

Okaloosa
SOP 103-23-17

**Pre-Exposure Prophylaxis for Prevention of HIV infection
Clinical Standard Operating Procedure****CLIENT INITIAL PrEP APPOINTMENT (ESTABLISHED OR NEW): USE PROGRAM
03A1 FOR ALL ENCOUNTERS AND LABS****1st clinical visit**

- Schedule client with dedicated ARNP provider for evaluation. (In HMS scheduling module use: Program Component - HIV/AIDS services, Appointment Reason – PrEP, schedule in appropriate clinic slot.)
- HMS EHR
 - **Nurse**
 - Open clinical visit
 - Complete RFV “PrEP”, chief complaint “desires PrEP”
 - Complete medical and sexual history in HMS.
 - Vital signs
 - Document in progress note using appropriate nurse PrEP documentation template
 - **Provider**
 - Review medical and sexual history in HMS.
 - Complete HPI
 - Physical Exam (as applicable)
 - A&P - Diagnosis (Z72.5 High-risk sexual behavior) use PrEP Provider documentation template.
 - Complete Superbill-Use E&M coding and capture HMC 5702 (Initial clinician visit)
 - Order laboratory test
- **LABORATORY TEST:**
Initial labs to Quest patient service center (PSC). Order as ‘3rd party’ for Medicaid or ‘client’ bill if other insurance or uninsured.
 - HIV 4th generation (Test # 91431)
 - Hepatitis Panel (Test #6462)
 - GC/CT (Test #11363) urine; rectal/oral swabs will need to be collected and sent as standard order
 - Urinalysis (Test #5463)
 - RPR (Test #36126)
 - Serum Creatinine (Test # 375) all 03A1
 - Pregnancy test (if applicable – In house)
- If uninsured, give client Gilead MAP application and instruction on obtaining medication from Gilead. Client is responsible for completing application.

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- Give client Truvada Medication guide for Patients.
 - Counsel on topics contained in PrEP visit documentation template.
 - Have PrEP nurse co-sign or review note so client can be added to case management tracking and follow-up.
 - **Provider and nurse document using PrEP templates on J drive**

RN/Provider Review:

- Set reminder in HMS for one week and add to care coordination.
- Review lab results from 1st visit to ensure all test are back and that client may proceed with process. If an abnormal test result is received, consult with provider to determine next steps.
- If all lab results are WNL, schedule follow-up appointment with provider within 7 days of negative HIV test. If uninsured, remind client to bring completed Gilead application for provider signature. Appointment should be scheduled in PrEP template slots.
- Document findings in HMS EHR progress note, update case management and complete client service record for HMC 03A1 9010.

2nd clinical visit w/ Provider and Q 3-month follow-up

- HMS EHR
 - **Nurse**
 - Open clinical visit
 - Complete RFV “PrEP”, chief complaint “desires PrEP”.
 - Vital signs
 - **Provider**
 - Review medical and sexual history in HMS.
 - Complete HPI
 - Physical Exam (as applicable)
 - A&P using PrEP Provider documentation template.
 - Complete Superbill- Use E&M coding and capture HMC 5703 (Initial Medical services visit – PrEP Rx)
 - **Complete the following as applicable**
 - Review lab results to determine if client is a candidate to take PrEP.
 - Use Cockcroft-Gault formula to determine creatinine clearance.
 - $$eCrCl = \frac{(140 - \text{Age}) \times \text{wt. (kg)}}{72 \times \text{Cr}} \times .85 \text{ if female}$$
 - If client isn't immune to Hepatitis A & B, order and administer vaccination during this visit using the 09 program vaccine.
 - Review side effects and signs and symptoms requiring urgent medical evaluation.

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- Give client medication fact sheet listing dosing instructions and side effects.
 - Counsel on consistent use of medication and condoms.
 - Review and sign agreement form for initiating Truvada.
 - Have client sign agreement form.
 - Have PrEP nurse co-sign or review note in HMS so client can be added to case management tracking and follow-up.
 - **Provider and nurse document using PrEP templates on J drive.**

INSURED CLIENTS:

- Rx for Truvada #90 electronically to preferred pharmacy if HIV test was completed and negative within the past week. An Alere Determine rapid HIV test should be completed if the client's lab based 4th generation HIV test is greater than 7 days old. Proceed with Rx for medication if HIV negative result.
- Offer Curant 340B services.
- Schedule client follow-up appointment for 3 months and order Quest labs as PSC order.
- Nurse will follow-up in 30 days to assess adherence, tolerance and commitment.

UNINSURED CLIENTS:

- Provider signs and completes applicable portions of the Gilead application. Application is faxed to Gilead.
- Issue/dispense 30-day supply of Truvada from state supplied PrEP medications (Nurse Issuance) if HIV test was completed and negative within the past week. An Alere Determine rapid HIV test should be completed if client's lab based 4th generation HIV test is greater than 7 days old. Proceed with medication dispensing if HIV negative result.
- Once the client receives the Truvada card from Gilead, the client should call and request an Rx for remaining 60-day supply.
- Schedule client follow-up appointment for 3 months and order Quest labs as PSC order.
- Nurse will follow-up in 30 days to assess adherence, tolerance and commitment.

FOLLOW-UP EVERY THREE MONTHS

- Provider visit
- Laboratory studies as below (focus on HIV and STD screenings)
- Use 2nd clinical visit w/provider and Q 3-month follow-up in this document as guide for ongoing care (see above)
- Complete Superbill capturing HMC 5704 (PrEP clinical follow-up visit)

FOLLOW-UP LABS TO QUEST AS PSC order: Order as '3rd party' for Medicaid or 'client' bill if other insurance or uninsured.

