name of Testing Laboratory:

GONORRHEA

☐ Uncomplicated
☐ Disseminated Gonococcal Infection (DGI)
☐ Ophthalmia neonatorum
☐ Oral / Pharyngeal
☐ Rectal
☐ Resistant Strain
☐ Pelvic Inflammatory Disease (PID)
☐ Other (specify):

Date of Specimen Collection:
_____/_____/_____

Test(s) Conducted:
☐ Culture
☐ NAATs
☐ Nucleic Acid Probe
☐ Point of Care Test
☐ Other (specify): _____

Date Treatment Administered:
_____/_____/_____

Date prescription given:
_____/_____/_____

Recommended Treatment:

☐ Ceftriaxone 250 mg IM in a single dose **OR**
(if Ceftriaxone is not available)
☐ Cefixime 400 mg orally in a single dose **PLUS**
☐ Azithromycin 1 g orally in a single dose **OR**
☐ Doxycycline 100mg PO twice a day for 7 days

If allergic to penicillin:
☐ Gentamicin 240 mg IM in a single dose **OR**
☐ Gemifloxacin 320 mg orally in a single dose **PLUS**
☐ Azithromycin 2 g orally in a single dose
☐ Other (specify): _____

Name of Testing Laboratory:

SYPHILIS

NOTE: Call to report [(504) 568-7474], then follow-up with form

☐ Primary (Genital or oral ulcer)
☐ Secondary (Rashes)
☐ Early Latent (<1 year)
☐ Late Latent (>1 year)
☐ Tertiary- Cardiovascular
☐ Tertiary- Neurosyphilis
☐ Congenital
☐ Unknown stage

Date of Specimen Collection:
_____/_____/_____

Test(s) Conducted & Results:

☐ RPR Titer_____
☐ VDRL Titer _____
☐ MHATP _____
☐ FTA _____
☐ IgG (EIA)_____
☐ TP-PA _____
☐ Other _____

Recommended Treatment:

☐ 2.4 million units Benzathine Penicillin G (BIC) IM X 1dose
Date Administered: _____/_____/_____

☐ 2.4 million units Benzathine Penicillin G (BIC) IM X 3 doses
Date 1st Dose Administered: _____/_____/_____

☐ Doxycycline 100 mg orally twice a day for 14 days
☐ Doxycycline 100 mg orally twice a day for 28 days
☐ Other: _____

Date prescription given:_____/_____/_____

Name of Testing Laboratory:

OTHER

☐ Chancroid
☐ Granuloma Inquinale
☐ Herpes Simplex Virus(Neonates only)
☐ Lymphogranuloma Venereum
☐ Other (specify): _____

Date of Specimen Collection:
_____/_____/_____

Test(s) Conducted:
☐ _____
☐ _____
☐ _____
☐ _____

Treatment:
☐ _____
☐ _____

Date Treatment Administered:_____/_____/_____

Date Prescription Given:_____/_____/_____

Name of Testing Laboratory:

For information regarding testing and treating of partners exposed to STD or HIV contact the Regional Operations Manager at (504) 568-7474.

Mail or FAX form to: Louisiana Office of Public Health STD/HIV Program, PO Box 60630, New Orleans, LA, 70160; (504)568-8384.
For more information call (504)568-7474. (Form: STD 43 Rev10/2014)

LOUISIANA CONFIDENTIAL REPORT OF SEXUALLY TRANSMITTED DISEASES (STDs)
Form: STD 43 Revised October 2014

DESCRTIPTION & PURPOSE
The STD 43 is a single page form to report newly diagnosed, re-infected, and treated STDs with the exception of HIV/AIDS.

Directions for reporting HIV/AIDS cases contact: STD/HIV Program, 1450 Poydras Street Suite 2136, New Orleans, LA 70112, (504)568-7474. For information about HIV/AIDS Surveillance: http://www.hiv.dhh.louisiana.gov.

INSTRUCTIONS FOR COMPLETING STD 43: CONFIDENTIAL REPORT OF SEXUALLY TRANSMITTED DISEASES
Use one (1) form per person to report all applicable STDs. P**rint legibly**.

Provider Information: Write the Name, Addresses, Phone number and Name of Person Reporting in the box or place a typed label with the same information over the box. If provider and facility are different, provide information for both. Services provided via the internet **must** list a valid medical provider and facility.

