

**AIDS PHARMACEUTICAL ASSISTANCE
(LOCAL PHARMACEUTICAL ASSISTANCE PROGRAM – LPAP)**

(Year 33 Service Priority: #3 for Part A)

- A. AIDS Pharmaceutical Assistance (Local Pharmaceutical Assistance Program – LPAP)** is a core medical service. The purpose of the LPAP component (i.e., prescription drug services) of the AIDS Pharmaceutical Assistance service category, in accordance with federal Ryan White Program guidelines, is “to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.” LPAPs must be compliant with the Ryan White HIV/AIDS Program’s requirement of payer of last resort.

This service includes the provision of medications and related supplies prescribed or ordered by a Physician or other licensed medical practitioner to prolong life, improve health, or prevent deterioration of health for people with HIV who are ineligible for Medicaid, Medicare Part D, ADAP, or other public sector funding, or have private insurance with limited or no prescription drug coverage. Supplies are limited to consumable medical supplies necessary for the administration of prescribed medications.

IMPORTANT NOTES: Services are restricted to outpatient services only. Inpatient, emergency room, and urgent care center prescription drug services are not covered. Vaccines provided during a medical office visit are no longer found in the local Ryan White Part A Program Prescription Drug Formulary but may be available under Outpatient/Ambulatory Health Services. Prescription drug copayment assistance is not provided for clients with prescription drug discount cards. LPAP services may not be provided on an emergency basis (defined as a single occurrence of short duration). See the General Revenue Short-term Medication Assistance protocol in Section XII of this FY 2023 Ryan White Program Service Delivery Manual for information on how to access to medications on a short-term, emergency basis.

- 1. Medications Provided:** This service pays for injectable and non-injectable prescription drugs, pediatric formulations, appetite stimulants, and/or related consumable medical supplies for the administration of medications. Medications are provided in accordance with the most recent release of the local Ryan White Part A Program Prescription Drug Formulary, with the Ryan White Part A/MAI Program as the payer of last resort. The local Ryan White Part A Program Prescription Drug Formulary is subject to change due to guidance from HRSA, the federal granting agency, and/or the Miami-Dade HIV/AIDS Partnership’s Medical Care Subcommittee.

2. Client Education and Adherence:

- Providers are expected to educate clients on the importance of adhering to their medication regimen with the objectives of reducing the risk of developing and spreading a resistant virus, and to ensure a healthy life for the client.
- Providers are expected to offer basic education to clients on various treatment options, including information about state-of-the-art combination drug therapies.
- Clients must be encouraged to take medications as prescribed, as well as to follow the recommendations made by Physicians, Nutritionists, and Pharmacists regarding medication management.

3. Coordination of Care:

- Providers must maintain appropriate contact with other caregivers (i.e., the client's Medical Case Manager, Physician, Nutritionist, Counselor, etc.) and with the client in order to monitor that the client adheres to their medication regimen; and ensures that the client receives coordinated, interdisciplinary support for adherence, and assistance in overcoming barriers to meeting treatment objectives.
- Providers will be expected to immediately inform Medical Case Managers when clients are not adhering to their medication regimen (i.e., the client misses prescription refills, misses physician visits, or is having other difficulties with treatment adherence).
- Providers are expected to ensure immediate follow-up with clients who miss their prescription refills, physician visits, and/or who experience difficulties with treatment adherence.

B. Program Operation Requirements:

- Providers are encouraged to provide county-wide delivery. However, Ryan White Program funds may not be used to pay for the delivery of medications or consumable medical supplies unless one of the following conditions is met by the client, is documented by the client's Physician, and said documentation is maintained in the client's chart:
 - 1) The client is permanently disabled (condition is documented once);

- 2) The client has been examined by a Physician and found to be suffering from an illness that significantly limits the client's capacity to travel [condition is valid for the period indicated by the Physician or for sixty (60) calendar days from the date of certification].

IMPORTANT NOTE: Medical Case Managers requesting home delivery must have documentation on file that meets one of the conditions listed above.

- Providers must specify provisions for home delivery of medications and related supplies and equipment for eligible Ryan White Program clients who require this service.
- Providers of this service are expected to be Covered Entities authorized to dispense PHS 340B-priced medications either directly, through an allowable subcontract arrangement, or via another federally acceptable affiliation.
 - Clients needing this service may only go to, or be referred to, the pharmacy in which their HIV/Primary Care Physician or prescribing practitioner is located or affiliated with (e.g., by subcontract, etc.). This is due to PHS 340B Pharmacy drug pricing limitations, and HRSA's requirements that the Ryan White Part A/MAI Program use PHS 340B drug pricing wherever possible.
 - If the provider is a PHS 340B covered entity and the client is enrolled in the Florida ADAP Program, that client is eligible for PHS 340B pricing for prescriptions not covered by the ADAP formulary regardless of whether or not the client is the agency's own client.
- Pharmacy providers are directed to use the most cost-effective product, either brand name or generic name, whichever is less expensive at the time of dispensing. An annual, signed assurance is required from the service provider regarding this directive.
- The LPAP-funded service provider must be linked to an existing Medical Case Management system through agreements with multiple Medical Case Management providers. Providers are contractually required to enter into formal referral agreements that detail responsibilities of both parties and penalties for not complying with the referral agreement.

A Ryan White Program In Network Referral for LPAP Services is not required. However, to access LPAP services, the client must be open at the LPAP-funded agency and must have their Client Service Category Profile in the Provide® Enterprise Miami data management system open to Outpatient/Ambulatory Health Services at the same agency. This is due to 340B covered entity drug pricing requirements.

Ryan White Program-funded LPAP services have a maximum of five (5) refills plus the original fill, regardless of recertification dates. However, if during the recertification process it is determined that the client is no longer eligible for Ryan White Program services or the client has missed their recertification deadline, the Medical Case Manager must immediately notify the pharmacy to cancel the remaining refills.

