

Outpatient/Ambulatory Health Services

Health Resources and Services Administration Definition: Outpatient/Ambulatory Health Services provide diagnostic and therapeutic-related activities directly to a client by a licensed healthcare provider in an outpatient medical setting. Outpatient medical settings may include clinics, medical offices, mobile vans, using telehealth technology, and urgent care facilities for HIV-related visits.

Allowable activities include:

- Medical history taking
- Physical examination
- Diagnostic testing, (including HIV confirmatory and viral load testing), as well as 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
- Education and counseling on health and prevention issues
- Referral to and provision of specialty care related to HIV diagnosis, including audiology and ophthalmology

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

Diagnostic Laboratory Testing includes all indicated medical diagnostic testing including all tests considered integral to the treatment of HIV and related complications (e.g. Viral Load, CD4 counts/percentage, 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 approved by the FDA, when required under the FDA Medical Devices Act and/or performed in an approval Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified laboratory or State exempt laboratory.
- Tests must be ordered by a registered, certified or licensed medical provider and necessary and appropriated based on established clinical practice standards and professional clinical judgment.

Program Guidance: Treatment adherence activities provided during an Outpatient/Ambulatory Health Service visit are considered Outpatient/Ambulatory Health Services, whereas treatment

adherence activities provided during a Medical Case Management visit are considered Medical Case Management services.

Non-HIV related visits to urgent care facilities are not allowable costs within the Outpatient/Ambulatory Health Services Category.

Emergency room visits are not allowable costs within the Outpatient/Ambulatory Health Services Category.

Note: Outpatient/Ambulatory Health Services in the Orlando Service Area shall not include coverage for urgent care facilities for non-HIV and/or HIV-related visits.

Eligibility: Clients shall meet eligibility requirements as defined in the System-Wide Service Standards.

1.0 Treatment Guideline Standards and Measures

The agencies shall ensure compliance with the most current U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), [HHS HIV Clinical Practice Guidelines, Guide for HIV/AIDS Clinical Care—2014 Edition](#) as cited in the following standards.

1.0 Treatment Guideline Standards and Measures

| Standards | Measure |
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| <p>1.1 Initial Medical Evaluation/Assessment: People with HIV (PWH) <u>entering care shall receive a comprehensive initial medical evaluation conducted by a licensed provider as soon as possible after diagnosis and preferably within 30 days of entry into care.</u></p> <p><u>Required Components:</u></p> <ul style="list-style-type: none"> • <u>Comprehensive HIV medical history</u> • <u>General medical history</u> • <u>Psychosocial assessment</u> • <u>Behavioral risk assessment</u> • <u>Medication history (including prior ART exposure)</u> • <u>Mental health and substance use screening</u> • <u>Alcohol use screening</u> • <u>Sexual health assessment</u> • <u>Social determinants of health assessment (housing, insurance, transportation)</u> <p>accessing primary medical care shall have a completed comprehensive medical evaluation/assessment and physical examination that adheres to the current HHS</p> | <p>1.1. Documentation in client's electronic health record.</p> |

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| <p>treatment guidelines within 3 months of HIV diagnosis and annually thereafter.</p> | |
| <p>1.2 Initial Comprehensive HIV related history: History shall include at a minimum, general medical history, a comprehensive HIV related history and psychosocial history. <u>Merged with 1.1</u></p> | <p>1.2 Documentation in client's electronic health record.</p> |
| <p>1.2 <u>Rapid Initiation of Antiretroviral Therapy (ART):</u> <u>Antiretroviral therapy (ART) should be initiated as soon as possible for all people with HIV, regardless of CD4 count. Programs should support rapid or same-day ART initiation whenever clinically appropriate.</u></p> <p><u>Note: It is recommended that providers initiate ART within three to seven calendar days from the initial contact with the client's OAHS agency.</u></p> | <p>1.2 <u>Documentation in client's electronic health record.</u></p> <p><u>Documentation that ART was offered or prescribed.</u></p> <p><u>If ART is delayed (more than seven calendar days), the clinical reason must be documented.</u></p> |
| <p>1.3 Physical Examination: Providers shall perform a complete history and physical examination upon entry to care and thereafter at least 1 per year.</p> <p>Objective assessment:</p> <ul style="list-style-type: none"> • Patient's general appearance | <p>1.3 Documentation in client's electronic health record.</p> |

