MIAMI-DADE HIV/AIDS PARTNERSHIP

Medical Care Subcommittee
Friday, October 22, 2021

9:30 a.m. – 11:30 a.m.

Behavioral Science Research
2121 Ponce de Leon Blvd.
Coral Gables, FL and Zoom

AGENDA

I.	Call to Order	Carlos Palacios
II.	Meeting Rules and Housekeeping	Carlos Palacios
III.	Roll Call and Introductions	Carlos Palacios
IV.	Floor Open to the Public	Carlos Palacios
V.	Review/Approve Agenda	All
VI.	Review/Approve Minutes of September 24, 2021	All
VII.	Reports	
	• Membership Vacancies	Marlen Meizoso
	• Partnership Report (informational)	Marlen Meizoso
	• Ryan White Program (no new report)	Ana Nieto
	• ADAP Program	Dr. Javier Romero
VIII.	Standing Business	
	• Conclusion of Cabenuva barriers discussion	All
	• ADAP formulary additions and RWP review	All
	• Primary Medical Care Standards	All
	• Service Descriptions -Outpatient Ambulatory and AIDS Pharma	All
IX.	New Business	
	• 2022 Meeting Dates	Marlen Meizoso
X.	Announcements	All
	• Anchor Study Release	Marlen Meizoso
XI.	Next Meeting: **November 19, 2021** at Main Library- **Auditorium**	Carlos Palacios
XII.	Adjournment	Carlos Palacios

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Partnership Meeting Housekeeping

Hybrid Meetings

(In-Person and Zoom)

Updated September 9, 2021

www.aidsnet.org

Disclaimer & Code of Conduct

- This meeting – including audio, Zoom video and Chat Box input – is being recorded and will become part of the public record.

- Members serve the interest of the Miami-Dade HIV/AIDS community as a whole.
- Members do not serve private or personal interests, and shall endeavor to treat all persons, issues and business in a fair and equitable manner.

Resource Persons

- Behavioral Science Research Corp. staff are the Resource Persons for this meeting.
  - *Will BSR staff please identify themselves?*
  - *Please see staff after the meeting if you are interested in membership or if you have a question that wasn't covered during the meeting.*

www.aidsnet.org

General Reminders – In Person Attendees

www.aidsnet.org

- Per County mandate, masks are to be worn in all County buildings.
- Place cell phones on mute or vibrate.
  - *If you must take a call, please excuse yourself from the meeting.*
- Only voting members should be seated at the meeting table.
  - *You may move your chair if concerned about social distancing.*
- Please identify yourself by name before speaking.
- If you are at the table, please use the microphone.
- Members shall refrain from side-bar conversations in accordance with Florida Government in the Sunshine laws.
- See the front desk attendee to have your parking validated (Library meetings only), or see Staff after the meeting for a parking sticker (available to members of the affected community).

General Reminders – Zoom Attendees

- Please remain on mute until called on by the Chair.
- Place cell phones on mute and turn off external devices (TVs, radios)
- Use the Chat Box to:
  - Record your name for the Roll Call
  - Make or second a motion (members only)
  - Vote in opposition to a motion (members only)
  - Ask a question
  - Ask to be recognized by the Chair to speak
- Chat is seen only by the moderator.

www.aidsnet.org

Attendance

- All members are expected to arrive on time and remain throughout the entire meeting.
  - *If you expect to arrive late or leave early, please notify staff in advance of the meeting as this may impact quorum.*

- In-Person Attendees must **SIGN IN** to be counted as present.

- Zoom Attendees must **CHAT YOUR NAME** to be counted as present.

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Meeting Participation

- All speakers must be recognized by the Chair.
  - ❖ *Raise your hand or chat to be recognized or added to the queue.*
  - ❖ *The Chair will call on speakers in order of the queue.*
- Discussion should be limited to the current Agenda topic or motion.
- Speakers should not repeat points previously addressed.
- Any attendee may be permitted to address the board as time allows and at the discretion of the Chair.

- Important!
  - *Please raise your hand or chat if you need clarification about any terminology or acronyms used throughout the meeting.*

www.aidsnet.org

Resources

- Today's presentation and supporting documents are online at http://aidsnet.org/meeting-documents/.

- Follow the Partnership on Facebook and Instagram!

Thank you for attending today's meeting!

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SIGN IN

to be counted as present.

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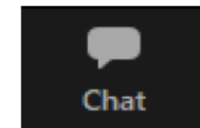

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Floor Open to the Public

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"BSR has a dedicated phone line and email for statements to be read into the record. No statements were received."

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Medical Care Subcommittee Meeting
Behavioral Science Research
2121 Ponce de Leon Blvd., Ste. 230, Coral Gables, FL 33134
September 24, 2021

#	Members	Present	Absent	Guests	
1	Baez, Ivet	x		Robert Greif	
2	Bauman, Dallas	x		John McFeely	
3	Cortes, Wanda	x		Ray Sawaged	
4	Dougherty, James	x		Michelle Soheil, DDS	
5	Goubeaux, Robert	*		Chris Varela	
6	Palacios, Carlos	x			
7	Pinero, Carmen		x		
8	Romero, Javier	*			
9	Thornton, Darren		x		
10	Torres, Johann	x		**Staff**	
11	Valle-Schwenk, Carla	x		Christina Bontempo	Susy Martinez *
12	Vasquez, Silvana		x	Barbara Kubilus	Marlen Meizoso
Quorum: 5	***virtual attendance**			Robert Ladner	

Note that all documents referenced in these minutes were accessible to members and the public prior to (and during) the meeting, at www.aidsnet.org/meeting-documents.

I. Call to Order

Carlos Palacios, the Chair, called the meeting to order at 9:39 a.m. He introduced himself and welcomed everyone.

II. Meeting Rules and Housekeeping

Mr. Palacios reviewed the meeting rules and housekeeping presentation (copy on file), which provided the ground rules and reminders for the meeting. He also identified Behavioral Science Research (BSR) staff as resource persons for the meeting. If anyone had any questions, they could speak to BSR after the meeting.

III. Roll Call and Introductions

Mr. Palacios requested members introduce themselves around the room. Staff introduced those members participating via Zoom.

IV. Floor Open to the Public

Dr. Robert Goubeaux read the following: *"Pursuant to Florida Sunshine Law, I want to provide the public with a reasonable opportunity to be heard on any item on our agenda today. If there is anyone who wishes to be heard, I invite you to speak now. Each person will be given three minutes to speak. Please begin by stating your name and address for the record before you talk about your concerns."*

"BSR has a dedicated phone line and email for statements to be read into the record. No statements were received."

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There were no comments, so the floor was closed.

V. Review/Approve Agenda

The Subcommittee reviewed the agenda. John McFeely indicated he had an announcement regarding the Anchor study. Carla Valle-Schwenk indicated the address on the agenda needed updating. The Subcommittee made a motion to adopt the agenda with change of address and addition of the announcement.

Motion to accept the agenda with the recommended addition.
Moved: Dallas Bauman Second: James Dougherty Motion: Passed

VI. Special Discussion: Oral Health Care Items

Marlen Meizoso explained that there were two issues for input by former members of the oral health care workgroup, one related to implants and the second to performance measures (copy on file). She explained that a member of the affected community requested that the topic of dental implants be revisited. In November 2014, based on the recommendations of the Ad Hoc Oral Health Care Workgroup, the Partnership made a motion that the local Ryan White Part A program will not cover the placement of implants or services related to restoration of implants, except for D6095 (Repair implant abutment, by report) since this code is already on the formulary with restrictions. Codes D6000-D6199, related to implant services, will not be covered. The recommendation was based on the Ryan White Part A program's limited resources and the need to restrict implant codes, no private health insurance pays for implants. The question before the committee is whether this restriction should be revisited. The maximum annual dollar cap is $6,500 for oral health care for an individual RWP client. There was a request for more information on the cost implications of implants. Staff can bring cost estimates to the next meeting. There was an additional request for a list of other programs that provide the service.

The second item was related to performance measures and was presented by Robert Ladner. The Clinical Quality Management program produces a quarterly 'CQM Performance Report Card' on services. There are two measures that relate to oral health care: (A) the proportion of all clients in care who receive at least one Ryan White-billed oral health service in the preceding 12 months, and (B) the proportion of all oral health care clients who see a dentist for a periodic oral examination in the preceding 12 months. The measure is the "percentage of clients who are receiving oral health care" is referenced in the CQM Report Card as "D1," and is calculated by dividing the unduplicated persons with one or more oral health care procedures billed to the RWP by the total number of RWP clients in RWP care. In FY 2020, 1,711 unduplicated clients had at least one OHC code billed, out of a total of 8,127 clients in care. This yields 21.1%. No standards have been set for what percentage is desired. Utilization of codes for 2020 will be provided for the next meeting.