- Every 3 months
 - HIV 4th generation (Test # 91431)

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- GC/CT (Test #11363) urine
 - RPR (Test #36126)
 - Pregnancy test (if applicable – In house)
 - Every 6 months add
 - Serum Creatinine (Test # 375)
 - Every 12 months add
 - Urinalysis (Test #5463)
 - Hepatitis C IgG (Test #8472)

NOTE: It is **HIGHLY** recommended that STD screening be completed every 3 months for clients not in monogamous relationships regardless of risk. This includes completing rectal/oral swabs* for GC/CT during the clinical visit.

*May be self-collected

**PrEP REFERAL DURING STD/FP APPOINTMENTS (ESTABLISHED OR NEW):
USE STD OR FP PROGRAM CODE**

Complete STD or FP clinical visit per program guidelines including documentation

- Complete routine testing during STD/FP visit – send to STATE LAB
 - GC/CT urine - rectal GC/CT, throat GC/CT as indicated
 - RPR syphilis
 - HIV 4th generation
- If desires or shows interest in PrEP refer to Quest for further testing – QUEST PSC order ('3rd party' if Medicaid, 'client' bill if other)
 - Hepatitis panel (#6462)
 - Urinalysis (#7048)
 - Serum Creatinine (#375)
- Give PrEP packet. Instruct uninsured to bring completed Gilead PAP application back for next visit.
- Complete Superbill capturing HMS 5701 (Initial nurse assessment/counseling)
- Have PrEP nurse co-sign or review note so client can be added to case management tracking and follow-up.

Follow-up with client in one week. If client completes PSC lab work, schedule 1st clinical visit and follow process above.

Common PrEP related codes:

ICD-10 Codes

- Z72.5 High-risk sexual behavior
- Z72.51 High Risk heterosexual behavior
- Z72.52 High Risk homosexual behavior
- Z72.53 High Risk bisexual behavior
- Z20.82 Contact with and (suspected) exposure to other viral communicable diseases

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SNOMED

- 102947004 - High Risk Sexual Behavior (finding)
- 288301000119101 - High Risk Heterosexual Behavior (finding)
- 288311000119103 High Risk Homosexual Behavior (finding)
- 288291000119102 - High Risk Bisexual Behavior (finding)
- 444107005 - Exposure to Communicable Disease (event)

CPT Description

- 99401 Preventive counseling (15 minutes)
- 99402 Preventive counseling (30 minutes)
- 99403 Preventive counseling (45 minutes)
- 99404 Preventive counseling (60 minutes)

DOH – Okaloosa: How to Obtain Medication

Medication Procurement and Payment Options for PrEP	
Private Insurance	<ul style="list-style-type: none"> • Most private insurances cover PrEP. • Coverage varies based on plan. There may be deductibles and co-payments <ul style="list-style-type: none"> ○ If using Curant co-payment will be covered by “cost savings”
Medicaid	<ul style="list-style-type: none"> • PrEP prescription costs, medical appointments and lab test covered. • Prior approval is required and renewed every 3 months
Uninsured	<ul style="list-style-type: none"> • DOH – Okaloosa serves HIV-negative persons who are residents of Florida who are uninsured or underinsured. Fees are based on sliding fee scale determined by income. <ul style="list-style-type: none"> ○ Fees include provider visits and lab testing, counseling, and supportive primary care services consistent with clinical guidelines of PrEP. • Medication assistance programs (MAP) will be used for medication procurement.
Medication Assistance Programs	
Gilead Co-Pay Coupon Card	<ul style="list-style-type: none"> • Gilead Co-Pay Coupon Card www.gileadcopay.com <ul style="list-style-type: none"> ○ Covers up to \$300/month in prescription co-payments ○ Patient must have insurance. ○ Patient must NOT be enrolled in Medicare or Medicaid ○ No income eligibility requirement
Gilead Medication Assistance Program	<ul style="list-style-type: none"> • Gilead Medication Assistance Program (855) 330-5479 http://start.truvada.com/individual <ul style="list-style-type: none"> ○ Covers prescription costs. ○ Patient must be uninsured or their insurance does not cover any prescription cost.

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	<ul style="list-style-type: none"> ○ Patient must have annual income less than 500% FPL.
Patient Access Network (PAN Grant)	<ul style="list-style-type: none"> ● Patient Access Network (866) 316-7263 <ul style="list-style-type: none"> ○ Offers help to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays. ○ One-time grant to cover up to \$4000 of prescription costs for one year. ○ Patient must have private insurance, Medicare, or Medicaid. ○ Patient must have annual income less than 500% FPL. If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.

**Pre-Exposure Prophylaxis for Prevention of HIV infection
Standing Order for laboratory testing**

The following laboratory test may be ordered by any Registered Nurse working at DOH-Okaloosa in order to facilitate PrEP services (See RN protocol). Quest as PSC ('3rd party' if Medicaid, 'client' bill if other) Program 03A1 (test # listed below)

- HIV 4th generation (#91431)
- Hepatitis Panel (#6462)
- GC/CT (#11363) urine; rectal/oral swabs will need to be collected and sent as standard order during clinic visit
- Urinalysis (Test #7048)
- RPR (#36126)
- Serum Creatinine (#375) all 03A1
- Pregnancy test (if applicable – In house)
- Hepatitis C IgG (Test #8472 annually only)

Sally Cooper, DO
Medical Director

Date

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Registered Nurse Acknowledgements:

_____ Signature: _____ Date: _____

_____ Signature: _____ Date: _____