Patient Information: Write the medical record #, Name, Type of Insurance used for visit, Address, Phone numbers, Date of Birth (DOB), Social Security Number (SSN), in the spaces provided. Check the appropriate boxes for Gender, Pregnancy status, marital status, Race, Ethnicity and Gender of Partner(s).

Disease: Check appropriate box (es) in this section depending on the diagnosis. **In addition to completing form, call the STD/HIV Program at (504)568-7474 to report all cases of primary & secondary syphilis.**
For each disease reported complete each box in the appropriate column including:
1. Check the box (es) for the disease(s) being reported
2. Write the date laboratory specimens were collected
3. Write the name of the laboratory where tests were conducted
4. Check the box (es) for type of test(s) conducted that were **positive.** Syphilis test(s) conducted must be reported **with results** to identify new cases:
   - If RPR/VDRL is positive and confirmatory test (e.g., TPPA or IgG-EIA) is negative, report NEGATIVE confirmatory test result also (to validate biological false positives).
   - Enter titer result for the RPR and/or VDRL test (e.g., RPR 1:16, VDRL 1:128).
   - Report non-reactive/negative RPR/VDRL result if confirmatory test is positive (i.e. TPPA or IgG-EIA)

5. Write / check box (es) of medication given; write date treatment was administered or prescription was provided

Important Note
Form STD 43 should be mailed to the STD Control Section as soon as the diagnosis is made. The form may be filled before treatment is completed. Patients should not be reported as cases unless the diagnosis is confirmed appropriately. All contacts of STDs should be tested for the disease(s) to which they were exposed. If contacts are treated in the absence of positive laboratory tests, then they are considered epidemiologically treated. Epidemiologic treatment is applicable only to persons exposed to known STD cases. Therefore, the term does not apply to persons who are treated for symptoms only and are not, therefore, definitively diagnosed. Reporting of epidemiologic treatment should be withheld and reported only with positive laboratory tests.

MAIL or FAX FORM TO:
LOUISIANA OFFICE OF PUBLIC HEALTH- STD CONTROL PROGRAM
1450 Poydras Street Suite 2136
New Orleans, LA 70112

or

PO BOX 60630
NEW ORLEANS LA 70160

FAX to: (504)568-8384

For questions contact the STD/HIV Program at: 504-568-7474 or visit our web site at: www.std.dhh.louisiana.gov.

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health

HIV/SYPHILIS DURING PREGNANCY REPORTING FORM

The Louisiana Public Health Sanitary Code mandates the reporting of pregnancy status for women diagnosed with HIV and/or syphilis, which allows Louisiana programs to target high-risk pregnancies for follow-up.

REPORT DATE:_____ **REPORTING FACILITY**: _____

Patient Information

Full Name			
	First	Last	Maiden
Address			
	Street Address		Apartment/Unit #
	City and Zip code	Phone Number	
Emergency Contact Name and Phone No.		**DOB (mm/dd/yyyy)**	
Date of Pregnancy Diagnosis (mm/dd/yyyy)			
Estimated Delivery Date (mm/dd/yyyy)			

Linkage to Care

The patient is currently diagnosed with:	☐ HIV ☐ Syphilis ☐ Both ☐ Other		
Is the patient engaged in OB and/or prenatal care?	☐ Y ☐ N ☐ UNK	**If the patient is currently infected with syphilis, what is the clinical stage of diagnosis?**	☐ Primary ☐ Secondary ☐ Early Latent ☐ Late Latent
Is the patient currently on antiretroviral therapy (ARVs) for HIV?	☐ Y ☐ N ☐ UNK ☐ N/A	**Has the patient been treated for the most recent infection of syphilis?**	☐ Y ☐ N ☐ UNK ☐ N/A
Is the patient currently engaged in HIV Care?	☐ Y ☐ N ☐ UNK ☐ N/A	**If the patient was treated for a current syphilis infection, please record treatment and dosage:**	☐ 2.4 MU benzathine penicillin ☐ 4.8 MU benzathine penicillin ☐ 7.2 MU benzathine penicillin ☐ Other ☐ N/A
		Date of Syphilis Treatment:	
Are you concerned about any of the following with your patient? Check all that apply.	☐ Housing ☐ Transportation ☐ Nutrition/Food Assistance ☐ Med Adherence ☐ Substance Abuse ☐ Mental Health ☐ None ☐ Other (please specify):		

Provider Information

Patient's Provider/Person Completing Form	
Phone Number	

Report diagnosis of HIV/syphilis during pregnancy within one business day.