The next measure is the "percentage of clients who have an annual check-up by their dentist." In discussions, it was agreed that clients should have one oral exam a year, and this measure is a HRSA OHC provider-based outcome measure intended to reflect the ability of the oral health care providers to engage RWP clients in regular oral care. It is referenced in the CQM Report Card as "D2" and is calculated by dividing the number of unduplicated OHC clients with one or more of the oral health examination codes (D0120, D0150, D0160, D0170 and D0180) billed to the RWP each year (numerator), by the number of clients receiving any kind of oral health care (D1) (denominator). In FY 2020, 986 clients at eight OHC providers had at least one of these D-codes billed by their dentist, out of a total of 1,711 clients who had any kind of OHC service billed at all. This yields 57.6% and a range across OHC providers from 29% to 90%. No standards have been set for what percentage is desired. In discussion, it was remarked that case managers should remind clients to see a dentist once a year.

An additional issue was raised regarding using D0140 (limited oral evaluation), which HRSA specifically excludes from "regular oral examination" codes because it is a problem-focused evaluation code with only two billable instances allowable per client per year. Should this code be "counted" as a periodic oral examination for measuring the degree to which an oral health care provider is providing regular ongoing dental services? In discussions, problem

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focused exams should not count as regular care, and the OHC providers concurred with the HRSA recommendation to exclude the code from the oral examination codes .

VII. Review/Approve Minutes of July 23, 2021

Members reviewed the minutes of July 23, 2021 and accepted them with no changes.

Motion to accept the minutes of July 23, 2021.
Moved: Dallas Bauman **Second: Dr. Johann Torres** **Motion: Passed**

VIII. Reports

- **Membership Vacancies** *All*

Mrs. Meizoso referenced the membership vacancy report (copy on file) which has been revamped to be more user friendly. Mrs. Meizoso indicated that Mr. McFeely had resigned from the Subcommittee. Vacancies were reviewed and attendees were encouraged to recommend that persons interested in joining the Subcommittee contact staff or download an application online at www.aidsnet.org.

- **Ryan White Program** *Carla Valle-Schwenk*

Ms. Valle-Schwenk reviewed the Ryan White Program expense reports and notes (copy on file). All contracts are out for execution, and half of them have been signed. By the next Subcommittee meeting, expenditures should be reflective of expenses. The County sent out a survey regarding the ACA plans that are being used, and advocates keeping the current plans. For those who did not reply, Ms. Valle-Schwenk will resend the email.

- **ADAP Program** *Dr. Javier Romero*

Dr. Javier Romero referenced the August 2021 report (copy on file). He indicated projections are on target for 2021. There are 24 clients on Cabenuva. There are issues with the medication. Clients indicate they have not been given information on the medication, clients were unaware they were on new medications, and some clients continued receiving and using their old medications since the DOH pharmacy was not informed of the medication change. Also, some providers send the prescriptions for Cabenuva directly to the ADAP pharmacy. In 2022, eligibility for ACA insurance premium reimbursement will be expanded for clients between 75%-99% FPL. Clients must be documented and have a valid social security number. The lower FPL levels will likely only add a small number of clients, since most would not qualify because of the requirements. There have been some changes to the ADAP formulary, with 54 new medications added and 5 ARVS being removed. There was a question regarding the new medication, semaglutide: are all brands covered since some brands are used to treat obesity. Dr. Romero indicated he would inquire.

VII.. Standing Business

- **Cabenuva Barriers** *All*

Mrs. Meizoso reviewed the replies submitted (copy on file). The form indicated at the top the items identified at the last meeting. There were three questions asked of providers: how many clients are on Cabenuva, a list of possible barriers, and finally, if there were any other issues. Any replies from today's meeting will be incorporated into the document and presented at the next meeting.

The following items were identified at the meeting:
- There is issue with application process, incomplete forms.
- The forms are completed online.

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- Additional training by ViiV is available and can be requested.
- Delays in receiving medications at doctor's office.
- Issue with bill and buy option; poor reimbursement rate through this option but this maybe an issue with insurance/health care center.
- CVS is unreliable, it took 1 hour 47 minutes to discuss 3 patients.
- Issue with a clinical trial client, called 10 days in advance as instructed and still had medication delays.
- Issues with getting orders on time with FL Blue or ADAP CVS Specialty.
- Medications will not ship Friday to Monday.
- Suggest calling ADAP pharmacy to make sure client does not receive old medication since ViiV is not contacting ADAP when a client is placed on Cabenuva.
- J-code for proper billing (J0741) will available as of October 1.

▪ **Primary Medical Care Standards** *All*

The full draft of the Primary Medical Care Standards was shared (copy on file). Because of time constraints the Subcommittee deferred discussion of the item until the next meeting.

Motion to defer the Primary Medical Care Standards until the next meeting.
Moved: Dr. Johann Torres **Second: Dallas Bauman** **Motion: Passed**

IX. **New Business**

▪ **ADAP formulary changes** *All*

Mrs. Meizoso provided an email from ADAP announcing the new formulary changes and the September 2021 formulary list (copies on file). The formulary was color coded with items in pink (ARVs) being automatically added to the Ryan White Formulary, yellow items are new medications to the formulary that the Subcommittee would need to address, blue items are new items already on the Ryan White Formulary, and green items have some restrictions on the Ryan White Formulary. The ADAP program also removed five ARV medications from the formulary because they were being discontinued or no longer used (standard of care). The Subcommittee decided to also remove the five medications from the Ryan White Formulary allowing for a 90-day window for any clients who may use those medications to access other options.

Motion to remove the following ADAP listed ARVs fosamprenavir, indinavir, nelfinavir, saquinavir and tipranavir from the Ryan White Prescription drug formulary effective within 90 days of approval.
Moved: Wanda Cortes **Second: Dr. Johann Torres** **Motion: Passed**

The list of new medications will be divided among the pharmacists. They will provide information on cost and any other concerns regarding the new medications. The information will be shared at the next meeting.

▪ **OI Medications and HIV Section Test and Treat program** *All*

The Subcommittee reviewed the email from the DOH regarding recommended OI medications that are being considered for inclusion in the Test and Treat program (copy on file). The County was looking for feedback on the proposed medications and the Subcommittee indicated the list was fine.

▪ **Service Descriptions-Outpatient Ambulatory and AIDS Pharmaceutical** *All*

The drafts of the Outpatient Ambulatory and AIDS Pharmaceutical service descriptions were distributed for discussion (copy on file). Because of time constraints the Subcommittee deferred discussion of the items until the next meeting.

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Motion to defer the Outpatient Ambulatory and AIDS Pharmaceutical service descriptions until the next meeting.
Moved: James Dougherty **Second: Dallas Bauman** **Motion: Passed**

IX. Announcements

Mr. McFeely announced the Anchor Study had met the study goals and indicated screenings help reduce mortality by identifying anal cancer early. An official announcement is expected in the next few weeks. The final recommendations will be forwarded to the National Guidelines. Additional capacity will need to be built for the screenings.

Christina Bontempo announced Community Coalition is hosting a roundtable at Empower U and indicated flyers were available at the meeting to post or distribute at agencies.

Dr. Romero indicated that ADAP open enrollment for ACA insurance plans has been extended until January 15, 2022. The Ryan White Program continues work with American Exchange to assist clients in the application process.

X. Next Meeting

The next Subcommittee is scheduled for October 22, 2021.

XI. Adjournment

Motion to adjourn.
Moved: James Dougherty **Second: Dr. Robert Goubeaux** **Motion: Passed**

Mr. Palacios adjourned the meeting at 11:30 a.m.

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Membership Report

October 20, 2021

The Miami-Dade HIV/AIDS Partnership

The official Ryan White Program Planning Council in Miami-Dade County and Advisory Board for HIV/AIDS to the Miami-Dade County Mayor and Board of County Commissioners

Opportunities for People with HIV

People with HIV who receive one or more Ryan White Program Part A services and who are not affiliated or employed by a Ryan White Program Part A funded service provider are invited to join the Partnership as a Representative of the Affected Community.