C. Rules for Reimbursement: Dependent on the type of pharmacy provider, please adhere to the following reimbursement structures.

- Where applicable, providers will be reimbursed for program-allowable prescription drugs based on the PHS 340B price of the prescription provided to the Ryan White client, plus a flat rate dispensing fee. Total costs should include the cost of home delivery, as allowable, and other direct costs associated with the provision of this service. Providers must stipulate the flat rate dispensing fee that will be added to the PHS price. (For example, if the PHS price of a prescription is \$185.00, and the provider's proposed flat rate dispensing fee is \$11.00, then the total reimbursement amount is equal to \$196.00.) An estimate of the number of clients (unduplicated caseload) expected to receive these services must be included on the corresponding budget narrative.
- Reimbursement for consumable medical supplies is limited and must be related to administering medications (e.g., for insulin injection in diabetics, etc.). Approved consumable medical supplies are found in Attachment B of the most current, local Ryan White Program Prescription Drug Formulary.
- No multiplier will be applied to Medicare or Medicaid rates for consumable medical supplies.

D. Additional Rules for Reporting and Documentation: Providers must document client eligibility for this service and report monthly activity (i.e., through reimbursement requests) in terms of the individual drugs dispensed (utilizing a locally-defined drug coding system to be provided by the County), the number of prescriptions filled for each drug, the number of pills or units dispensed, the amount of Ryan White Program funds spent dispensing each drug, and the unduplicated number of clients that received each drug limited to those medications listed in the

most recent release of the local Ryan White Part A Program Prescription Drug Formulary.

Provider monthly reports (i.e., reimbursement requests) for consumable medical supplies must include the number of clients served, medical supply distributions with HCPCS codes as appropriate per client, and dollar amounts per client.

E. Ryan White Part A Program Prescription Drug Formulary: Ryan White Program funds may only be used to purchase or provide vitamins, appetite stimulants, and/or other prescription medications to program clients as follows:

- Prescribed medications that are included in the most recent release of the Ryan White Part A Program Prescription Drug Formulary. This formulary is subject to periodic revision; and
- Medications, appetite stimulants, or vitamins that have been prescribed by the client's Physician. **IMPORTANT NOTE:** Prescriptions for vitamins may be written for a 90-day (calendar days) supply.

F. Letters of Medical Necessity:** The following medications and medication-related test require a completed Ryan White Letter of Medical Necessity (LOMN) or Prior Authorization Form (See Section V of this FY 2023 Service Delivery Manual for copies of the Letters of Medical Necessity, as may be amended):

Medications:

- **Neupogen** (Filgrastim)
- **Procrit or Epogen** (Epoetin Alpha)
- **Roxicodone** (Oxycodone) **and Percocet** (Oxycodone/APAP)

Test:

- **Highly Sensitive Tropism Assay** [required to prescribe Selzentry (Maraviroc)] – (The Ryan White Program LOMN for the Highly Sensitive Tropism Assay is only required when no other funding source can pay for the test.)

**** NOTE: The four LOMNs listed directly above are discontinued effective May 15, 2023. ****

ADDITIONAL IMPORTANT NOTES:

- **Medical Case Managers must work with clients to explore in a diligent and timely manner all health insurance options and evaluate the client's best option to ensure that health insurance premiums, deductibles and prescription drug copayments are reasonable and covered by the appropriate payer source. For Medicare Part D recipients, any client whose gross household income falls**

below 150% of the 2023 Federal Poverty Level (FPL) must be enrolled in the Low Income Subsidy (LIS) Program. In addition, for Medicare Part D recipients, any client whose gross household income falls between 135% and 150% of the FPL must be enrolled in ADAP for assistance with prescription drug expenses. For Medicare Part D recipients, any client whose gross household income falls above 150% of the FPL or does not qualify for the LIS and who falls into the “donut hole,” must be referred to the ADAP Program.

- **AS OMB RECEIVES ADDITIONAL INFORMATION FROM FEDERAL FUNDERS AND/OR STATE LEGISLATIVE BODIES REGARDING IMPLEMENTATION OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA), HEALTH EXCHANGES, OR ANY SUBSEQUENT HEALTH CARE LAW, THIS MANUAL MAY BE REVISED.**

MENTAL HEALTH SERVICES

(Year 33 Service Priorities: #9 for Part A and #4 for MAI)

Mental Health Services are a set of core medical services that consist of counseling and treatment for diagnosed behavioral health disorders. These services are designed to reduce harmful behaviors and episodes of instability and improve mental status and client health outcomes. These Mental Health Services include the provision of outpatient psychological and psychiatric screening, assessment, diagnosis, treatment, and counseling services offered to people with HIV. Services are based on an individualized treatment plan and are conducted in group and individual sessions. All services are provided by mental health professionals licensed or otherwise authorized within the State of Florida to render such services. All clients receiving this service must have at least one mental or behavioral health diagnosis specified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) or International Classification of Disease, Tenth Revision, Clinical Modification (ICD-10-CM; Codes F01-F99, excluding “Mental and behavioral disorders due to psychoactive substance use” – codes F10-F19).

Mental Health Services require an individualized treatment plan, as noted above. Treatment plans incorporate the findings of assessment and diagnostic tools and specify the goals and objectives to be achieved during the treatment episode. The treatment plan also specifies the recommended clinical interventions and frequency with which these interventions shall be delivered. Mental health providers may use this service category to conduct the assessment and diagnostic steps for the development of a treatment plan. If ongoing mental health services are being provided to a client, it is expected that the client receives a mental health treatment plan at least every six months.

