Outpatient/Ambulatory Health Services
Service Standard

**HRSA Definition:** Outpatient/Ambulatory Health Services (OAHS) are diagnostic and therapeutic services provided directly to a client by a licensed healthcare provider in an outpatient medical setting. Outpatient medical settings include clinics, medical offices, and mobile vans where clients do not stay overnight.

**Limitations:** Emergency room or ambulance services are NOT considered outpatient settings; therefore, services cannot be reimbursed. (RWHAP Legislation, HRSA PCN 16-02)

**Services:** Allowable activities include:
- Medical history taking
- Physical examination
- Diagnostic testing, including laboratory testing
- Treatment and management of physical and behavioral health conditions
- Behavioral risk assessment, subsequent counseling, and referral
- Preventive care and screening
- Pediatric developmental assessment
- Prescription, and management of medication therapy
- Treatment adherence services *provided during an OAHS visit*
- Education and counseling on health and prevention issues
- Referral to and provision of specialty care related to HIV diagnosis

Care must include access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies (ART).

Diagnostic Laboratory Testing includes all indicated medical diagnostic testing, including all tests considered integral to treatment of HIV and related complications (e.g., viral Load, CD4 counts, and genotype assays). Funded tests must meet the following conditions:
- Tests must be consistent with medical and laboratory standards as established by scientific evidence and supported by professional panels, associations, or organizations;
- Tests must be (1) approved by the U.S. Food and Drug Administration (FDA), when required under the FDA Medical Devices Act; and/or (2) performed in an approved Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified laboratory or State-exempt laboratory; and
- Tests must be (1) ordered by a registered, certified, or licensed medical provider, and (2) necessary and appropriate based on established clinical practice standards and professional clinical judgment.

Telemedicine is an acceptable means of providing OAHS but must conform to the Texas Medical Board (TMB) guidelines for providing telemedicine, Texas Administrative Code, Texas Medical Board, Rules, Title 22, Part 9, Chapter 174, RULE §174.1 to §174.12 and the January 2020 Texas Medicaid Provider Telecommunication Services Handbook, Volume 2.
Service Standard and Performance Measure

The following Standards and Performance Measures are guides to improving clinical care throughout the State of Texas within the Ryan White Part B and State Services Program. The most current U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Guide for HIV/AIDS Clinical Care – 2014 Edition are sources cited throughout the Standards for additional reference materials for direct care service providers.

<table>
<thead>
<tr>
<th>Standard</th>
<th>HRSA: HAB Performance Measure</th>
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<tr>
<td><strong>Medical Evaluation/Assessment</strong>&lt;br&gt; All HIV patients receiving medical care shall have a completed initial comprehensive medical evaluation/assessment and physical examination that adheres to the current HHS guidelines within one (1) month of HIV diagnosis or within 15 business days of initial contact with patient who has been in care. Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.</td>
<td>Percentage of patients who attended a routine HIV medical care visit within one (1) month of HIV diagnosis. <em>(HRSA HAB Measure – Linkage to Care)</em>&lt;br&gt; Percentage of existing patients (returning to care and those in current medical care for more than one year) with a documented comprehensive assessment/evaluation completed by the MD, NP, CNS, or PA within 15 business days of initial contact with patient in accordance with professional and established HIV practice guidelines.</td>
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<tr>
<td><strong>Comprehensive HIV-related history</strong>&lt;br&gt; Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. History shall consist of, at a minimum, general medical history, a comprehensive HIV related history, and psychosocial history to include:&lt;br&gt; • Documented past medical and surgical history with regard to chronic diseases such as diabetes, high blood pressure, heart disease, cholesterol, asthma or emphysema, sickle cell disease, etc. per HHS guidelines.&lt;br&gt; • Psychosocial history to include socio-cultural assessment, occupational history, hobbies (as applicable), travel history, mental</td>
<td>Percentage of new patients with a documented comprehensive HIV-related history that is inclusive of all components listed in the OAHS Standard as referenced in the HHS guidelines.&lt;br&gt; Percentage of existing patients with a documented comprehensive HIV-related history that is inclusive of all components listed in the OAHS Standard as referenced in the HHS guidelines.</td>
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2 Page<br>Revised 12/2019
health, and housing status.