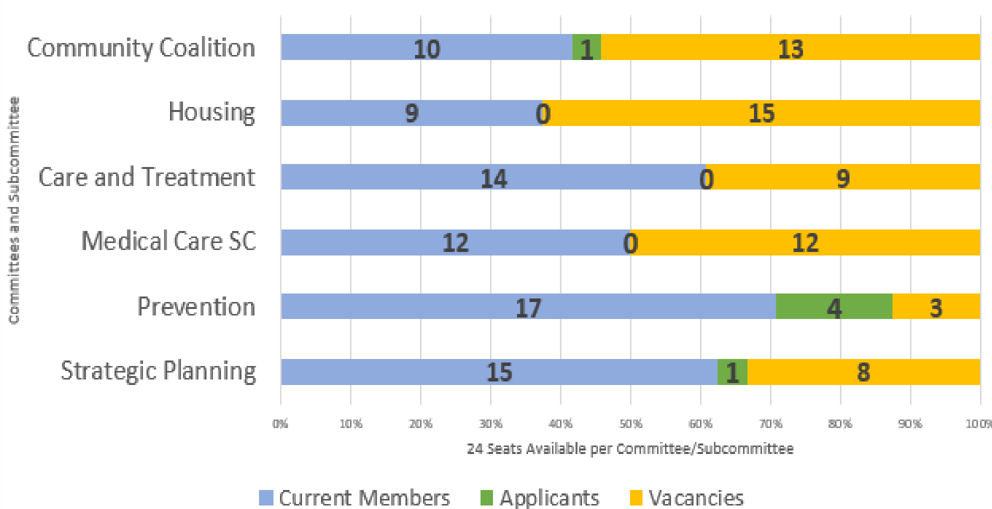
9 available seats / *1 application pending approval*

General Membership Opportunities

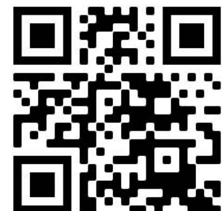
These Partnership positions are open to people with HIV, service providers, and community stakeholders who have reputations of integrity and community service, and possess the knowledge, skills and expertise relevant to these positions:

Former Inmate of Local, State, or Federal Prison Representative *1 application pending approval*
Representative Co-infected with Hepatitis B or C
Hospital or Health Care Planning Agency Representative
Other Federal HIV Program Grantee Representative (SAMHSA)
Federally Recognized Indian Tribe Representative
Mental Health Provider Representative
Miami-Dade County Public Schools Representative
Non-Elected Community Leader, not an HIV Provider

Partnership Committees



Committees are accepting applications for new members. People with HIV are encouraged to apply.



Scan the QR code with your phone's camera for membership applications!

MEMBERSHIP

Are you a Member?

Thank you for your service to people with HIV!

Be sure to bring a Ryan White client to your next meeting!

Do You Qualify for Membership?

If you answer "Yes" to these questions, you could qualify for membership!

Are you a resident of Miami-Dade County?

Are you a registered voter in Miami-Dade County?
Note: Some seats for people with HIV are exempt from this requirement.

Can you volunteer three to five hours per month for Partnership activities?

Committee Activities

Work with a dedicated team of volunteers on these and more Partnership activities to better serve people with HIV in Miami-Dade County!
People with HIV are encouraged to join!

- Allocate more than $27 million in Ryan White Program funds with the **Care and Treatment Committee**
- Develop an Annual Report on the State of HIV and the Ryan White Program in Miami-Dade County with the **Strategic Planning Committee**
- Recruit and train new Partnership members with the **Community Coalition**
- Work with the City of Miami Housing Opportunities for Persons with AIDS Program to address housing challenges for people with HIV/AIDS with the **Housing Committee**
- Oversee updates and changes to medical treatment guidelines for the Ryan White Part/ MAI Program with the **Medical Care Subcommittee**
- Set priorities for Ryan White Program HIV health and support services in Miami-Dade County with the **Care and Treatment Committee**
- Share a meal and testimonials at Roundtable Luncheons with the **Community Coalition**
- Develop and monitor the official HIV Prevention and Care Integrated Plan with the **Strategic Planning Committee** & **Prevention Committee**
- Develop your leadership skills and be a committee leader with the **Executive Committee**
- Oversee updates and changes to the Ryan White Prescription Drug Formulary with the **Medical Care Subcommittee**
- Develop and monitor local Ending the HIV Epidemic activities with the Florida Department of Health in Miami-Dade County with the **Prevention Committee** & **Strategic Planning Committee**
- Be in the know about the latest HIV activities of the Prevention Mobilization Workgroups with the **Prevention Committee**

Visit aidsnet.org/membership for the complete list of applications and details on Partnership and committee membership opportunities. Contact us at hiv-aidsinfo@behavioralscience.com or 305-445-1076 for assistance.

MIAMI-DADE HIV/AIDS PARTNERSHIP

Medical Care Subcommittee
Friday, October 22, 2021

9:30 a.m. – 11:30 a.m.

Behavioral Science Research
2121 Ponce de Leon Blvd.
Coral Gables, FL and Zoom

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I.	Call to Order	Carlos Palacios
II.	Meeting Rules and Housekeeping	Carlos Palacios
III.	Roll Call and Introductions	Carlos Palacios
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X.	Announcements	All
	• Anchor Study Release	Marlen Meizoso
XI.	Next Meeting: **November 19, 2021** at Main Library- **Auditorium**	Carlos Palacios
XII.	Adjournment	Carlos Palacios

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Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

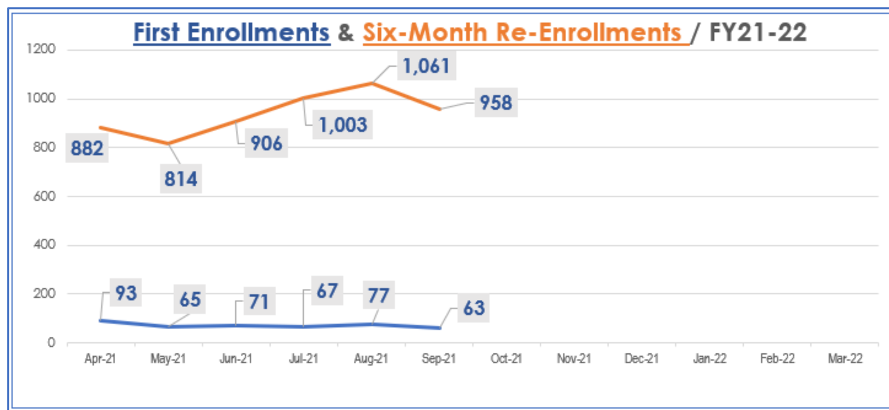
Ron DeSantis
Governor

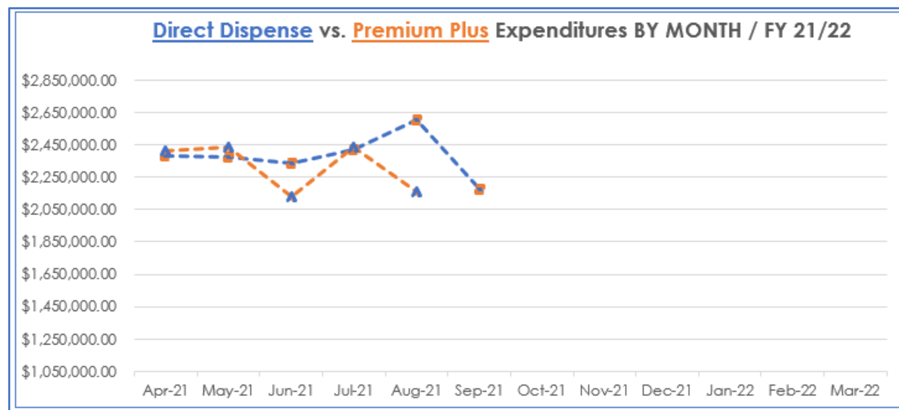
October 10, 2021

ADAP Miami-Dade / Summary Report – SEPTEMBER 2021

FY 21/22	First Enrollments	6-mo. Re-Enrollments	TOTAL OPEN		CHD Pharmacy Expenditures	RXs	Patients	RX/Pt		Premium Payments	Number of Premiums	Average Premium
FY20/21 >>	795	10,979	5,766		$32,843,354.32	52,678	17,944	2.9		$23,115,161.17	25,395	$ 910.22
Apr-21	93	882	5,921		$2,379,896.89	3,824	1,285	3.0		$2,413,106.07	2,366	$1,019.91
May-21	65	814	5,935		$2,376,870.79	3,856	1,289	3.0		$2,435,148.77	2,392	$1,018.04
Jun-21	71	906	5,915		$2,337,952.33	3,997	1,313	3.0		$2,131,887.00	1,917	$1,030.20
Jul-21	67	1,003	5,879		$2,423,002.81	4,396	1,356	3.2		$2,436,296.66	2,403	$1,013.86
Aug-21	77	1,061	5,686		$2,602,360.80	4,490	1,456	3.1		$2,157,974.33	1973	$1,093.75
Sep-21	63	958	5,755		$2,176,932.46	3,788	1,319	2.9		$2,430,671.29	2,395	$1,014.89
Oct-21												
Nov-21												
Dec-21												
Jan-22												
Feb-22												
Mar-22												
TOTAL	436	5,624	5,915		$14,297,016.08	24,351	8,018	3.0		$ 14,005,084.12	13,446	$1,041.58

SOURCE: Provide - DATE: 10/09/21 - Subject to Review & Editing - West Perrine: NOT INCLUDED. (Estimate ~450 clients ~$6+ million/TBC).