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| <ul style="list-style-type: none"> • Patient's affect and demeanor in answering questions • Body language • Other relevant characteristics • Measure vital signs • Perform physical examination | |
| <p>1.4 <u>Baseline Laboratory Testing</u></p> <p><u>Initial laboratory testing shall include:</u></p> <ul style="list-style-type: none"> • <u>HIV antigen/antibody testing (if prior documentation is not available or if HIV RNA is below the assay's limit of detection)</u> • <u>Plasma HIV RNA (viral load)</u> • <u>CD4 T lymphocyte (CD4) cell count (AI)</u> • <u>Drug resistance genotype testing</u> • <u>Complete blood count (CBC)</u> • <u>Comprehensive metabolic panel (CMP)</u> • <u>Hepatitis A, B, and C screening</u> • <u>Tuberculosis screening</u> • <u>Lipid panel</u> • <u>Urinalysis</u> • <u>Sexually transmitted infections screening</u> • <u>Opportunistic infections screening</u> • <u>Cancer screening</u> • <u>Pregnancy testing for persons of child-bearing potential</u> <p><u>Additional laboratory testing may be ordered as clinically indicated.</u></p> <p>Initial laboratory tests, as clinically indicated by licensed provider.</p> | <p>1.4 Documentation in client's electronic health record.</p> |

1.5 Viral Load and CD4 Monitoring

The following laboratory testing schedule provides general guidance for laboratory monitoring for people with HIV before and after antiretroviral therapy (ART) initiation. Clinicians should use their clinical judgment to determine the monitoring frequency for an individual person based on clinical needs. This schedule is not intended to be a guide on how often people with HIV should undergo clinical evaluation, as some individuals may need to be seen more frequently to accomplish other aspects of clinical care.

Viral Load Monitoring:

- At entry into care
- ART Initiation or Modification
- 4–8 weeks after ART initiation
- Every 3–4 months thereafter
- Every 6 months for stable patients with sustained viral suppression
- Treatment Failure
- Clinically Indicated

CD4 Monitoring:

- At entry to care
- 3 months (after ART initiation only)
- Every 3–4 months If CD4 count is <300 cells/mm³
- Every 6 months during the First 1-2 Years on ART and With Viral Suppression, if CD4 count is ≥ 300 cells/mm³
- Optional unless clinically indicated after 1-2 Years on ART With Consistently Suppressed Viral Load and CD4 Count >300 cells/mm³
- Treatment Failure monitor CD4 count every 3-6 months.
- Clinically Indicated

1.5 Documentation in client's electronic health record

1.65 Opportunistic Infection Prevention and Treatment

Providers shall follow current national guidelines for prophylaxis and treatment of opportunistic infections.

Examples include:

PCP prophylaxis for CD4 <200

Toxoplasmosis prophylaxis for CD4 <100

MAC prophylaxis for CD4 <50 when not on fully suppressive ART

- CD4 count 100-200 cells/mm³, if plasma HIV RNA level above detection limits (AI), or
- CD4 count <100 cells/mm³, regardless of plasma HIV RNA level (AIII)
- Mycobacterium avium complex (MAC) prophylaxis for CD4 <50 when not on fully suppressive ART
- Toxoplasma IgG positive patients with CD4 count <100 cells/mm³ (AIII)

Labs listed in 1.1 and 1.4:

Initial Screenings/Assessments: Screening should include at a minimum:

- Quantitative HIV RNA viral load testing
- Hepatitis A, B & C screens at initial intake
- Mental health assessment that includes screening for clinical depression
- CD4_i
- CBC_i
- CMP
- UA
- Drug Resistance Testing
- Psychosocial assessment
- Substance use and misuse screening
- Alcohol use screening
- Patients on ART receive lipid screening at least annually
- Tobacco use screening
- Oral health assessment and screening
- Cervical/Anal Cancer Screening
- Breast Cancer Screening
- Tuberculosis (TB) Screening (T-spot or Quantiferon)
- Serum VDRL or RPR (Syphilis Screening)
- Gonorrhea (GC) and Chlamydia (CT) Testing

1.65 Documentation of prophylactic treatment, as appropriate in client's electronic health record

~~Documentation in client's electronic health record.~~

- **Pregnancy Test for females**

1.76 Immunizations:/Antibiotic Treatment:
Clients shall be assessed for and offered recommended vaccinations according to current CDC and HHS immunization guidelines for people with HIV, as medically indicated.