Psychiatric treatment with medication management and evaluation should be billed and recorded under Outpatient/Ambulatory Health Services. Additional mental health services may be billed under Outpatient/Ambulatory Health Services when provided by a licensed psychiatrist or other doctor, clinical psychologist, clinical social worker, clinical nurse specialist, nurse practitioner or physician assistant.

Mental Health Services are allowable only for program-eligible clients. This service is not available to family members without HIV. Ryan White Program funds may **not** be used for bereavement support for uninfected family members or friends.

Mental Health Services reimbursed under Part A or MAI of the Ryan White Program are limited to conditions impacting the treatment of the client’s underlying HIV disease (e.g., assessing, diagnosing, and treating a mental health condition that hinders HIV treatment adherence) and treated within the context of the client’s HIV or AIDS diagnosis. This service is intended to address issues that impact a person’s ability to remain engaged in HIV care, strengthen coping skills and self-care, and promote engagement in ongoing medical care and treatment. It is important for the Level I or Level II mental health

professional to regularly gauge and document the client's progress and determine if the client is still in need of the service.

- **Mental Health Services (Level I):** This level includes *intensive* mental health therapy and counseling (individual, family, and group) provided solely by *state-licensed mental health professionals*. Direct service providers would possess **a Doctorate degree in psychology or counseling or related field (PhD, EdD, PsyD), and must be licensed by the State of Florida** as a Licensed Clinical Psychologist, LCSW, LMHC, or LMFT to provide such services.
- **Mental Health Services (Level II):** This level includes *intensive* mental health therapy and counseling (individual, family, and group) provided solely by *state-licensed mental health professionals*. Direct service providers would possess **a Master's degree in psychology, psychotherapy or counseling or related field (MS, MA, MSW, or M.Ed.), and must be licensed by the State of Florida** as a LCSW, LMHC or LMFT to provide such services. **Direct service providers may also be:** 1) Florida registered interns as defined by Florida Statute (F.S.) 491.0045 (Clinical Social Work Intern, Mental Health Counselor Intern, or Marriage and Family Therapy Intern), or 2) a Psychology Intern, Postdoctoral Resident, or Fellow satisfying Rule 64B19-11.005 of the Florida Administrative Code (F.A.C.). Such interns must provide services under the supervision of a LCSW, LMHC, LMFT or Licensed Psychologist who is licensed in the State of Florida.

Mental Health Service Components:

Level I counseling services provided to Ryan White Program clients include psychosocial assessment and evaluation, testing, diagnosis, treatment planning with written goals, crisis counseling, periodic re-assessments, re-evaluations of plans and goals, documenting progress, and referrals to psychiatric and/or other services as appropriate. Issues of relevance to program-eligible people with HIV (clients) such as risk behavior, substance abuse, adherence to medical treatments, depression, panic, anxiety, maladaptive coping, safer sex, and suicidal ideation will be addressed. Mental health professionals are encouraged to practice and introduce motivational interviewing and harm reduction strategies to their clients, if deemed clinically appropriate. Services at this level are provided for clients experiencing acute, sporadic mental health problems and are generally not long term [individual counseling shall not exceed 32 encounters per Fiscal Year and five (5) units (maximum of 2 ½ hours) per session; 1 encounter = 1 day of service].

Level II counseling services provided to Ryan White Program clients include crisis counseling, re-evaluations of plans and goals, documenting progress, and referrals to psychiatric and/or other services as appropriate. Issues of relevance to program-eligible people with HIV (clients) such as risk behavior, substance abuse, adherence to medical treatments, depression, panic, anxiety, maladaptive coping, safer sex, and suicidal ideation will be addressed. Mental health professionals are encouraged to practice and introduce motivational interviewing and harm reduction strategies to their clients, if deemed

clinically appropriate. Services at this level are provided for clients experiencing acute, sporadic mental health problems and are generally not long term [individual counseling shall not exceed 32 encounters per Fiscal Year and five (5) units (maximum of 2 ½ hours) per session; 1 encounter = 1 day of service].

Group Counseling (Levels I and II) refers to a group of individuals [minimum of three (3) Ryan White Program clients, maximum of fifteen (15) total clients] with similar problems meeting under the expert guidance of a trained mental health professional. Members of the group will be selected by the mental health professional in order to maximize the interaction, learning, and benefits derived from a group dynamic. Group counseling provides therapy in a social context, reduces the feeling of isolation many clients experience, provides an opportunity for clients to share methods of problem-solving, and allows the therapist an opportunity to observe how an individual interacts with others.

- A. Program Operation Requirements:** Staff must demonstrate knowledge of HIV disease, its psychosocial dynamics and implications, including cognitive impairment, and generally accepted treatment modalities and practices. Services may be delivered to non-HIV+ family members (as defined by the client) only if the program-eligible client is also being served. Providers will comply with super-confidentiality laws as per State of Florida's guidelines. The ratio of group counseling participants to counselors may not be lower than 3:1 and may not be higher than 15:1, as described above. One visit is equal to one half-hour counseling session.

Clients who are newly diagnosed with HIV or have returned to care should be offered the opportunity to speak with a mental health provider as a routine component of the services available through the local Ryan White Part A Program. An initial mental health visit could be used to identify, assess, or verify mental health conditions that may affect a client's treatment adherence. Subsequent or on-going Mental Health Services under the Ryan White Part A Program require a mental health diagnosis documented in the client's chart. To facilitate this process for newly diagnosed or returned to care clients who are receiving TTRA mental health services are limited to one encounter (all mental health services provided on one day) within 30 days of starting the TTRA protocol, while program eligibility is being determined. For clients following the Newly Identified Client (NIC) protocol, Mental Health Services may be provided with these same limitations.

Tele-mental health services are also available. Please see Section XVI, Additional Policies and Procedures, of this Service Delivery Manual for more details.