PROGRAM UPDATE

09/10	Cabenuva ® utilization	ADAP Miami clients	RESULTS: 36 clients. 17 Direct Dispense (47%); 19 Premium Plus (53%).
09/13	2022 ACA-MP Open Enrollment	New ADAP Income limit 75-400 % FPL	RESULTS: new 75-99%: ~620 pts. *(222/36% No SSN; 398/64% SSN)*
09/15	ADAP Formulary Expansion	Additions: 54 - Deletions: 5	SEARCH: Florida ADAP Formulary. Also @ ADAPMiami.com

For additional information: www.ADAPMiami.com or ADAP.FLDOHMDC@flhealth.gov

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Cabenuva Barriers Discussion

Items identified at the July meeting:

- Issues with pharmacy authorizations
- Medication not being approved yet on the Jackson formulary
- Misperceptions that any pharmacy can fill the Cabenuva prescriptions
- Issues with insurance plans (some bill medication as a pharmacy benefit others bill under medical services e.g., Medicare, private insurance
- Patients are being denied because they were receiving the medication originally via a study.

Query Results

A query with three questions was sent to a contact at provider agencies in August, the results of replies are below. Additional discussion from September has been included in this section.

1. **How many clients have you transitioned to Cabenuva?**

   1) 11
   2) 9**,** these nine clients have either started an oral lead in or received a subsequent injection. Seven clients are in the process of enrolling in Cabenuva.
   3) 23 currently

2. **Have you faced any barriers? If so, were these related to any of the following reasons:**

   a. Enrollment process.

   1) Coordinating the completion of the enrollment with a provider and patient signature: The nurse is messaged stating the patient is interested in Cabenuva.
   2) For tele health visits, the nurse must contact patient to answer any questions and explain how the enrollment process works for Cabenuva.
   3) Once a patient leaves an in-office visit, or disconnects from a tele health visit, it becomes more challenging to contact a patient and coordinate the completion of the enrollment form.
   4) The patient can present to clinic to sign the form or do so electronically. When completed electronically, there is usually a processing time of 3-5 business days before receiving a summary of benefits.
   5) We are currently collecting provider signatures for enrollment forms of Cabenuva to decrease delays in the patient receiving their medication.
   6) Yes, enrollment with ViiV can cause delays.

   b. Ordering the medication.

   1) Several calls to ViiV connect are required to order and schedule deliveries of the oral leading dose.
   2) We need to remind providers not to place oral leads of Cabenuva or injections themselves. Doing so bypasses the enrollment process to determine if the medication is covered by insurance and the need to determine the payor.

3) We are also not able to send prescriptions electronically under a pharmacy benefit. Ticket has been placed, but no solution to date.
4) Yes, ordering with specialty pharmacies has caused delays.

c. Delays in receiving the medication.

1) Yes, the oral leading dose.
2) Delays have occurred in shipment of the medication.
3) Delays in receiving medication at doctor's office.
4) Clinical trial client told to call 10 days in advance of need, but medication was not delivered (medications don't ship Friday for Monday).
5) Issue with getting orders on time either through FL Blue or ADAP (CVS Specialty).

d. Issues with authorizations, if so, for pharmacy or medical office?

1) One Pharmacy denial from private insurance stated that there was no indication that patient had difficulty maintaining compliance with daily antiretroviral therapy". However, federally approved medical practice guidelines for HIV/AIDS recommend these therapies for populations consistently engaged in care, similar to the ones enrolled in clinical trials**.**
2) Prior authorizations pending by the medical and or pharmacy office for approval of Cabenuva. The time commitment it takes to complete the required prior authorizations and the length of time is takes before the patient receives the oral lead in is often significant. By the time the PA is completed, we often check in with patient to determine if they still have interest in transitioning to Cabenuva.
3) Medical authorizations have been very challenging as Medical Prior Authorizations is not typical for them. Also, we have had two denials on a prior authorization for a new start from the pharmacy side.

e. Billing the medication.

1) Meetings and trainings held to discuss properly billing for the medication. Initial issues with J codes and training staff on using the correct code under buy and bill acquisition and or not properly billing for each injection since Cabenuva consists of two injections per visit – Rilpivirine and Cabotegravir.
2) Billing Medical Insurance has been an issue as it may take a month or longer to know if there will be reimbursement.
3) Billing through buy and bill process offers poor reimbursement, this maybe issue with either the insurance or health center.

f. Providing the injection at the office.

The only known issue is correctly billing for the injection at the clinic, see above.

g. Compliance with appointments by clients.

Patients have been compliant. If any appointments have been missed, patients have come in appropriately the following day.

h. Other, please detail.

1) Issues with applications process, applications are incomplete.
2) Communication with CVS specialty is unreliable close to 2 hours to review 3 patients.
3) Some clients signed up but are not aware the medication is injectable or that would require regimen change.
4) Some clients still picked up medications from ADAP while taking Cabenuva. It was suggested that the pharmacy calls ADAP to ensure they discontinue dispensing other medications since ViiV is not contacting ADAP.
5) New J-code (J0741) should go into effect after October1 which may improve billing reimbursement.

3. **Any other issues you wish to share regarding accessing Cabenuva?** No replies

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Florida AIDS Drug Assistance Program (ADAP) Formulary
September 2021 Additions
Estimated Cost Analysis

	Generic Name	Therapeutic Classification	Pharmacologic Classification	Estimated Cost (per unit or monthly cost)	Notes/Comments
1	semaglutide	Antidiabetic	Glucagon-like peptide-1 receptor agonist (GLP-1 RA)	Rybelsus (oral): $27.16 per unit/$814.90 per month; Wegovy (SC) $322.72 per unit/$1290.88 per month	
2	dulaglutide	Antidiabetic	Glucagon-like peptide-1 receptor agonist (GLP-1 RA)	$201.99 per unit/$807.97 per month	
3	liraglutide	Antidiabetic	Glucagon-like peptide-1 receptor agonist (GLP-1 RA)	Victoza: $648.30-972.45 per month/$258.17 per unit; Saxenda: $1,290.88 per month; $258.17 per unit	
4	canagliflozin	Antidiabetic	Sodium-glucose co-transporter 2 (SGLT2) inhibitor	$519.75 per month/$866.25 per unit	
5	dapagliflozin	Antidiabetic	Sodium-glucose co-transporter 2 (SGLT2) inhibitor	$509.87 per month/$16.99 per unit	
6	empagliflozin	Antidiabetic	Sodium-glucose co-transporter 2 (SGLT2) inhibitor	$524.90 per month/$17.49 per unit	
7	allopurinol	Antigout	Xanthine oxidase inhibitor	$6.60 per month/$0.22 per unit	
8	sofosbuvir/velpatasvir	Anti-infective	Hepatitis C antiviral	Brand: $24,297 per month/$867.75 per unit; Generic: $7,800 per month/$278.57 per unit	
9	sofosbuvir/velpatasvir/voxilaprevir	Anti-infective	Hepatitis C antiviral	$24,297 per month/$897.75 per unit	
10	naltrexone ER/bupropion ER	Anti-obesity	Anoretic agents	$290.51 per month/$2.41 per unit	
11	orlistat	Anti-obesity	Gastrointestinal lipase inhibitor	$656.25 per month/$7.29 per unit	
12	apixaban	Blood formation and coagulation	Anticoagulant	$477.56 per month/$7.96 per unit	
13	dabigatran	Blood formation and coagulation	Anticoagulant	$456.36 per month/$7.61 per unit	
14	rivaroxaban	Blood formation and coagulation	Anticoagulant	$454.78 per month/$15.16 per unit	
15	hydralazine	Cardiovascular	Antiangina	0.0100 to 0.6700 per tablet 340B;	Indication: Hypertension. Heart failure with reduced ejection fraction. Class: Peripheral Vasodilator
16	carvedilol	Cardiovascular	Beta-blocker	0.0100 to 0.8270 per tablet 340B	Indication: Heart Failure with reduced ejection fraction, Hypertension. Class: Alpha/Beta Adrenergic Blocker
17	labetalol	Cardiovascular	Beta-blocker	0.0100 to 0.1516 per tablert 340B	Indication: Hypertension. Chronic hypertension and Hypertensive emergency in pregnancy. Class: Alpha/Beta-Adrenergic Blocker
18	propranolol	Cardiovascular	Beta-blocker	0.0100 to 0.1709 per cap/tab 340B	Indication: Angina pectoris (chronic), Cardiac Dysrhythmia, Hypertension, Idiopathic hypertrophic cardiomyoathy, Migraine (prophylaxis), Pheochromocytoma. Class: Beta-Adrenergic Blocker (Nonselective), Cardiovascular Agent