Recommended vaccines include:

- COVID-19
- Hepatitis A Virus (HAV)
- Hepatitis B Virus (HBV)
- Human Papillomavirus (HPV)
- Influenza
- Measles, Mumps, and Rubella (MMR)
- Meningococcus Serogroup A, C, W, Y (MenACWY)
- Meningococcus Serogroup B (MenB)
- Mpox
- Pneumococcal
- Respiratory Syncytial Virus (RSV)

1.76 Documentation of vaccine or refusal thereof in client's electronic health record.

- Tetanus, Diphtheria, and Pertussis
- Varicella (Chickenpox)
- Zoster

~~Patients will be offered vaccinations for the following:~~

- ~~• Pneumococcal is recommended for all clients~~
- ~~• Completion of hepatitis B (HBV) vaccines series, unless otherwise documented as immune~~

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| <ul style="list-style-type: none"> • Completion of hepatitis A (HAV) vaccines series, unless otherwise documented as immune. • Varicella-Zoster (VZV) • Zoster vaccine • Meningitis • Influenza <p><u>Listed in 1.6</u></p> <p>Antibiotic treatment for opportunistic infection will be initiated if active infection has been ruled out and positive for:</p> <ul style="list-style-type: none"> • Mycobacterium avium complex (MAC) if CD4 < 50 cells/μL • Toxoplasmosis if CD4 < 100 cells/μL <p>*HPV vaccine is recommended for females and males up to age 45; given as a three-dose regimen over 6 months.</p> | <p>Documentation of prophylactic treatment, as appropriate in client's electronic health record.</p> |
| <p>4.7 <u>Listed in 1.2</u></p> <p>Antiretroviral Therapy (ART) and Pneumocystis jirovecii pneumonia (PCP) Prophylaxis: Antiretroviral therapy shall be prescribed in accordance with the HHS established guidelines.</p> <p>Patients who meet current guidelines for ART are offered and/or prescribed ART.</p> <p>PCP Prophylaxis shall be completed adhering to the current HHS Guidelines.</p> | <p>4.7 Documentation of ART in client's electronic health record.</p> |
| <p>1.8 <u>Preventive Care and Screening</u></p> <p><u>Routine preventive care shall include screening for:</u></p> <ul style="list-style-type: none"> • <u>Sexually transmitted infections</u> • <u>Cervical cancer</u> • <u>Anal cancer (when indicated)</u> • <u>Breast cancer</u> • <u>Colorectal cancer</u> • <u>Cardiovascular disease risk</u> • <u>Diabetes</u> • <u>Kidney disease</u> • <u>Depression and mental health conditions</u> <p><u>Substance use disorders</u></p> | <p>1.8 <u>Documentation of Preventive Care and Screening in client's electronic health record.</u></p> |

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| <p>1.98 Drug Resistance Testing: Drug resistance testing must follow most recent, established resistance testing guidelines, including genotypic testing on all naïve patients.</p> | <p>1.98 Documentation of drug resistance testing in client's electronic health record.</p> |
| <p>1.10 Health Education/Risk Reduction: Health education shall adhere to the most current HHS guidelines. Providers shall provide routine HIV risk-reduction <u>and adherence counseling</u>, and behavioral health counseling, for PWH at every visit.</p> <p><u>Providers shall ensure the following:</u></p> <ul style="list-style-type: none"> • <u>Antiretroviral Therapy (ART) Education</u> • <u>Adherence Counseling (Required at Each Visit)</u> • <u>HIV Transmission Risk Reduction</u> • <u>Engagement and Retention in Care</u> • <u>Behavioral Health and Substance Use</u> • <u>Reproductive and Sexual Health Counseling</u> • <u>Prevention of perinatal HIV transmission</u> • <u>Prevention and Management of Co-Occurring Conditions</u> • <u>Individualized, Culturally Responsive Education</u> • <u>Women of Childbearing age shall receive preconception counseling at every visit.</u> | <p>1.10 Documentation of Health Education/Risk Reduction counseling in client's electronic health record.</p> <p>Documentation of preconception counseling in client's <u>electronic health record</u>.</p> |

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| <p>1.11 0 Treatment Adherence: Assessment of treatment adherence and counseling shall be provided at every visit and adhere to current HHS guidelines.</p> <p><u>Adherence counseling may include:</u></p> <ul style="list-style-type: none"> • <u>Medication education</u> • <u>Barrier assessment</u> • <u>Referral to case management</u> • <u>Behavioral support services</u> | <p>electronic health record.</p> <p>1.11 0 Documentation in Client's electronic health record.</p> |
| <p>1.12 4 Follow-up Visits: Outpatient Medical Care shall adhere to the current HHS guidelines for on-going health care.</p> <p><u>Patients receiving ART shall be scheduled for follow-up visits:</u></p> <ul style="list-style-type: none"> • <u>Every 3–4 months for routine monitoring</u> • <u>Every 6 months for stable patients with sustained viral suppression and good adherence</u> <p><u>Clinical reassessment must include:</u></p> <ul style="list-style-type: none"> • <u>Updated medical history</u> • <u>Medication review</u> • <u>Adherence assessment</u> • <u>Mental health and substance use screening</u> • <u>Laboratory monitoring</u> • <u>Patients on ART receive lipid screening annually</u> <p>Reassessment/reevaluation of health history, comprehensive physical examination, and annual laboratory testing should be documented in patient medical record.</p> <p>Patients receiving ARV therapy (ART) shall have follow-up visits scheduled every three to four months, except at the practitioner's discretion when a patient has demonstrated long-term stability and adherence. Patients on ART receive lipid screening annually.</p> | <p>1.12 4 Documentation in Client's electronic health record.</p> |