- B. Additional Service Delivery Standards:** Level I and Level II providers must adhere to generally accepted clinical guidelines for psychological treatment of persons with HIV/AIDS-related illnesses. (Please refer to Section III of this FY 2023 Service Delivery Manual for details, as may be amended.)
- C. Rules for Reimbursement:** Reimbursement for individual and group Mental Health Services will be based on a half-hour counseling session “unit” not to exceed \$32.50 per unit for Level I individual counseling; \$35.00 per unit for Level I group counseling; \$32.50 per unit for Level II individual counseling; and \$35.00 per unit for Level II group counseling. Reimbursement for individual counseling units are calculated for each client receiving the therapy (i.e., number of individual counseling units per client), whereas, reimbursement for group counseling units are calculated for the counselor that provided the group counseling (i.e., number of group counseling units per counselor).

Tele-mental health services are reimbursed as follows:

Billing Code	Description	Flat rate Reimbursement
THMHT1	Tele-Mental Health provided by a Level I provider (individual client only)	\$32.50 per 30-minute session
THMHT2	Tele-Mental Health provided by a Level II provider (individual client only)	\$32.50 per 30-minute session

- D. Additional Rules for Reporting:** The unit of service for reporting monthly activity of individual and group Mental Health Services is a one-half-hour counseling session and the unduplicated number of clients served. Providers will report individual and group activity separately for Level I and Level II Mental Health Services.
- E. Additional Rules for Documentation:** Providers must also maintain certifications and licensure documents of the mental health professionals providing services to Ryan White Program clients and must make these documents available to OMB staff or authorized persons upon request. Client charts **must** include a specific mental or behavioral health diagnosis and detailed treatment plan for each eligible client that includes all required components and the mental health professional’s signature and/or the signature of the person supervising the professional.
- F. Additional Treatment Guidelines and Standards:** Providers of Mental Health Services (Levels I and II) will adhere to generally accepted clinical guidelines for mental health therapy/counseling of people with HIV. The following are examples of such guidelines:

- American Psychiatric Association (APA). HIV Psychiatry - Training and Education, as well as HIV Psychiatry Resources and Publications [e.g., Fact Sheets (Last Updated: 2012): HIV and Clinical Depression; HIV and Anxiety; HIV and Cognitive Disorders; HIV and Delirium; HIV and Substance Use; HIV and People with Severe Mental Illness (SMI); Sleep Disorders and HIV; and Pain in HIV/AIDS; Publications (including links to other related books and journals, such as the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition - DSM-5); and additional web-based materials. Available at:

<https://www.psychiatry.org/psychiatrists/practice/professional-interests/hiv-psychiatry> and

<https://www.psychiatry.org/psychiatrists/search-directories-databases>

Accessed 11/13/2023.

- American Psychiatric Association. Latest Published and Legacy APA Clinical Practice Guidelines; including, but not limited to, The American Psychiatric Association Practice Guidelines for the Psychiatric Evaluation of Adults, Third Edition, 2015. Available at:

<https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines>

and <https://psychiatryonline.org/guidelines>

Accessed 11/13/2023.

OUTPATIENT/AMBULATORY HEALTH SERVICES

(Year 33 Service Priorities: #5 for Part A and MAI)

- A. **Outpatient/Ambulatory Health Services** are core medical services. These services include primary medical care and outpatient specialty care required for the treatment of people with HIV or AIDS. These services focus on timely/early medical intervention and continuous health care and disease treatment and management over time. Primary medical care for the treatment of HIV infection includes the provision of care that is consistent with the Public Health Service (PHS) guidelines. Such care must include access to antiretroviral (ARV) and other prescription drug therapies, including prophylaxis and treatment of opportunistic infections (OI) and combination ARV therapies.

IMPORTANT NOTE: Services are restricted to outpatient services only.

For the outpatient medical services to be considered Ryan White Program allowable, such services must be provided in relation to a client's HIV+ diagnosis, co-morbidity, or complication related to HIV treatment. This program allowable relationship must be clearly documented in the client's medical chart, in the Primary Care Physician's referral to specialty care services, and in any corresponding Ryan White Program In Network Referral or general Out of Network Referral. A list of the most current Allowable Medical Conditions, as may be amended, is included in Section VIII of this FY 2023 Service Delivery Manual for reference. For clarity, one or more of the listed conditions along with one of the following catch-phrases should be included in the Physician's notation and related referral, as appropriate:

- Service is in relation to this client's HIV diagnosis.
- Service is needed due to a related co-morbidity.
- Service is needed due to a condition aggravated or exacerbated by this client's HIV.
- Service is needed due to a complication of this client's HIV treatment.
- Routine diagnostic test conducted as a standard of care (SOC)
 - The SOC should be implemented as recommended by established medical guidelines, including, but not limited to, Public Health Service (PHS), American Medical Association, Health Resources and Services Administration; see Minimum Primary Medical Care Standards for Chart Reviews in Section III of this Service Delivery Manual document or other local guidelines, as may be amended.

Telehealth services are also available. Please see Section XVI, Additional Policies and Procedures, of this Service Delivery Manual for more details.

I. Primary Medical Care

1. **Primary Medical Care Definition and Functions:** Primary medical care includes the provision of comprehensive, coordinated, professional diagnostic and therapeutic services rendered by a Physician, Physician Assistant, Clinical Nurse Specialist, Nurse Practitioner, Advanced Practice Registered Nurse, or other health care professional who is licensed in the State of Florida to practice medicine to prescribe ARV therapy in an outpatient setting. Outpatient settings include clinics, medical offices, and mobile vans where clients in general do not stay overnight. **Emergency rooms are not considered outpatient settings; therefore, emergency room services are not covered by the Ryan White Part A/MAI Program. Inpatient (hospital, etc.) services are also not covered.**

Although HRSA allows for urgent care center services to be payable through the Ryan White Program, non-HIV related visits to urgent care facilities are not allowable or reimbursable costs within the Outpatient/Ambulatory Health Services Category (see HRSA Policy Clarification Notice #16-02). The Miami-Dade HIV/AIDS Partnership, as advised by its Medical Care Subcommittee, has elected not to include this component as an allowable service locally. This decision was made due to the complex logistics involved in limiting this component to the treatment of HIV-related services, as required by HRSA; and the fact that Ryan White Part A/MAI Program-funded Outpatient/Ambulatory Health Services subrecipients are required to maintain procedures (i.e., an accessible phone line for clients to call for assistance) for clients who have urgent/emergent health issues after hours.