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19	clopidogel	Cardiovascular	Platelet inhibitor	0.0276 to 0.4901 per tablet 340B	Indication: Acute coronary syndrome, Myocardial infarction, ischemic stroke, or peripheral atherosclerotic disease. Class: Antiplatelet Agent, Thienopyridine, P2Y12 Antagonist
20	prasugrel	Cardiovascular	Platelet inhibitor	0.0300 to 0.2583 per tablet 340B	Indications: acute coronary syndrome, percutaneous coronary intervention, thrombosis. Class: ADP- induced aggregation Inhibitor, Platelet aggregation Inhibitor, Thienopyridine; P2Y12 Antagonist
21	chlorthalidone	Cardiovascular	Thiazide-like diuretic	0.0100 to 0.1899 per tablet 340B	Indication: Edema (refractory), Hypertension. Class: Thiazides, Diuretic.
22	benztropine	Central nervous system	Anticholinergic	0.0100 to 0.0442 per tablet 340B	Indication: Parkinsonism, extrapyramidal disease. Class: Anticholinergic, Antiparkinsonian
23	topiramate	Central nervous system	Anticonvulsant	0.0100 to 0.652 per tablet 340B	Indication: Migraine Prophylaxis, Seizure. Antipsychotic-induced weight gain; Binge eating disorder. Class: Anticonvulsant, Central Nervous System Agent
24	frovatriptan	Central nervous system	Antimigraine	0.0089 to 4.5033 per tablet 340B	Indication: Acute treatment of Migraine. Class: Antimigraine, Serotonin Receptor Agonist (5HT1)
25	naratriptan	Central nervous system	Antimigraine	0.1644 to 6.4978 per tablet 340B	Indication: Migraine. Class: Antimigraine, (5HT1)
26	rizatriptan	Central nervous system	Antimigraine	0.1975 to 2.47 per tablet	Indication: Migraine. Class: Antimigraine, (5HT1)
27	sumatriptan	Central nervous system	Antimigraine	0.0100 to 4.9222 per tablet	Indication: Migraine. Class: Antimigraine, (5HT1)
28	buspirone	Central nervous system	Anxiolytic	0.0138 to 0.1326 per tablet 340B	Indications: GAD, Antiety. Class: Antiety, Azaspirodecanedione
29	baclofen	Central nervous system	Muscle relaxant	0.0100 to 0.1135 per tablet 340B	Indication: Spasticity. Class: Skeletal Muscle Relaxant
30	cyclobenzaprine	Central nervous system	Muscle relaxant	0.0100 to 0.8242 per tablet 340B	Indication: Muscle spasm. Class: Skeletal Muscle Relaxant
31	dicyclomine	Gastrointestinal	Antispasmodic	*10mg = $2.37 per 100ct 20mg = $2.12 per 100ct ; 10mg/5ml = $43.19 per 473ml	GR; No similar agents in formulary
32	sucralfate	Gastrointestinal	Gastric acid buffer	*1 gm tabs(brand) = $0.92 per 100ct.	Significant drug interactions; Similar agents: ranitidine, omeprazole
33	calcium polycarbophil	Gastrointestinal	Laxative, bulk-forming	*625mg = $1.89 per 60 ct.	OTC; GR; products like Fibercon; no equivalent in RW formulary
34	methylcellulose	Gastrointestinal	Laxative, bulk-forming	*500 mg = $13.37 per 100ct.	OTC; GR; products like Citrucel; no equivalent in RW formulary
35	psyllium	Gastrointestinal	Laxative, bulk-forming	*3.5gm = $12.55 per 30 pkt.	OTC; products like Metamucil; no equivalent in RW formulary
36	bisacodyl	Gastrointestinal	Laxative, stimulant	*10mg supp = $5.83 per 50ct. ; 5mg tab = $0.90 per 100ct.	OTC; GR; products like Dulcolax; no equivalent in RW formulary

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	Generic Name	Therapeutic Classification	Pharmacologic Classification	Estimated Cost (per unit or monthly cost)	Notes/Comments
37	**docusate sodium**	Gastrointestinal	Laxitive, stool softener	*100 mg = $1.03 per 100ct.	OTC; GR; products like Colace; no equivalent in RW formulary
38	**oxybutynin**	Genitourinary	Bladder antispasmodic	*5mg = $1.80 per 100 ct ; *10mg = $2.98 per 100 ct; *15mg = $3.02 per 100ct	GR
39	**fexofenadine**	Respiratory	Antihistamine	*60mg = $9.69 per 100ct ; *180mg = $8.83 per 100ct	OTC; GR; similar agent in formulary Benadryl
40	**montelukast**	Respiratory	Leukotriene receptor antagonist	*4mg = $0.82 per 30ct ; *5mg = $0.61 per 30 ct ; *10mg = $0.65 per 30ct	GR
41	**hydroxyzine**	Respiratory or CNS	Antihistamine or anxiolytic	*10mg = $1.11 per 100ct; *25mg = $1.49 per 100ct; *50mg = $0.92 per 100ct	GR
42	**disulfiram**	Substance abuse	Alcohol deterrent	*250mg = $17.82 per 100ct.	GR
43	**nicotine**	Substance abuse	Nicotine replacement	*7mg(patch) = $9.75 per 14ct ; 14mg(patch) = $10.17 per 14 ct ; 21mg(patch) = $10.05 per 14 ct.	GR, Varenicline in RW formulary; usually used in addition to varenicline for smoking cessation with better results.
44	**naltrexone (oral)**	Substance abuse	Opiate antagonist	*50mg = $9.72 per 30 ct ; *380mg(vial) = $543.78 per 1 package	GR
45	**ammonium lactate**	Topical	Humectant	*12% lotion = $3.07 per 226gm	GR
46	**magnesium oxide**	Vitamin	Vitamin	*400mg = $2.02 per 100ct.	GR, OTC

MIAMI-DADE HIV/AIDS PARTNERSHIP

Medical Care Subcommittee
Friday, October 22, 2021

9:30 a.m. – 11:30 a.m.

Behavioral Science Research
2121 Ponce de Leon Blvd.
Coral Gables, FL and Zoom

AGENDA

I.	Call to Order	Carlos Palacios
II.	Meeting Rules and Housekeeping	Carlos Palacios
III.	Roll Call and Introductions	Carlos Palacios
IV.	Floor Open to the Public	Carlos Palacios
V.	Review/Approve Agenda	All
VI.	Review/Approve Minutes of September 24, 2021	All
VII.	Reports	
	• Membership Vacancies	Marlen Meizoso
	• Partnership Report (informational)	Marlen Meizoso
	• Ryan White Program (no new report)	Ana Nieto
	• ADAP Program	Dr. Javier Romero
VIII.	Standing Business	
	• Conclusion of Cabenuva barriers discussion	All
	• ADAP formulary additions and RWP review	All
	• Primary Medical Care Standards	All
	• Service Descriptions -Outpatient Ambulatory and AIDS Pharma	All
IX.	New Business	
	• 2022 Meeting Dates	Marlen Meizoso
X.	Announcements	All
	• Anchor Study Release	Marlen Meizoso
XI.	Next Meeting: **November 19, 2021** at Main Library- **Auditorium**	Carlos Palacios
XII.	Adjournment	Carlos Palacios