- Lifestyle including tobacco use, alcohol use, illicit substance use, exercise, travel history.
- Sexual Health including partners, practices, past sexually transmitted infections (STIs), contraception use (past and present).
- HIV-related health history including most recent CD4 and Viral Load results, current ART (if applicable), previous adverse ART drug reactions, history of HIV-related illness and infections, HIV treatment history and staging.

Physical examination will include the documentation from the complete review of systems as indicated within the comprehensive medical history. This can be completed during the initial visit or divided over the course of two or three early visits.


**Physical examination**

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.

Providers should perform a baseline and annual comprehensive physical examination, with particular attention to areas potentially affected by HIV.

Examination of the oral cavity should be included in both the initial and interim physical examination of all HIV patients.


| Percentage of new patients with a documented annual physical examination. |
| Percentage of new patients with a diagnosis of HIV who received an oral cavity exam during the physical exam as documented in the patient’s primary record. |
| Percentage of existing patients with a documented annual physical examination. |
| Percentage of existing patients with a diagnosis of HIV who received an oral cavity exam during the physical exam as documented in the patient’s primary record. |
**Initial laboratory tests, as clinically indicated by licensed provider**: Tests will include as clinically indicated:

- HIV Antibody, if not documented previously;
- CD4 Count and/or CD4 Percentage
- Quantitative Plasma HIV RNA (HIV Viral Load)
- Standard genotypic drug-resistance testing *Refer to Table 3 in the “Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV” for guidance on other scenarios where genotype testing is recommended*
- Co-receptor Tropism Test (if considering use of CCR5 co-receptor antagonist or for patients who exhibit virologic failure on a CCR5 antagonist)
- HLA-B*5701 testing (only before initiating abacavir-containting regimen per guidelines)
- Complete Blood Count (CBC) with Differential and Platelets
- Chemistry Profile: Electrolytes, Creatinine, Blood Urea Nitrogen (BUN)
- Liver Transaminases, Bilirubin (Total and Direct)
- Urinalysis with Urine Protein and Creatinine
- Quantitative HCV RNA viral load testing (for Hepatitis C (HCV)-positive patients who are candidates for treatment)
- Hepatitis A antibody, Hepatitis B surface antigen, core Ab, and surface antibody & Hepatitis C antibody screens at initial intake (providers should screen all HIV-infected patients for anti-HCV antibodies at baseline)
- Lipid Profile – random or non-fasting (Total Cholesterol, LDL, HDL, Triglycerides)
- Glucose (random or non-fasting) or hemoglobin A1C
- Pregnancy Test (for female clients of childbearing potential)
- RPR or treponemal antibody (Syphilis Screening)
- Gonorrhea (GC) and Chlamydia (CT) Testing
- *Toxoplasma gondii* IgG
- Trichomoniasis Testing

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2 Initial Laboratory Tests: [https://aidsinfo.nih.gov/guidelines/htmltables/1/7267](https://aidsinfo.nih.gov/guidelines/htmltables/1/7267), see Table 3.
Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.


### Other diagnostic testing

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.

Chest x-ray will be completed if pulmonary symptoms are present; if positive LTBI test (either TST or Interferon Gamma Release Assay (IGRA)); or if prior evidence of LTBI or pulmonary TB (perform annually).


### Initial Screenings/Assessments

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.

Patients should receive screening for opportunistic infections and assessment of psychosocial needs initially and annually according to the most current HHS guidelines.

Screening should include at a minimum:

- Mental health assessment that includes screening for clinical depression (PHQ 2 at a minimum)
- Psychosocial assessment, including domestic violence and housing status
- Substance use and abuse screening
- Tobacco use screening

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Pediatric patients (14 years and younger) will be screened for child abuse as defined in Chapter 261 of the Texas Family Code and DSHS policy. Consider screening youth 14-17 for child abuse.