Allowable activities include: medical history taking; physical examination; diagnostic testing, including, but not limited to, laboratory testing; treatment and management of physical and behavioral health conditions; behavioral risk assessment, subsequent counseling, and referral; preventive care and screening; pediatric development assessment; prescription and management of medication therapy; treatment adherence; education and counseling on health and prevention issues; and referral to specialty care related to client's HIV diagnosis, co-morbidity, or complication of HIV treatment. Services also include diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, continuing care and management of chronic conditions, and referral to specialty care (including all medical subspecialties if related to the client's HIV diagnosis, co-morbidity, or complication of HIV treatment), as necessary. Chronic illnesses usually treated by primary care providers include hypertension, heart failure, angina, diabetes, asthma, chronic obstructive pulmonary disease (COPD), depression, anxiety, back pain, thyroid dysfunction, and HIV.

Visits to ensure readiness for and adherence to complex HIV treatments shall be considered either billable under Medical Case Management or Outpatient/Ambulatory Health Services, depending on how the visit occurred. Treatment Adherence Services provided during an Outpatient/Ambulatory Health Service visit shall be reported under the Outpatient/Ambulatory Health Services category (using the appropriate CPT billing code); whereas Treatment Adherence Services provided during a Medical Case Management visit shall be reported in the Medical Case Management service category (using the ADH billing code).

a. New to Care Clients

One (1), initial primary medical care visit may be provided to a newly identified client (i.e., a newly diagnosed client) who has a preliminary reactive test result and a pending confirmatory HIV test result, if the client was properly referred by a Medical Case Manager or Outreach Worker. To be valid for this purpose, the referral must have an indication that the client is a “newly identified client” (NIC). Such initial primary medical care visit must be scheduled and provided within 30 calendar days of referral from the Medical Case Manager or Outreach Worker. Otherwise, a confirmatory HIV test result will be required to obtain further services.

b. Limitations on Specialty Testing

Before prescribing Selzentry (Maraviroc), a Highly Sensitive Tropism Assay (test), formerly known as the Trofile Tropism Assay, must be performed and documented in the client’s chart to determine appropriateness of the treatment regimen. The Highly Sensitive Tropism Assay includes the Trofile, Trofile DNA, or Quest Diagnostics Tropism assay. If the cost of the Highly Sensitive Tropism Assay is being covered by any other payer source, clients must access the test through those resources first. **(NOTE: ViiV Healthcare discontinued the Trofile Access Program on July 1, 2018.)**

When the cost of the Highly Sensitive Tropism Assay is not covered by any other source, then the client’s medical provider must verify and document on the corresponding Ryan White Program Letter of Medical Necessity that the client has been found to be ineligible for the test to be paid for by any other payment source.

ViiV Healthcare currently covers the cost of the following test at no charge to eligible clients or the Ryan White Program: the HLA-B*5701 screening test. This screening test is available to assist clinicians in identifying clients who are at risk of developing a hypersensitivity reaction to abacavir (Ziagen). Whenever the cost of the HLA-B*5701 screening test can be covered by the ViiV Healthcare or any other source, providers **cannot** bill the local Ryan White Program for reimbursement of this test. As of December 1, 2019, FDOH/ADAP clients do not need certificates for HLA Aware program. They simply use either their designated

Quest Diagnostic lab or LabCorp code (that was listed on their certificates) for reimbursement by ViiV Healthcare. Contracted providers that serve FDOH/ADAP clients do not need to send clients to FDOH/ADAP, they just need to enter the appropriate code depending on which lab they use. FDOH already has this code as part of their EHR system. The Ryan White Program must be the payer of last resort. Utilization of the HLA-B*5701 screening test as billed to the local Ryan White Program will be monitored, and reimbursement may be denied if documentation does not support the use of Ryan White Program funds as a last resort.

2. Client Education: Providers of primary medical care services are expected to provide the following basic education as part of client care:

- Treatment options, with benefits and risks, including information about state-of-the-art combination drug therapies and reasons for treatment;
- Self-care and monitoring of health status;
- HIV/AIDS transmission and prevention methods; and
- Significance of CD4 counts, viral load and related disease aspects, adherence and resistance concepts.

3. Adherence Education: Providers of primary medical care services are responsible for assisting clients with adherence in the following ways:

- Adherence with medication regimens in order to reduce the risk of developing and spreading a resistant virus and to maintain health;
- Taking medications as prescribed, and following recommendations made by Physicians, Physician Assistants, Advanced Practice Registered Nurses, Nutritionists, and Pharmacists;
- Client involvement in the development and monitoring of treatment and adherence plans; and
- Ensuring immediate follow-up with clients who miss their prescription refills, medical appointments, and/or who experience difficulties with treatment adherence.

4. Coordination of care: Providers of primary medical care services are responsible for ensuring continuity and coordination of care. They must:

- Maintain contact as appropriate with other caregivers (Medical Case Manager, Nutritionist, Specialty Care Physician, Pharmacist, Counselor,

etc.) and with the client in order to monitor health care and treatment adherence;

- Ensure that the client receives coordinated, interdisciplinary support for adherence and assistance in overcoming barriers to meeting treatment objectives; and
- Identify a single point of contact for Medical Case Managers and other agencies that have a client's signed consent and other required information.