Please turn off or mute cellular devices – Thank you

For more information, regarding the Miami-Dade HIV/AIDS Partnership's Medical Care Subcommittee please contact Marlen Meizoso at 305-445-1076 or marlen@behavioralscience.com

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Miami-Dade County Ryan White Program
Minimum Primary Medical Care Standards

Drafted and Reviewed by the Medical Care Subcommittee
and Approved by the
Miami-Dade HIV/AIDS Partnership

Statement of Intent: *All local Ryan White Program-funded practitioners are required by contract to adhere, at a minimum, to the Public Health Service (PHS) Guidelines.*

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Requirements

1. **Requirements for New Practitioners** (Physicians, Advance Practice Registered Nurse, and Physician Assistants):

   - New practitioners should be linked to existing Ryan White Program providers, AETC or through an AAHIVM specialist to support the new provider.
   - New providers will receive a chart review within 6 months by supervising physician, medical director or agency team.
   - When a new practitioner is working with a contracted practitioner, new practitioner is encouraged to comply within one year to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits

   Requirements for All Practitioners (Physicians, Advance Practice Registered Nurse, and Physician Assistants):

   - Practitioner must be a Physician (MD or DO), Nurse Practitioner, or Physician Assistant with current and valid license to practice medicine within the State of Florida
   - Practitioners must have a minimum experience treating 20 HIV+ clients over the past two years or currently working and under supervision of a practitioner meeting these qualifications.
   - Practitioners are strongly encouraged to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits within a period of two years.
   - Treat and monitor patients in adherence with current DHHS Guidelines and other standards of care, to include, but not limited to:
     a. DHHS Clinical Guidelines
        https://clinicalinfo.hiv.gov/en/guidelines
     b. US Preventive Taskforce
        https://www.uspreventiveservicestaskforce.org/uspstf/
     c. American Cancer Society Guidelines for the Early Detection of Cancer
        http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp
     d. European AIDS Clinical Society (EACS) guidelines on the prevention and management of metabolic diseases in HIV
        https://www.eacsociety.org/guidelines/eacs-guidelines/
     e. ACC/AHA Guideline on the Treatment of Blood Cholesterol
        https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625
     f. CDC Recommended Adult Immunization Schedule
        http://www.cdc.gov/vaccines/schedules/hcp/adult.htlm

g. Incorporating Recommendations for HIV Prevention with Adults and Adolescents with HIV in the US
   http://stacks.cdc.gov/view/cdc/26062
h. Although not paid for by the Ryan White Program, below are PrEP, nPEP and PEP guidelines:
   https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
   https://www.cdc.gov/hiv/clinicians/prevention/prep-and-pep.html
   https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
i. National HIV Curriculum
   https://www.hiv.uw.edu/alternate
j. American Association for the Study of Liver Diseases
   https://www.aasld.org/publications/practice-guidelines-0
k. HIV Drug Interactions University of Liverpool
   https://hiv-druginteractions.org/
l. HEP Drug Interactions University of Liverpool
   https://www.hep-druginteractions.org/
m. American Medical Association Telehealth Quick Guide
   https://www.ama-assn.org/practice-management/digital/ama-telehealth-quick-guide
n. Miami-Dade County Ryan White Program Telehealth Policy
   https://www.miamidade.gov/grants/library/ryanwhite/telehealth.pdf
o. Miami-Dade County Ryan White Program Test and Treat / Rapid Access (TTRA) Protocol
   https://www.miamidade.gov/grants/library/ryanwhite/section-XIV-test-treat-rapid-access-protocol.pdf
   https://www.ama-assn.org/practice-management/digital/ama-telehealth-quick-guide

- Follow an action plan to address any areas for performance improvement that are identified during quality assurance reviews.

Minimum Standards by Which Practitioners Will Be Measured

Assessments and Referrals

2. **Initial** - At initial visit:
   a. If enrolled as Test and Treat/Rapid Access (TTRA) client (patient), follow TTRA protocol for visit
   b. Comprehensive initial history
   c. Mental health and substance abuse assessment
   d. Physical examination, including review of systems
   e. Vital signs, including weight, BMI, height (no shoes) This may not happen on first visit due to COVID and telehealth but should be scheduled for inhouse appt ASAP
   f. Gynecological exam per guidance for females-need consent pursuant to FL Statues.
   g. Wellness exam for females
   h. Rectal examination and stool guaiac testing-not done usually (FIT or GI referral for colonoscopy); Need consent pursuant to FL Statutes
   i. Sexually transmitted infection assessment as appropriate including at a minimum GC, Chlamydia at anatomical sites of potential exposure, RPR, and for females trichomoniasis NAAT of vaginal secretions.
   j. Age appropriate cancer screening
   k. Adherence to medications

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l. Risk reduction
m. Safer sex practices-discussions may include PrEp, PEP, nPEP for sexual partners and should include condom usage
n. Pregnancy Planning:
   1) Preconception counseling for men and women
   2) Contraceptive counseling for men and women including assessment and type of birth control method
o. Targeted initial history and physical examination with expectation that a complete history and physical examination will be completed within 3 months.
p. Education that they should never run out of ARV medications and need to call the FDOH-MDC clinic if they cannot obtain ART.

Item to be covered by subrecipient staff: Documented HIV education, including: transmission, reduction of morbidity/mortality with ART; resistance; compliance with ARV and office visits and lab monitoring; life expectancy; divulging HIV status and state statute

3. **Interim Monitoring and Problem-Oriented visits** - At every visit:
   a. Vital signs, including weight/BMI-may not occur every time with telehealth
   b. Physical examination related to specific problem, as appropriate
   c. Interval changes in vital signs addressed, especially trend in weight over time
   d. Adherence to medications and lab and office visits for monitoring
   e. Risk reduction
   f. Safer sex practices-discussions may include PrEp, PEP, nPEP for sexual partners and should include condom usage
   g. Interval risk for acquiring STD and screening as indicated
   h. In women of childbearing age, assessment of adequate contraception

4. **Annual** - At each annual visit:
   a. Update comprehensive initial history, as appropriate
   b. Physical examination, including review of systems
   c. Vital signs, including weight, BMI, height (no shoes)-may not occur every time with telehealth. Annual exams should be done in office and include the above.
   d. Interval changes in vital signs addressed, especially trend in weight/BMI over time
   e. Mental health and substance abuse assessment
   f. Gynecological exam per guidance for females -may need to be scheduled if done by telehealth, should be done in office.
   g. Wellness exam for females
   h. Rectal examination and stool guaiac testing-not done usually (FIT or GI referral for colonoscopy)
   i. Sexual transmitted infection assessment
   j. Age appropriate cancer screening
   k. Adherence to medications
   l. Risk reduction
   m. Safer sex practices-discussions may include PrEp, PEP, nPEP, for sexual partners and should include condom usage
   n. Preconception counseling for men and women

   Assess and document health education on:
   o. Nutritional assessment/care
   p. Oral health care

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q. Mental Health assessment (particularly clinical depression)/care
r. Exercise
s. Drugs/Alcohol/Tobacco (including smokeless) assessment/care
t. Domestic violence
u. Birth control
v. Advance Directives (completion or review)

Item to be covered by subrecipient staff: If client knows of others who need PrEP or Test and Treat / Rapid Access, information and referral are offered.

5. **Additional Charting/Documentation at least annually:**
   a. Problem list complete and up-to-date
   b. Medications list complete with start and stop dates, dosages
   c. Allergies list complete and up-to-date
   d. Immunization list complete and up-to-date

6. **Telehealth**

   Telehealth may be used in place or conjunction with an office visit. Necessary assessments will be conducted as needed and follow-ups will be scheduled as appropriate.

<u>Assessments to be included at Incremental Visits</u>

HIV Specific

7. **CD4 cell count** [i] - Entry into care; at ART initiation or modification; every 3-6 months during the first 2 years of ART, or if viremia develops while patient is on ART, or if CD4 count is <300 cells/mm^3; every 12 months after 2 years on ART with consistently suppressed viral load, CD4 count 300-500 cells/mm^3, if CD4 count >500 cells/mm^3: CD4 monitoring is optional; if ART initiation is delayed monitor every 3-6 months; if treatment failure or if clinically indicated. *In accordance with the HRSA HAB performance measures, the local program defines consistently suppressed viral load as <200 copies/ml.*

8. **HIV viral load** [i] - Entry into Care; at ART initiation or modification; 2-8 weeks after ART initiation or modification if HIV RNA is detectable at 2-8 weeks, repeat testing every 4-8 weeks until viral load is suppressed to <200 copies/mL. Thereafter, repeat testing every 3-6 months; every 3 to 6 months or every 6 months, in patients on ART, viral load typically is measured every 3-4 months. More frequent monitoring may be considered in individuals who are having difficulties with ART adherence. However, for adherent patients with consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended to 6-month intervals; if ART initiation is delayed, repeat testing is optional; treatment failure or if clinically indicated.