- Oral health exam and assessment
- Tuberculosis (TB) Screening
- Cervical Cancer Screen (following the most current clinical recommendations)4
  - Women Aged <30 Years with HIV:
    - If younger than age 21, known to have HIV or newly diagnosed with HIV, and sexually active, Pap test should be performed within one (1) year of onset of sexual activity regardless of mode of HIV transmission.
  - Women Aged >30 Years with HIV
    - Pap Testing Only:
      - Pap test should be done at baseline and every 12 months
      - If results of three (3) consecutive Pap tests are normal, follow-up Pap tests can be performed every three (3) years

Additional screenings as medically indicated include:
- Dilated eye exam every 6 to 12 months if the CD4≤50 by an ophthalmologist

Anal Cancer (Dysplasia) Screening
The Anal Cancer (Dysplasia) Screening Guidelines recommend, at a minimum, annual digital examination to detect masses on palpation that could be anal cancer. However, performing the digital exam alone as a screening procedure for anal dysplasia or cancer will miss many lesions. Anal cancer screening using a Pap test can improve sensitivity for detecting anal dysplasia or cancer. Cytology combined with high-resolution anoscopy (HRA) is considered the best strategy for screening of precancerous lesions. If anal Pap


housing status.

Percentage of new patients with a diagnosis of HIV who have been screened for substance use (alcohol & drugs) in the measurement year. (HRSA HAB Measure)

Percentage of new patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user. (HRSA HAB Measure)

Percentage of new patients, if applicable, with completed child abuse assessment (completed if patient aged 14 years and younger).

Percentage of new patients aged three months and older with a diagnosis of HIV, for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for TB skin tests) as least once since the diagnosis of HIV. (HRSA HAB Measure)
is performed, clinicians should refer patients with abnormal anal cytology for HRA. In communities where HRA is not available, clinicians should consider referring patients with abnormal anal cytology to a surgeon for evaluation.


### Immunizations

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.

Immunizations/vaccinations will be given according to the most current HHS guidelines and the CDC’s “Table 2: Recommended Adult Immunization Schedule by Medical Condition and Other Indications, US 2019.” See: [https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html](https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html)

Providers will initiate prophylaxis for specific opportunistic infections.

Patients will be offered vaccinations for the following:

- Tetanus, Diphtheria, and Pertussis (Tdap) per recommended treatment guidelines for immunizations.
- Measles, Mumps, Rubella (MMR) per recommended treatment guidelines for immunizations. Adults and adolescents with a CD4 cell count <200 cells/uL should not receive MMR.
- Influenza (inactivated vaccine) - annually during flu season October 1st - March 31st
- Pneumococcal is recommended for all patients, two separate vaccines are recommended:
  - Receive a dose of PCV13, (Prevnar 13), followed by a dose of PPV23 (Pneumovax) at least eight (8) weeks later. For specific guidance on doses and frequency see: [https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html](https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html)

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• Completion of Hepatitis B (HBV) vaccines series, unless otherwise documented as immune, vaccinated patients should be tested for HBsAb response 1–2 months or at the next scheduled clinic visits after the third dose see: https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/365/figure--immunization

• Completion of Hepatitis A (HAV) vaccines series, unless otherwise documented as immune.


*HPV vaccine: The 2019 ACIP recommends and DHHS states: “because of the potential benefit in preventing HPV-associated disease and cancer in this population, HPV vaccination is recommended for HIV infected males and females aged 13 through 26. For persons 27-45, ACIP recommends a conversation between provider and client regarding vaccine for this age group.