Completed forms should be sent to the Perinatal STD/HIV Surveillance Supervisor at the Office of Public Health STD/HIV Program.

Report by Phone: (504) 568-3384

Confidential Fax: (504) 568-8384

Mail (completed forms must be mailed in a sealed enveloped marked "Confidential"):

STD/HIV PROGRAM ▪ 1450 Poydras St., Suite 2136▪ New Orleans, Louisiana 70112
Phone #: 504/568-7474 ▪ Fax #: 504/568-7044 ▪ www.ldh.la.gov

"An Equal Opportunity Employer"

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of Public Health

CONFIDENTIAL REPORTING WORKSHEET

Pt. Name: _____ **MRN:** _____ **SS#:** _____-_____-_____

Address: _____ Tel: ( ) _____-_____

City: _____ Parish: _____ State: _____ Zip: _____

Sex (at birth): ❑ Male ❑ Female	**Date of Birth:** ___/___/_____	**Country of Birth:** ☐ USA ☐ Other:_____	**Date of death:** **State of death:** ___/___/_____ _____
Gender (as applicable): ❑ Male to female transgender ❑ Female to male transgender	**Race** (check all that apply): ❑ American Indian/Alaskan ❑ Native Hawaiian ❑ White ❑ Black/African American ❑ Asian ❑ Unknown		**Hispanic Ethnicity:** ❑ Y ❑ N ❑ Unknown

Diagnostic Tests	**Collection Date** (mm/dd/yyyy)	**Ordering Site** (if other than reporting facility)
Preliminary (report positives): ❑ IA 1 ❑ IA 1/2 Check if rapid❑ ❑ Ag/Ab Combo (4th Gen, lab-based) ❑ Determine (rapid) Ag+___ Ab+___	/ /	
Supplemental/Differentiating (report all): ❑ Western Blot Pos___ Neg___ ❑ Multispot 1+___ 2+___ Neg ___ ❑ Geenius 1+___ 2+___ Neg ___	/ / ❑ Check if result Indeterminate	
❑ **Viral detection - Qual** DNA or RNA PCR (NAT): Pos/Det ____ Neg ____	/ /	
❑ **Other** (specify):	/ /	
If labs not available, date reporting facility documented pt's diagnosis:	/ /	
Clinical Status Tests		
❑ **Viral load –** Quant RNA PCR (NAT) **Copies/ml** :_____	/ /	
❑ **CD4 T-lymphocytes:** Count _____ Percent: _____	/ /	
Opportunistic Infections (OIs) – see list on reverse. Please document type and date of diagnosis in Comments section.		
Most recent negative test: ❑ per lab report ❑ per patient	/ /	Test type (if known)

Patient History / Risk Factors *(please complete all lines)*

Yes	No	Unk	
❑	☐	☐	Sex with male
❑	☐	☐	Sex with female
❑	☐	☐	Injected nonprescription drugs
❑	☐	☐	**Heterosexual** relations with (check all that apply): ☐ Injecting Drug User ☐ Bisexual Male (for female pts) ☐ Person with hemophilia/coagulation disorder ☐ Transfusion/transplant recipient ☐ Person with known HIV infection
❑	☐	☐	Rec'd clotting factor for hemophilia/coag. disorder
❑	☐	☐	Rec'd transfusion of other blood/blood components Dates (mo/yr): Earliest _____ Latest _____
❑	☐	☐	Rec'd tissue/organ transplant or artificial insemination
❑	☐	☐	Blood/body fluid exposure in a healthcare or clinical lab setting (mo/yr): ____/____ (*Include details on reverse)*

Treatment History

Has patient ever taken antiretroviral medications (ARVs)?
❑Yes (treatment) ❑Yes (prevention-PrEP/PEP) ❑No ❑ Unknown

Date of earliest ARV use: _____/_____/_____

Date ARVs last used: _____/_____/_____ ❑ Ongoing

Please list known ARV medications:

Insurance provider:

For Females: Is patient currently pregnant? ❑ Yes ❑ No ❑ Unk If yes, estimated date of delivery: _____/_____/_____

Has the patient delivered a live-born infant? ❑ Yes ❑ No ❑ Unk If yes, date of most recent delivery: _____/_____/_____

Delivery hospital (most recent live-born infant): _____ City/State: _____

Patient Notification: Has the patient been notified of his/her HIV test results? ❑ YES ❑ NO

Partner Services: (see reverse for info)
❑ I give Office of Public Health staff permission to conduct partner services for this patient.
❑ I will conduct partner notification for this patient.
❑ I have discussed partner notification with this patient and s/he will notify partners.