9. ***ARV therapy is recommended and discussed*** [i, iv]- Risks and benefits are discussed including reduced morbidity and mortality and prevention of HIV transmission to others and if treatment initiated, follow-up with adherence. If refused, document in record and refer to ARTAS and or Department of Health Treatment Adherence Specialist.

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10. **Treatment of opportunistic infections and prophylaxis for opportunistic infections** [ii] - Specifically, but not limited to, Mycobacterium avium complex (MAC), Pneumocystis jirovecii pneumonia (PCP), and Toxoplasmosis (Toxo) prophylaxis per DHHS Guidelines.

11. **Resistance Testing** [i] - Entry into care; at ART initiation or modification; if ART initiation is delayed; treatment failure or clinically indicated. Based on current rates of transmitted drug resistance to different ARV medications, standard genotypic drug-resistance testing in ARV-naïve-persons should focus on testing for mutations in the reverse transcriptase and protease genes. If transmitted INSTI resistance is a concern or if a person presents with viremia while on an INSTI, providers should also test for resistance mutations to this class of drugs. In ART-naïve patients who do not immediately begin ART, repeat testing before initiation of ART is optional if resistance testing was performed at entry into care. In patients with virologic suppression who are switching therapy because of toxicity or for convenience, viral amplification will not be possible; see the DHHS section on Drug Resistance Testing for discussion of the potential limitations and benefits of proviral DNA assays in this situation. Results from prior resistance testing can be helpful in constructing a new regimen.

12. **HLA-B*5701** [i] - If considering start of abacavir (ABC) at ART initiation or modification and document in record carrying data forward to most current volume. *(Currently not paid for by the Ryan White Program due to payer of last resort restrictions; must access ViiV sponsored testing directly through labs. For LabCorp, HLA-AWARE HLA-B*5701 ViiV code #006940 and for Quest Diagnostic ViiV HLA-B*B5701 test code #19774)*

13. **Tropism testing** [i] - If considering use of CCR5 antagonist (requires plasma HIV RNA level ≥ 1000 copies/mL) in ART initiation or modification, or for patients experiencing virologic failure on a CCR5 antagonist-based regimen or if clinically indicated. If performed, record carried forward to most current volume.

STI Screenings

14. **Anal Dysplasia Screening** [iii] - ***Optional-*** Anal cytology screening for MSM, cisgender women, transgender women, and transgender men who have HIV and are ≥35 years. Anal cytology for screening is not currently recommended for men who have sex with women (MSW); however, clinicians may perform anal cytology testing for any patient with HIV who requests it. If clinicians have previously adopted screening for anal cancer, including anal cytology, HRA, and treatment in younger individuals, they may engage their patients in shared decision-making regarding ongoing screening or deferral until age 35. Considerations that may be weighed in the discussion include cytology results, HPV HR status, previously identified ASC-H/HSIL, and previous treatment. Additional information at https://www.hivguidelines.org/hiv-care/anal-dysplasia-cancer/.

15. **Bacterial STIs (Syphilis**, **N. gonorrhoeae** (GC), **C. trachomatis** (Chlamydia) and **parasitic STIs (Trichomoniasis)** [iv]- At the initial HIV care visit, providers should test all sexually active persons with HIV infection for curable STDs (e.g., syphilis, gonorrhea, and chlamydia) and perform testing at least annually during the course of HIV care. Specific testing includes syphilis serology and NAAT for N. gonorrhoeae and C. trachomatis at the anatomic site of exposure, as the preferred approach. Women with HIV infection should also be screened for trichomonas at the initial visit and annually thereafter. Women should be screened for cervical cancer precursor lesions by cervical Pap tests per existing guidelines. More frequent screening for curable STDs might be appropriate depending on individual risk

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behaviors and the local epidemiology of STDs. Many STDs are asymptomatic, and their diagnosis might indicate risk behavior that should prompt referral for partner services and prevention counseling. USPSTF recommends high-intensity behavioral counseling for all sexually active adolescents and for adults at increased risk for STDs and HIV. The following are recommended annual for sexually active MSM, syphilis serology, testing for urethral infection with N. gonorrhoeae and C. trachomatis in men who have had insertive intercourse during the preceding year, test for rectal infections with N. gonorrhoeae and C. trachomatis for men who have receptive anal intercourse during the preceding year and test for pharyngeal infection with N. gonorrhoeae in men who have had receptive oral intercourse during the preceding year. More frequent STD screenings at 3-6-month intervals is indicated if risk behaviors persist. Additional information at https://www.cdc.gov/std/tg2015/tg-2015-print.pdf.

General Health including Labs

16. **ALT, AST, Total Bilirubin** [i] - Entry into care; ART initiation or modification; 2-8 weeks after ART initiation or modification; every 6 months; or if ART initiation is delayed, every 6-12 months, or if clinically indicated.

17. **Basic chemistry** [i,v] - Entry into care; ART initiation or modification; 2-8 weeks after ART initiation or modification; every 6 months; if ART initiation is delayed every 6-12 months, or if clinically indicated. Serum Na, K, HCO_3, Cl, BUN, creatinine, glucose, and creatine-base glomerular filtration rate. Serum phosphorus should be monitored in patients with chronic kidney disease who are on TDF(tenofovir)-containing regimens. Consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America for recommendations on managing patients with renal diseases. More frequent monitoring may be indicated for patients with evidence of kidney diseases (e.g. proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g. patients with diabetes, hypertension). Additional information at https://academic.oup.com/cid/article/59/9/e96/422813

18. **CBC w/ differential** [i] - Entry into care; ART initiation or modification; every 3-6 months when monitoring CD4 cell count; perform CBC cell count and CD4 concurrently; every 12 months when no longer monitoring CD4 cell count; if ART initiation is delayed, every 3-6 months, or if when clinically indicated. CBC with differential should be done when a CD4 count is performed. When CD4 count is no longer being monitored, the recommended frequency of CBC with differential is once a year. More frequent monitoring may be indicated for persons who are receiving medications that potentially cause cytopenia [e.g. ZDV (zidovudine), TMP-SMX (trimethoprim-sulfamethoxazole)].

19. **Random or Fasting Glucose** [i,vi] - Entry into care; ART initiation or modification; every 12 months; if ART initiation is delayed but if normal at baseline, annually, or if clinically indicated. If random glucose is abnormal, fasting glucose should be obtained. HbA1C is no longer recommended for diagnosis of diabetes in person with HIV on ART, see ADA guidelines. Additional information at https://care.diabetesjournals.org/content/43/Supplement_1.

20. **Random or Fasting Lipid Profile** [i,vii] - Entry into care; ART initiation or modification; every 12 months; if ART initiation is delayed but if normal at baseline, annually, or if clinically indicated. If random lipids are abnormal, fasting lipids should be obtained. Consult the 2018 Guideline on the Management of Blood Cholesterol for diagnosis and management of

patients with dyslipidemia. Additional information at https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2018/11/09/14/28/2018-guideline-on-management-of-blood-cholesterol.

21. **Urinalysis** [i,v] - Entry into care; ART initiation or modification; every 6 months in patients with on a tenofovir-containing regimen (TDF). For those patients serum Na, K, HCO_3, Cl, BUN, creatinine, glucose, and creatine-base glomerular filtration rate. Serum phosphorus should be monitored in patients with chronic kidney disease who are on TDF(tenofovir)-containing regimens.; every 12 months or if clinically indicated. Consult the Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Disease Society of America for recommendations on managing patients with renal disease. More frequent monitoring may be indicated for patients with evidence of kidney disease (e.g., proteinuria, decreased glomerular dysfunction) or increased risk of renal insufficiency (e.g., patients with diabetes, hypertension). Urine glucose and protein should be assessed before initiating tenofovir alafenamide (TAF)-or tenofovir (TDF)-containing regimens and monitored during treatment with these regimens.
    Additional information at https://academic.oup.com/cid/article/59/9/e96/422813

22. **TB Testing** [ii] - QuantiFERON TB Gold, T-SPOT, or Tuberculin Skin Test (TST), placed by the Mantoux method, should be performed as close to diagnosis of HIV infection and annually thereafter. If tested when CD4 < 200, repeat after CD4 increases to above 200. Annual TB test is recommended if patient is deemed high risk (repeated or ongoing exposure to known active TB, after incarceration, after living in congregate setting, active drug user or other risk factor for TB). If TB test is positive or has had active Tuberculosis documented with adequate treatment, annual chest X-ray should be performed. If chest X-ray cannot be afforded, cough screen questionnaire may be used as suggested by David Ashkin, MD.