5. Additional primary medical care services may include:

- Respiratory therapy needed as a result of HIV infection.

II. Outpatient Specialty Care

- 1. Outpatient Specialty Care Definition and Functions:** This service covers short-term ambulatory treatment of specialty medical conditions and associated diagnostic procedures for program-eligible clients who are referred by a primary care provider through a Ryan White Program In Network Referral, OON referral, or prescription referral. Specialty medical care includes cardiology, chiropractic, colorectal, clinical psychiatry, dermatology, ear, nose and throat/otolaryngology, endocrinology, gastroenterology, hematology/oncology, hepatology, infectious disease, orthopedics/rheumatology, nephrology, neurology, nutritional assessments or counseling (performed by a Registered Dietitian), obstetrics and gynecology, ophthalmology/optometry, pulmonology, respiratory therapy, urology, and other specialties **as related to the client's HIV diagnosis, co-morbidities, or complications of HIV treatment (see Allowable Medical Conditions List in Section VIII of this FY 2023 Service Delivery Manual).**

Additional medical services, which may be provided by other Ryan White Program subrecipients, may include outpatient rehabilitation, podiatry, physical therapy, occupational therapy, and speech therapy as related to the client's HIV diagnosis, co-morbidities, or complications of HIV treatment. Pediatrics and specialty pediatric care are included in the list of specialties above. A Mental Health Services provider may also make referrals to clinical psychiatry. **(IMPORTANT NOTE: Referrals to outpatient specialty care services for ongoing treatment must include documentation or a notation to support the specialty's relation to the client's HIV diagnosis, co-morbidity, or complication of HIV treatment.)**

a. Other Specialty Care Limitations or Guidelines:

- i. **Chiropractic services** under the Ryan White Program are limited to services in relation to the client's HIV diagnosis. These services may relate to pain caused by the disease itself or pain that is a consequence of HIV medications. Chronic pain is also considered a co-morbidity to HIV and may also be treated when appropriate. Chiropractors affect the nervous system and immune system by utilizing spinal adjustments and physiotherapy to the spine and body that may assist the nervous system in operating to the best of its ability to fight HIV-related infection, disease, and symptomatology. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise, or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required. Chiropractic services for non-HIV related injuries or conditions are not covered. Examples of non-HIV related injuries or conditions are slip and falls, car accidents, sports injuries, and acute pain.

- ii. **Podiatry services** under the County's Ryan White Program are limited to services in relation to a client's HIV diagnosis or co-morbidity (e.g., diabetes). The local Ryan White Part A/MAI Program will reimburse providers for the diagnostic evaluation of foot and ankle pain. Podiatry services for the treatment of peripheral neuropathy, HIV-related medication side effects (e.g., HAART/protease inhibitor medication regimens may cause ingrown toenails), onychomycosis, and diabetic foot care due to circulatory problems will be covered by the County's Ryan White Program. Conditions such as hammer toes, bunions, heel spurs may be covered if related to neuropathies. Sprains or fractures are not covered unless a direct connection to neuropathies is present. Furthermore, general podiatry services for non-HIV-related or non-diabetic-related foot injuries or conditions are not covered by the County's Ryan White Program.

- iii. **Optometry and ophthalmology services** under the Ryan White Program are also limited to services in relation to a client's HIV diagnosis or co-morbidity. An annual eye exam solely for the purpose of routine eye care (especially for vision correction with glasses or contact lenses) is not covered by the local Ryan White Part A/MAI Program. In accordance with the local Ryan White Part A Program's Allowable Medical Conditions list, last updated May 15, 2023 and September 27, 2023, as may be amended, clients must

meet at least one of the following criteria to access ophthalmology/optometry services:

- Client has a low CD4 count (at or less than 200 cells/mm³ *currently*)
- Client has a comorbidity (e.g., diabetes, hypertension, STI, etc.)
- Client has a prior diagnosis of cytomegalovirus retinitis (CMV)
- Client has Immune Reconstitution Syndrome

Furthermore, referrals to an optometrist or ophthalmologist must indicate a condition attempting to rule out complications of HIV. See the Allowable Medical Conditions List in Section VIII of this Service Delivery Manual for a list of conditions that would apply, such as manifestations due to opportunistic infections, visual disturbances to rule out complications of HIV, and history of sexually transmitted infections (STI) or complications of STI.

- iv. Per Federal guidelines, **acupuncture services** are not covered under this service category, as Ryan White Program funds may only be used to support limited acupuncture services for program-eligible clients as part of substance abuse treatment services.
- v. **Obstetric services:** Although the selection of a Ryan White Program-funded service provider is based on client choice, pregnant women should be referred to the University of Miami OB/GYN Department (Ryan White Part D Program, etc.) whenever possible due to its specialized care for this HIV population.
- vi. **Pediatric, adolescent and young adult services:** Whenever possible and also based on client choice, providers are strongly encouraged to refer clients who are 13 to 24 years of age to the University of Miami's pediatric and adolescent care departments due to their specialized care for this HIV population and age group.

IMPORTANT NOTE: Under the local Ryan White Part A/MAI Program, primary medical care provided to people with HIV is not considered specialty care.

2. **Client Education:** Providers of specialty care services will be expected to provide the following basic education as part of client care:

- Basic education to clients on various treatment options offered by the specialist;

- Taking medications pertaining to specialty care treatment as well as adhering to treatment recommendations made by the Primary Care or HIV Physician; and
 - Educating clients about HIV/AIDS and its relationship to the specialty care service being provided.
3. **Coordination of Care:** The specialist must communicate, as appropriate, with the Primary Care Physician and client for results, follow-up, and/or to re-evaluate the client in order to coordinate treatment.