Reporting Facility: _____ **Date:** _____

Address: _____ **City:**_____ **State:**_____ **Zip:** _____

Reporting Physician: _____ **Phone:** _____

Person Completing Form: _____ **Phone:** _____

Please send or fax to:
James Hubbard / Monica Pendelton
LDH Office of Public Health / SHP
1450 Poydras St, Ste 2136
New Orleans, LA 70112
P:(504)568-7474 Fax:(504)568-8384

To Our Providers:

This worksheet was developed to assist with timely reporting of HIV cases by the diagnosing and/or managing physician, by collecting the most critical information requested on the Centers for Disease Control and Prevention (CDC)'s Adult Case Report Form. In some cases, staff of the STD/HIV Program (SHP), under the Dept of Health and Hospitals Office of Public Health, may need to contact the provider for additional information not included on this worksheet. If a provider prefers to complete the CDC Adult Case Report Form him- or herself, copies may be obtained from the SHP contact listed at the bottom of the form. Case reports may also be made by phone to the SHP contact, or SHP staff can complete the required forms on site via a chart review. *Please include as much information as is available; partial or approximate dates are acceptable for historical information*.

Reporting Requirements: Louisiana's Public Health Sanitary Code (Title 51, Part II, Chapter 1) requires that any physician practicing medicine in the State of Louisiana who attends, examines, or prescribes to a person with HIV infection must report the case by the end of the work week after the existence of a case, suspected case, or a positive laboratory result is known (Class C). HIV infection in pregnancy and perinatal HIV exposure are reportable within one business day (Class B). Other health care providers, laboratories, and other entities have similar reporting requirements.

HIPAA Guidelines Related to Disclosures for Public Health Activities: The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. See 45 CFR 164.512(b)(1)(i).

Risk Factors and Cases of Public Health Importance: Information on patient risk factors and likely mode of HIV transmission is used in planning prevention activities and to more effectively allocate HIV-related resources. The CDC also closely monitors for any new cases of **HIV-2;** for HIV transmission through a rare or unusual route such as transfusion, transplant, or occupational exposure; and for any cases in children age 12 and under not due to perinatal HIV exposure. Such cases, collectively known as "Cases of Public Health Importance (COPHI)", often require a special investigation and should be reported to your regional contact as soon as suspected.

Partner Services: OPH Disease Intervention Specialists (DIS) make a good faith effort to locate any individual identified as a spouse, sexual contact, or needle-sharing partner of a person newly diagnosed with HIV infection (source patient), to notify the partner(s) of the possible exposure, provide counseling about the risk of infection, and offer testing for HIV infection and other STDs. In performing these activities, the DIS first attempt to contact the source patient's medical provider to determine how partner notification will be conducted. If neither the source patient nor the medical provider is able to adequately conduct this notification, the DIS will seek to interview the source patient directly to identify partners for counseling, testing, and referral. *Notification of partners is conducted in such a manner as to maintain the confidentiality of the source patient.* Partner Services is a valuable prevention activity, as well as a means to offer follow-up services and support to newly diagnosed patients and promote their linkage to care.

(Continued from Clinical Status section on front)

Opportunistic Infections (OIs): *If patient has a current or previous diagnosis of any of the following, please note the condition and date of diagnosis in Comments.*

- Candidiasis, bronchi, trachea, or lungs
- Candidiasis, esophageal
- Carcinoma, invasive cervical
- Coccidiodomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 mo. duration)
- Cytomegalovirus disease (other than in liver, spleen, or lymph nodes)
- Cytomegalovirus retinitis (with loss of vision)
- HIV encephalopathy
- Herpes simplex: chronic ulcer(s) (>1 mo. duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 mo. duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary in brain
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary
- *M.tuberculosis*, pulmonary
- *M.tuberculosis*, disseminated or extrapulmonary
- *Mycobacterium*, of other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jerovecii* pneumonia (formerly *P. carinii*)
- Pneumonia, recurrent, within a 12-month period
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV

Comments (Opportunistic infections, additional risk information, antiretroviral meds, partner information, etc.):

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