• For providers who need vaccine to provide their patients at no cost to the provider, please reference: https://www.dshs.texas.gov/immunize/ASN/providers.aspx

• For providers who want to refer their patients out for vaccines that are offered at no cost or reduced cost, please reference: https://www.dshs.texas.gov/immunize/ASN/public.aspx

<table>
<thead>
<tr>
<th>Antibiotic Treatment (Recommend Prophylactic Antibiotic Treatment)</th>
<th>Percentage of patients, regardless of age, who are offered MAC Prophylaxis as medically indicated.</th>
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<tbody>
<tr>
<td>Antibiotic prophylaxis for opportunistic infections will be initiated if active infection has been ruled out and the following conditions are met:</td>
<td>Pneumocystis prophylaxis should be discontinued in adult and adolescent patients who have responded to ART with an increase in CD4 counts from &lt;200 cells/mm3 to &gt;200 cells/mm3 for &gt;3 months.</td>
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<tr>
<td>• Mycobacterium avium complex (MAC): if CD4 &lt;50</td>
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<tr>
<td>• Toxoplasmosis: if CD4 &lt;100 and toxoplasma IgG is positive</td>
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<tr>
<td>• PCP Prophylaxis will be completed adhering to the current HHS Guidelines.</td>
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### Preventing 1st Episode of PCP (Primary Prophylaxis)

**Indications for Initiating Primary Prophylaxis:**
- CD4 count <200 cells/mm³ or
- CD4% <14% of total lymphocyte count or
- CD4 count >200 but <250 cells/mm³, if ART cannot be initiated, and if CD4 cell count monitoring (e.g., every 3 months) is not possible


### Anti-retroviral Therapy (ART):

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.

ART will be prescribed in accordance with the HHS established guidelines.

Patients who meet current guidelines for ART are offered and/or prescribed ART.


### Drug Resistance Testing

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.


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Drug resistance testing must follow most recent, established resistance testing guidelines, including genotypic testing on all ARV-naïve patients.

Counseling and education about drug resistance testing must be provided by the patient’s medical practitioner, registered nurse and/or other appropriate licensed healthcare provider (if designated by the practitioner).


**Drug-Resistance Assay Not Usually Recommended**

- **After therapy is discontinued:** Drug-resistance testing is not usually recommended more than 4 weeks after ARV drugs are discontinued.
- **In patients with low HIV RNA levels:** Drug-resistance testing is not usually recommended in patients with a plasma viral load of <500 copies/mL.

**Health Education/Risk Reduction**

Health education will adhere to the most current HHS guidelines.

Providers will provide routine HIV risk-reduction counseling and behavioral health counseling for HIV-infected patients.

Since patients’ behaviors change over time as the course of their disease changes and their social situations vary, health education providers will tailor routine risk-reduction counseling and behavioral health counseling not only to the individual patient but also to the particular point in time in the patient’s life.

The following will be conducted initially and as needed:

| Percentage of patients with a diagnosis of HIV who received HIV risk counseling in the measurement year. **(HRSA HAB Measure)** |
| Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user. **(HRSA HAB Measure)** |
| Percentage of patients with documented counseling about family planning method appropriate to patient’s status, as applicable. |
- Providers should discuss safer sexual practices so to decrease risk of transmitting HIV.
- Providers should counsel HIV-infected patients about the risk of acquiring syphilis and other STIs from unprotected sexual contact, including all sites of possible transmission, such as anus, cervix, vagina, urethra, and oropharynx.
- Providers should discuss family planning with patients
- Contraception counseling/hormonal contraception
- Drug interaction counseling
- Providers should counsel patients on tobacco cessation annually for those patients that were screened and positive for smoking (or document decline of tobacco use)
- When current alcohol or other substance use is identified, providers should discuss the possible effects of such use on the patient’s general health and HIV medications, as well as options for treatment if indicated
- Providers should routinely discuss with patients the importance of disclosure to partners. Patients should be educated about the options for voluntary partner notification.
- When HIV patients are diagnosed with early syphilis (primary, secondary, or early latent), providers should intensify risk-reduction counseling, including discussions about the importance of condom use.
- Nutritional Counseling regarding:
  - Quality and quantity of daily food and liquid intake
  - Exercise (as medically indicated)

**Source:** (Smoking Cessation) page 189-196; https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf.


| Percentage of patients with documented instruction regarding new medications, as appropriate. | Percentage of patients with documented counseling regarding the importance of disclosure to partners. |
**Treatment Adherence**
Assessment of treatment adherence and counseling will be provided that adheres to current HHS guidelines.