The following subsections B. through I. are for both Primary and Specialty Care, unless otherwise noted:

B. Program Operation Requirements:

- Providers must offer, post, and maintain walk-in hours to ensure maximum accessibility to Outpatient/Ambulatory Health Services, to ensure that medical services are available to clients for urgent/emergent issues;
- Providers must demonstrate a history and ability to serve Medicaid and Medicare eligible clients; and
- **For Primary Medical Care Only:** Providers must ensure that medical care professionals: 1) have a minimum of three (3) years of experience treating HIV clients; or 2) have served a high volume of people with HIV (i.e., >50% of individual caseload per practitioner) in the past year. Certification from the American Academy of HIV Medicine (AAHIVM) is encouraged, but not required.
- **For Outpatient Specialty Care Only:** A referral from the client's Primary Care or HIV Physician is required for all program-allowable specialty care services. Referrals to Outpatient Specialty Care services must be issued through the Provide® Enterprise Miami data management system and must indicate whether the referral is for a diagnostic appointment/test or for ongoing medical treatment. If the specialty care referral is for ongoing medical treatment the referrals must include supporting documentation that the ongoing care is HIV-related, comorbidity-related, and related to a complication of HIV treatment, as detailed in the most current, local Allowable Medical Conditions list.

- C. **Additional Service Delivery Standards:** Providers of Outpatient/Ambulatory Health Services will also adhere to the following guidelines and standards, as may be amended (please refer to Section III of this FY 2023 Service Delivery Manual for details):

- Public Health Service Clinical Guidelines for the Treatment of AIDS Specific Illnesses (as amended and current); also see Section I, below.
- HAB HIV Performance Measures to include the following, as may be amended: (<https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio>)
 - Frequently Asked Questions
 - Core
 - All Ages
 - Adolescent/Adult
 - Children
 - HIV-Exposed Children
 - Medical Case Management (MCM)
 - Oral Health [Care]
 - ADAP [AIDS Drug Assistance Program]
 - Systems-Level
- Minimum Primary Medical Care Standards

D. Rules for Reimbursement: Providers will be reimbursed for program allowable outpatient primary medical care and specialty care services as follows, unless a procedure has been disallowed or discontinued by the Miami-Dade County Office of Management and Budget-Grants Coordination:

- Reimbursements for medical procedures and follow-up contacts to ensure client’s adherence to prescribed treatment plans will be no higher than the rates found in the “2023 Florida Medicare Part B Physician Fee Schedule (Participating, Locality/Area 04), revised/modified January 9, 2023.” Codes 99205 and 99215 remain discontinued under this local Ryan White Part A/MAI Program. Code 99201 was also discontinued.
- Reimbursements for lab tests and related procedures will be based on rates no higher than those found in the “2023 Medicare Clinical Diagnostic Laboratory Fee Schedule, Calendar Year (CY) 2023 Quarter 1 (Q1) Release, added for January 2023, modified January 12, 2023.”
- Reimbursements for injectables will be based on rates no higher than those found in the “2023 Medicare Part B Drug Average Sales Price (ASP) Drug Pricing Files, Payment Allowance Limits for Medicare Part B Drugs, updated January 30, 2023 (payment limit column).”
- Reimbursements for medical procedures performed at Ambulatory Surgical Centers (ASC) will be no higher than the rates found in the “2023 Florida Medicare Part B ASC Fee Schedule, by HCPCS Codes and Payment Rates,

PDF dated January 5, 2023, electronic file modified January 11, 2023; for Core Based Statistical Area 33124 (Miami, FL).” (Applies only to organizations with on-site or affiliated Ambulatory Surgical Centers).

- Reimbursements for medical procedures performed at Outpatient Hospital centers will be no higher than the rates found in the approved “Medicare Addendum B Outpatient Prospective Payment System (OPPS) by HCPCS Code for CY 2023 (January 2023), corrected January 20, 2023 (note “b.01.20.23” in file name).” (Applies only to organizations with on-site or affiliated outpatient hospital centers).
 - Opposite to Medicare’s procedure guidelines, the local Ryan White Program discontinued the use of HCPCS code G0463 (hospital outpatient clinic visit). It is necessary for the local Ryan White Program to track the level of service provided to clients; therefore, providers of OPPS-APC services should continue to use CPT codes 99202-99204 or 99211-99214, as applicable to the services provided, instead of G0463.
- Evaluation and management visits and psychiatric visits will be reimbursed at rates no higher than the Medicare “allowable” rates times a multiplier of up to 2.5.
- If the client is eligible for ADAP, that program should be accessed for genotype and phenotype testing if available.
- A Letter of Medical Necessity (LOMN) is required for the Highly Sensitive Tropism Assay if no other payer source is covering the cost of the test. This is necessary to ensure use of the Ryan White Program as the payer of last resort. This LOMN is discontinued May 15, 2023.
- No multiplier will be applied to reimbursement rates for laboratory tests and related procedures, for non-evaluation and management procedures, for injectables, or for supplemental procedures.
- Medical procedures with an active Current Procedural Terminology (CPT) code that are excluded from the Medicare Fee Schedules may be provided on a supplementary schedule, upon request from the provider to the County for review. A flat rate along with a detailed description of the procedure and a cost justification for each supplemental procedure must be included in the provider’s submission request for review and approval by the County.
- Consumable medical supplies are limited and are only covered when needed for the administration of prescribed medications. Allowable consumable medical supplies are available only through the local Ryan White Program’s

AIDS Pharmaceutical Assistance (Local Pharmaceutical Assistance Program – LPAP) service category. A list of allowable consumable medical supplies can be found as an attachment to the most current, local Ryan White Program Prescription Drug Formulary (i.e., Attachment B of the referenced Formulary).