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| <p>1.12 Documentation in Patients Charts: Advance directive in chart or documentation that advance directive has been discussed</p> <p>Clinicians shall develop/update plan of care at each visit. Problem list documented. Organized and complete medication list including past ART.</p> | <p>1.12 Documentation in Client's electronic health record.</p> |
| <p>1.13 Documentation of Missed Appointments: <u>Agencies shall implement procedures to re-engage clients who miss appointments.</u></p> <p><u>Documentation must include:</u></p> <ul style="list-style-type: none"> • <u>Attempts to contact the client</u> • <u>Barriers to care identified</u> • <u>Efforts to reschedule appointments</u> <p><u>Referrals for supportive services when appropriate</u></p> <p><u>Methods to attempt to contact the client may include, but are not limited to:</u></p> <ul style="list-style-type: none"> • <u>Phone calls</u> • <u>Text messages</u> • <u>Email</u> • <u>(Align with MCM, EIS, RS SS): This is re: exit interviews</u> <ul style="list-style-type: none"> ○ <u>Face-to-face visit;</u> ○ <u>Telephone; or</u> ○ <u>Written communication</u> <p>Efforts for Re-engagement with clients who have missed appointments shall be documented to include what prevented them from attending, offer to reschedule, and try to eliminate barriers to clinic attendance.</p> | <p>1.13 Documentation in Client's electronic health record.</p> |

2.0 Scope of Services (These are program specific policies and procedures)

Agencies shall comply with all of the requirements outlined in this Service Standard, unless otherwise specified in their contract.

2.0 Scope of Services

| Standards | Measures |
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| 2.1 Agencies shall have a written policy for making specialty care referrals in relation to the HIV diagnosis and for tracking such referrals with outcomes included in the client record. | 2.1 Policies and procedures available for review. |
| 2.2 Agencies shall ensure that specialty care services are not being provided in an emergency room, hospital, nursing home or any other type of inpatient treatment center. | 2.2 Documentation of verification of location in place. |
| 2.3 Agencies shall develop and maintain an appropriate relationship with entities that constitute key points of entry as defined by HRSA. | 2.3 Copy of Agreement or documentation of relationship showing key points of entry on file and documented referrals from these points of entry. |
| 2.4 Agencies shall have written policies and procedures for after hours, urgent and emergency care and treatment and referrals. | 2.4 Policies and procedures in place |
| 2.5 Agencies shall have written policies and procedures on the Imposition & Cap on Charges. | 2.5 Policies and procedures available for review. |
| 2.6 RWHAP services shall be integrated with other services and coordinated with other programs (including Medicaid) to enhance the continuity of care and prevention services for PWH. | 2.6 Policies and procedures for the coordination of services available for review. |
| 2.7 Agencies shall maintain program-wide clinical protocols for the following: <ul style="list-style-type: none"> • TB prophylaxis, diagnosis, treatment and referral • Hepatitis diagnosis, treatment and referral • STI diagnosis, treatment and referral • Plans for patients who experience a disruption in outpatient care • Tracking and coordination of inpatient care • Systematic tracking and monitoring for referrals including documentation of the referral outcome in the EHR | 2.7 Protocols/policies available for review. |

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| <ul style="list-style-type: none"> • Continuing annual HIV education for program staff on clinical advancements in HIV and familiarity with the most recent HHS guidelines • Documentation, implementation, and practice according to the HHS guidelines | |
| <p>2.8 Agencies shall maintain Memoranda of Understanding/Agreements or contracts that demonstrate coordination with other local, state, and/or private organizations that strengthen the care system for PWH and establishes a full range of service referrals.</p> | <p>2.8 MOUs, contracts, agreements available for review.</p> |
| <p>2.9 Agencies shall have a Clinical Quality Management infrastructure that has leadership, a CQM committee, dedicated staffing, dedicated resources, a written quality management plan, PWH involvement, stakeholder involvement, and a CQM program evaluation mechanism.</p> | <p>2.9 CQM plan that meets HAB PCN-15-02 available for review.</p> |