Patients are assessed for treatment adherence and counseling at a minimum of twice a year.

Those who are prescribed on-going ART regimen must receive adherence assessment and counseling on every HIV-related clinical encounter.

If adherence issue is identified by another member of the healthcare team (MCM, MA, LVN, RN), there is documented evidence of adherence counseling and follow-up action. This adherence counseling documentation must be evident in the patient’s medical record and clearly indicated that the prescribing provider was made aware of the adherence issue.


<table>
<thead>
<tr>
<th>Percentage of patients with documented assessment for treatment adherence two or more times within the measurement year if patient is on ART.</th>
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<tbody>
<tr>
<td>Percentage of patients with documented adherence issues who received counseling for treatment adherence two or more times within the measurement year.</td>
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**Referrals**
Providers will refer to specialty care or other systems as appropriate in accordance with current HHS guidelines.

At a minimum, patients should receive referrals to specialized health care/providers/services *as needed or medically indicated* to augment medical care:
- AIDS Drug Assistance Program (ADAP)
- Medication Assistance Programs
- Medical care coordination
- Medical specialties
- Mental health and substance use services -Treatment education services
- Partner counseling and referral
- Annual oral hygiene and intraoral examinations, including dental caries

<table>
<thead>
<tr>
<th>Percentage of patients, as medically indicated, who had documentation of referrals for:</th>
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<tbody>
<tr>
<td>Mental Health and/or Substance Use</td>
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<tr>
<td>Oral Health</td>
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<tr>
<td>Ophthalmological services</td>
</tr>
<tr>
<td>Child abuse if suspected abuse</td>
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<tr>
<td>Disease intervention specialist</td>
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<tr>
<td>Other specialty services.</td>
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| Percentage of patients with a documented referral in the measurement year, has a progress note in the patient’s chart regarding attendance, and outcomes of the referral. |
and soft-tissue examinations.

- Medical Nutrition Therapy (MNT)
- Health maintenance, as medically indicated, such as:
  - Cervical Cancer Screening
  - Family Planning
  - Colorectal cancer screening
  - Breast cancer screening
- Specialty medical care for any preexisting chronic diseases
- Case Management Services or a Disease Investigation Specialist (DIS) for follow-up if missing appointments.
- Vision Care
- Audiology

Providers/staff are expected to follow-up on each referral to assess attendance and outcomes. For specific details regarding screening modalities and timeframes see: the United States Preventive Services Task Force (http://www.ahrq.gov/clinic/USpstfix.htm).


### Follow-up Visits

Outpatient Medical Care will adhere to the current HHS guidelines for ongoing health care.

Reassessment/reevaluation of health history, comprehensive physical examination, and annual laboratory testing should be documented in patient medical record.

All HIV patients should have the following lab tests documented:
- Annually: urinalysis, with urine protein and creatinine; fasting lipid profile; syphilis screening; and gonorrhea and chlamydia testing (screen all sites of possible exposure). These tests may need to be performed more frequently, if clinically indicated.

<table>
<thead>
<tr>
<th>Percentage of existing patients with documented initial medical screenings and assessments as indicated in the OAHS Standard and in accordance with HHS guidelines.</th>
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<tbody>
<tr>
<td>Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits. (HRSA HAB Measure)</td>
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<tr>
<td>Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year. (HRSA HAB Measure)</td>
</tr>
<tr>
<td>Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year. (HRSA HAB Measure)</td>
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</table>
Every 3-6 months\(^9\): HIV-RNA viral load; CBC with differential; chemistry profile (to include electrolytes, BUN, creatinine, HCO\(_3\), estimated GFR); liver function tests (to include transaminases, total and direct bilirubin); and glucose\(^10\) (preferably fasting) or hemoglobin A1c. These tests may need to be performed more frequently, if clinically indicated.

Providers will continually evaluate patients for adverse outcomes and documents actions taken, outcomes, and follow-up.


\(^9\) Please reference: https://aidsinfo.nih.gov/guidelines/htmltables/1/5570, see Table 3.