- Please see Section XVI, Additional Policies and Procedures, of this Service Delivery Manual for details regarding the reimbursement of telehealth/telemedicine services.

- E. Rules for Reporting:** Providers’ monthly reports (i.e., reimbursement requests) for Outpatient/Ambulatory Health Services must include the number of clients served, billing code for the medical procedures provided, number of units of service provided, and the corresponding reimbursement rate for each service provided. Providers must also develop a method to track and report client wait time (e.g., the time it takes for a client be scheduled to see the appropriate medical provider after calling for an appointment; and upon arrival for the appointment, the time the client spends waiting to see the medical provider) and to make such reports available to OMB staff or authorized persons upon request.
- F. Additional Rule for Reimbursement:** Requests for reimbursement of primary and/or specialty medical care services that are not submitted to the County within four (4) calendar months from the date of service may be denied.
- G. Additional Rules for Documentation:** Providers must ensure that medical records document services provided (e.g., medical visits, lab tests, diagnostic tests, etc.), the dates and frequency of services provided, as well as an indication that services were provided for the treatment of HIV infection, a co-morbidity, or complication of HIV treatment. Clinician notes must be signed by the licensed provider of the service and maintained in the client chart or electronic medical record. Providers must maintain professional certifications and licensure documents of the medical staff providing services or ordering tests and must make them available to OMB staff or authorized persons upon request. Providers must ensure that chart notes are legible and appropriate to the course of treatment as mandated by Florida Administrative Code 64B8-9.003; and pursuant to Article VII, Section 7.1, of the provider’s Professional Services Agreement with Miami-Dade County for Ryan White Program-funded services.
- H. Additional Client Eligibility Criteria:** Clients receiving Outpatient/Ambulatory Health Services must be documented as having been properly screened for other public sector funding as appropriate annually, every 366 days. (NOTE: The recertification period for ADAP and Part A is expected to be updated within this grant fiscal year, with no less than 30 calendar days’ notice.) While clients qualify for and can access medical services through other public funding [including, but not limited to, Medicare, Medicaid, Medicaid Managed Medical Assistance

(MMA), or Medicaid Long-Term Care (LTC)], or private health insurance, they will not be eligible for Ryan White Part A Program-funded Outpatient/Ambulatory Health Services, except for such program-allowable services that are not covered by the other sources.

I. Additional Treatment Guidelines and Standards

Guidelines: Providers will adhere to the following clinical guidelines for treatment of HIV/AIDS specific illnesses (which can be found at <https://clinicalinfo.hiv.gov/en/guidelines>, unless otherwise noted below):

- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv>; pp 1-604; updated March 23, 2023. Accessed 11/13/2023.
- Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Department of Health and Human Services. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv>; pp 1-671; updated April 11, 2023. Accessed 11/13/2023.
- Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/perinatal>; pp 1-614; updated January 31, 2023. Accessed 11/13/2023.
- Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. National Institutes of Health, Centers for Disease Control and Prevention, HIV Medicine Association, and Infectious Diseases Society of America. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections>; pp 1-670; updated September 25, 2023. Accessed 11/13/2023.

- Panel on Opportunistic Infections in Children with and Exposed to HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Children with or Exposed to HIV. Department of Health and Human Services. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/updates-guidelines-prevention>; pp 1-485; updated September 14, 2023. Accessed 11/13/2023.
- Guidelines Working Groups of the NIH Office of AIDS Research Advisory Council. Guidance for COVID-19 and People with HIV. Department of Health and Human Services. 2023. Available at: <https://clinicalinfo.hiv.gov/en/guidelines/guidance-covid-19-and-people-hiv/guidance-covid-19-and-people-hiv>; pp 1-19; updated February 22, 2022. Accessed 11/13/2023.
- U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau. Clinical Care Guidelines/Protocols, including the following, as appropriate: Guide for HIV/AIDS Clinical Care (2014), A Guide to the Clinical Care of Women with HIV (2013), A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV (2011); and reference guides to help health care professionals as their aging population grows (e.g., “Incorporating New Elements of Care” and “Putting Together the Best Health Care Team”. Available at: <https://ryanwhite.hrsa.gov/grants/clinical-care-guidelines-resources#clinical-protocols>. Date Last Reviewed: February 2022. Accessed 11/13/2023.
- Additional Education Materials (e.g., fact sheets, infographics and glossary) on HIV Overview; HIV Prevention; HIV Treatment; Side Effects of HIV Medicines; HIV and Pregnancy; HIV and Specific Populations; HIV and Opportunistic Infections, Coinfections and Conditions; and Living with HIV (including but not limited to finding HIV treatment services; Mental Health; Nutrition and Food Safety; and Substance Use). Available at: <https://hivinfo.nih.gov/understanding-hiv/fact-sheets> Accessed 11/13/2023.
- In addition, providers will adhere to other generally accepted clinical practice guideline standards, as follow:

Standards:

- Providers will inform clients as to generally accepted clinical guidelines for pregnant women with HIV, treatment of AIDS specific illnesses,

clients infected with tuberculosis, hepatitis, or sexually transmitted diseases, and other priorities identified by the Miami-Dade HIV/AIDS Partnership's Medical Care Subcommittee.

- Providers will screen for TB and make necessary referrals for appropriate treatment. In addition, providers will follow Universal Precautions for TB as recommended by the CDC. Providers will also screen for hepatitis, sexually transmitted diseases, and other priorities identified by the Miami-Dade HIV/AIDS Partnership's Medical Care Subcommittee.

IMPORTANT NOTE: FEDERAL FUNDERS AND/OR STATE LEGISLATIVE BODIES REGARDING IMPLEMENTATION OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA), HEALTH EXCHANGES, OR ANY SUBSEQUENT HEALTH CARE LAW, THIS MANUAL MAY BE REVISED.