\(^10\) Fasting Glucose or Hemoglobin A1c Annually and only every 2-6 months if the last measurement was abnormal. Please reference https://aidsinfo.nih.gov/guidelines/htmltables/1/5570, see Table 3.
Percentage of existing patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user. *(HRSA HAB Measure)*

Percentage of existing patients, if applicable, with completed child abuse assessment (completed if patient aged 14 years and younger).

Percentage of existing patients aged three (3) months and older with a diagnosis of HIV, for whom there was documentation that a tuberculosis (TB) screening test was performed and results interpreted (for TB skin tests) as least once since the diagnosis of HIV. *(HRSA HAB Measure)*

Percentage of existing patients, regardless of age, for whom Hepatitis B screening was performed at least once since the diagnosis of HIV or for whom there is documented infection or immunity. *(HRSA HAB Measure)*

Percentage of existing patients for whom HCV screening was performed at least once since the diagnosis of HIV. *(HRSA HAB Measure)*

Percentage of patients, regardless of age, with a diagnosis of HIV who were prescribed HIV ART and who had a fasting lipid panel during the measurement year. *(HRSA HAB Measure)*

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**Documentation in Patients’ Medical Chart**

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. Clinicians (included but not limited to Providers with prescriptive authority, PharmD, PhD, LCSW, LCDC, RN, LVN, MA or MCM) will develop/update plan of care at each visit.

Percentage of patient medical records with signed clinician entries.

Percentage of flow sheets present and updated in the patient medical records.
If a patient refuses a treatment, such as vaccinations, documentation of denial will be written in the patient's medical chart.

The provider developing the plan will sign each entry.


| Percentage of problem lists present and updated in the patient medical records. |
| Percentage of medication lists present and updated in the patient medical records. |

### Documentation of missed patient appointments and efforts to bring the patient into care.

Provider and/or staff will conduct the following:
- Contact patients who have missed appointments, using at least 3 different forms of contact (phone, mail, emergency contact, phone call, referral to DIS for home visit) prior to determining they are lost to follow-up;
- Address any specific barriers to accessing services;
- Document number of missed patient appointments and efforts to bring the patient into care.


| Percentage of patient medical records with documentation of any specific barriers and efforts made to address missed appointments. |

### Perinatally Exposed Infants: Neonatal Zidovudine (ZDV) Prophylaxis

All newborns perinatally exposed to HIV should receive postpartum antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV.

Newborn ARV regimens—at gestational-age-appropriate doses—should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery.

The selection of a newborn ARV regimen should be determined based on maternal and infant factors that influence risk of perinatal transmission of HIV.


| Percentage of infants born to HIV + women who were prescribed ZDV prophylaxis for HIV within 12 hours of birth during the measurement year. *(HRSA HAB Measure)* |
The uses of ARV Regiments in Newborns include:

- **ARV Prophylaxis:** The administration of one or more ARV drugs to a newborn without documented HIV infection to reduce the risk of perinatal acquisition of HIV.

- **Empiric HIV Therapy:** The administration of a three-drug ARV regimen to newborns at highest risk of perinatal acquisition of HIV. Empiric HIV therapy is intended to be preliminary treatment for a newborn who is later documented to have HIV but also serves as prophylaxis against HIV acquisition for those newborns who are exposed to HIV in utero, during the birthing process, or during breastfeeding and who do not acquire HIV.

- **HIV Therapy:** The administration of a three-drug ARV regimen at treatment dosages (antiretroviral therapy [ART]) to newborns with documented HIV infection.

Providers with questions about ARV management of perinatal HIV exposure should consult the National Perinatal HIV Hotline (1-888-448-8765), which provides free clinical consultation on all aspects of perinatal HIV, including newborn care.

All newborns with perinatal exposure to HIV should receive antiretroviral (ARV) drugs in the neonatal period to reduce perinatal transmission of HIV, with selection of the appropriate ARV regimen guided by the level of transmission risk.

- The most important factors that influence the risk of HIV transmission to a newborn exposed to HIV are whether the mother has received antepartum/intrapartum antiretroviral therapy (ART) and her viral load.
- The risk of transmission is increased in the absence of maternal ART or if maternal antepartum/intrapartum treatment was started after early pregnancy or was ineffective in producing virologic suppression; higher maternal viral load, especially in later pregnancy, correlates with higher risk of transmission.

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There is a spectrum of transmission risk that depends on these and other maternal and infant factors, including mode of delivery, gestational age at delivery, and maternal health status. HIV transmission can occur in utero, intrapartum, or during breastfeeding.

Drug selection and dosing considerations are related to the age and gestational age of the newborn. Consultation is available through the National Perinatal HIV Hotline (888-448-8765).

**Diagnostic Testing to Exclude HIV Infection in Exposed Infants.**

Newborns Born to Mothers Who Received Antepartum/Intrapartum Antiretroviral Drugs with Effective Viral Suppression: According to the US Department of Health and Human Services, (DHHS) the risk of HIV acquisition in newborns born to women who received ART regimens during pregnancy and labor and had undetectable viral loads at delivery is <1%.

- DHHS recommends a 4-week neonatal zidovudine prophylaxis regimen for newborns if the mother has received ART during pregnancy with viral suppression (usually defined as confirmed HIV RNA level below the lower limits of detection of an ultrasensitive assay) at or after 36 weeks’ gestation, and there are no concerns related to maternal adherence.

Percentage of infants born to HIV + women who received recommended virologic diagnostic testing for exclusion of HIV infection in the measurement year. *(HRSA HAB Measure)*

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**Newborns Born to Mothers with Unknown HIV Status at Presentation in Labor**

- Expedited HIV testing is recommended during labor for women with unknown HIV status and, if not performed during labor, as soon as possible after birth for the mothers and/or their newborns (see Identification of Perinatal Exposure). Expedited test results should be available within 60 minutes.
- If maternal or infant expedited testing is positive, the newborn should be immediately initiated on a multi-drug ARV prophylaxis regimen or empiric HIV therapy, without waiting for the results of supplemental tests.
- Expedited HIV testing should be available on a 24-hour basis at all facilities with a maternity service and/or neonatal intensive care unit or special care or newborn nursery.
- A nursing mother who is suspected of having HIV based on an initial positive antibody or antibody/antigen test result should stop breastfeeding until HIV is confirmed or ruled out.
- Breastfeeding is not recommended for women with confirmed HIV in the United States, including those receiving ART.

**Newborns Born to Mothers with Antiretroviral Drug-Resistant Virus**

- The optimal ARV regimen for newborns delivered by women with ARV drug-resistant virus is unknown. The ARV regimen for newborns born to mothers with known or suspected drug resistance should be determined in consultation with a pediatric HIV specialist before delivery or through consultation via the [National Perinatal HIV Hotline](tel:888-448-8765) (888-448-8765).
- Data exist to provide dosing recommendations appropriate for the treatment of HIV in neonates.\(^\text{13}\)

**For Comprehensive Guidance Please See:**

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\(^\text{13}\) Please reference: [https://aidsinfo.nih.gov/guidelines/html/2/pediatric-arv/0](https://aidsinfo.nih.gov/guidelines/html/2/pediatric-arv/0)
References

American College of Obstetricians and Gynecologists (ACOG); 2011 Aug. 11 p. (ACOG practice bulletin; no. 122)


Commission on HIV. (2010). Medical Outpatient Standards of Care, Department of Health Services, Los Angeles. (available online at http://hivcommission-la.info/cms1_122082.pdf)


MMWR (January 31, 2014 / 63(04); 69-72) CDC Grand Rounds: Reducing the Burden of HPV- Associated Cancer and Disease (available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6304a1.htm?s_cid=mm6304a1_w)


Primary Care Guidelines for Management of HIV. CID 2014:58 (1 January).


Recommended Immunization Schedule for Adults Aged 19 Years or Older. United States. 2017 Advisory Commission on Immunization Practices, Figure 2.