23. **Bone Densitometry** [viii, ix] - Age 40-50 calculate FRAX to determine earlier screening and use "secondary causes" check box when using FRAX calculator. FRAX calculator: http://www.shef.ac.uk/FRAX/. All greater than or equal to age 50 men and postmenopausal women need DEXA. Additional information at http://hivinsite.ucsf.edu/InSite?doc=md-ward86-osteoporosis&page=md-ward86-index.[v]

24. **Colon and Rectal Cancer Screening** [x] - Colorectal cancer screening recommended for individuals between 45-75 years of age. For ages 76-85 screening should be based on personal preference, life expectancy, overall health, and prior screening history. Those over 85 years old should no longer get colorectal cancer screening. Discussion should take place earlier (1) for those with a personal history of colorectal cancer or certain types of polyps, (2) for those with a family history of colorectal cancer, (3) for those with inflammatory bowel disease (ulcerative colitis or Crohn's disease), (4) for those with confirmed or suspected hereditary colorectal cancers syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC), or for those for with a personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer.

25. **Lung Cancer Screening** [xi] -Annually with low-dose compute tomography (LDCT) for patients age 55-80 who have a 20 pack-year smoking history and currently smoke or have quit within the last 15 years. Screening should be discontinued once a person has not

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smoked for 15 years,or has developed a health problem that substantially limits life expectancy or ability or willingness to have curative lung surgery.

26. H**epatitis A Screening** [xii] - At initial screening, if non-immune, offer vaccination and after vaccination received do postvaccination serologic testing ≥1 month after completing the hepatitis A vaccine series. See additional recommendations in guidelines.

27. **Hepatitis B Serology (HBsAb, HBsAg, HBcAb total)** [i] - At entry into care; at ART initiation or modification, may repeat if patient is nonimmune and does not have chronic HBV infection; every 12 months, may be repeated if patient is nonimmune and does not have chronic HBV infection, or if clinically indicated, including prior to starting HCV direct-acting antiretroviral (see HCV/HIV Coinfection). If patient has HBV (as determined by a positive HBsAg or HBV DNA test result), TDF(tenofovir) or TAF (tenofovir alafenamide) plus either FTC (emtricitabine) or 3TC (lamivudine) should be used as part other ARV regiment to treat both HBV and HIV infections (HBV/HIV). If HBsAg, HBsAb, and HBcAb test results are negative, hepatis B vaccine series should be administered. Refer to the HIV Primary Care Guidelines and the Adult and Adolescent Opportunistic Infection Guidelines for detailed recommendations. Most patients with isolated HBcAb have resolved HBV infection with loss of HBsAb. Consider performing an HBV viral load test for confirmation. If the HBV viral load test is positive, the patient may be acutely infected (and will usually display other signs of acute hepatitis) or chronically infected. If the test is negative, the patient should be vaccinated. Refer to the HIV Primary Care Guidelines and the Adult and Adolescent Opportunistic Infection Guidelines for detailed recommendations.

28. **Hepatitis C Screening (HCV antibody or, if indicated, HCV RNA)** [i] - At entry into care; every 12 months, for at-risk patients-injection drug users, person with a history of incarceration, men with HIV who have unprotected sex with men, and persons with percutaneous/parenteral exposure to blood in unregulated settings are at risk for HCV infection; or when clinically indicated. The HCV antibody test may not be adequate for screening in the setting of recent HCV infection (defined as acquisition within the past 6 months), or advanced immunodeficiency (CD4 count <100 cells/mm^3). HCV RNA screening is indicated in persons who have been successfully treated for HCV or who spontaneously cleared prior infection. HCV antibody-negative patients with elevated ALT may need HCV RNA testing.

29. **Gynecological Exam** [xiii] (females) - In women and adolescents with HIV, initiation of cervical cancer screening with cytology alone should begin within one year of onset of sexual activity, or if already sexually active, within the first year after HIV diagnosis but no later than 21 years of age. Cervical cancer screenings in women who are infected with HIV should continue throughout a woman's lifetime (i.e. not stopping at age 65 years). In women infected with HIV who are younger than 30 years, if the initial cytology screening result is normal, the next cytology screening should be in 12 months. If the results of three consecutive annual cervical cytology screenings are normal, follow-up cervical cytology screen should be every 3 years. Co-testing (cervical cytology and human papillomavirus [HPV] screening) is not recommended for HIV-infected women younger than 30 years. Women infected with HIV who are 30 years and older can be screened with cytology alone or co-testing. After women screened with cytology alone have had three consecutive annual test results that are normal, follow-up screening can be every 3 years. Women infected with HIV who have one negative co-test results (normal cytology and HPV negative) can have their next cervical cancer screening in 3 years. In women with HIV infection, co-testing results that are cytology negative, but HPV positive are managed as in the general

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population. Women with HIV who have cervical cytology results of low-grade squamous intraepithelial lesions or worse should be referred for colposcopy. For women with HIV infection who are 21 years or older and have atypical squamous cells of undetermined significance (ASC-US) test results, if reflex HPV testing results are positive, referral to colposcopy is recommended. If HPV testing is not available, repeat cervical cytology in 6-12 months is recommended, and for any result of ASC-US or worse on repeat cytology, referral to colposcopy is recommended. Repeat cytology in 6-12 months, but not HPV testing, is recommended for HIV-infected women younger than 21 years with ASC-US test results. Although not explicitly stated in the Panel guidelines, women with HIV infection who have ASC-US, HPV-negative results (whether from reflex HPV testing or co-testing) can return to regular screening.

30. **Mammogram (**females) [xiv] - Starting at age 40, screening recommended annually. After age 55 every 2 years or can continue yearly screening. Screenings should continue as long as a woman is in good health and is expected to live at least 10 more years.

29. **Pregnancy test** [i] (For people of childbearing potential)- At entry into care; art initiation or modification or when clinically indicated.

30. **Annual wellness visit** (females) [xv]- Should include screenings for anxiety, breast cancer, cervical cancer, interpersonal and domestic violence, sexually transmitted infections, urinary incontinence, and contraception. For those who are pregnant, lactation support and screenings for diabetes mellitus, as applicable.

31. **Prostate-specific antigen (PSA) Screening** [xvi] (males) - PSA testing is an individualized decision to be made by clinician and patient based on current guidelines.

Immunizations

Document in medical record carrying data forward to most current volume

32. **Hepatitis A vaccination** [xi, xvii] - Offer vaccination if not immune per guidance. Assess for response 30-60 days after vaccination by performing Hep A IgG antibody or Hep A Total antibody.

33. **Hepatitis B vaccination** [xvii] - Offer vaccination if not immune per guidance. Assess for response 30-60 days after vaccination by performing Hepatitis B surface antibody quantitative (anti-HBs).

34. **Human Papillomavirus (HPV) Vaccine** [xvii] - HPV vaccination as indicate by current guidelines.

35. **Influenza vaccination** [xvii] - Offer IIV or RIV4 annually.

36. **Meningococcal vaccination** [xvii] - Use 2-dose series MenACWY-D (Menactra, Menveo or MenQuadfi)) at least 8 weeks apart and revaccinate every 5 years if risk remains. See vaccination guidelines**.**

37. **Pneumococcal polysaccharide (PPSV23) and Pneumococcal conjugated (PCV13) vaccination** [xvii] - Should receive a dose of PCV13 (Prevnar 13), followed by a dose of PPSV23 (Pneumovax 23) at least 8 weeks later, then another dose PPSV23 at least 5 years

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after previous PPSV23; at age 65 or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23 (note: only 1 dose PPSV23 recommended at age 65 year or older).

38. **Tetanus, diphtheria, pertussis (Td/Tdap)** [xvii] - One dose Tdap, then Td or Tdap every 10 years.

39. **Varicella** [xvii] – Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 count <200 cells/mm^3.

40**. Zoster vaccination** [xvii] - Recommended for 50 years and older per guidelines, use RZV.

41. **SARS-CoV-2 vaccination** [xvii] - Vaccinate per CDC guidance.

[i] Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/tests-initial-assessment-and-follow?view=full. Accessed on July 19, 2021.
[ii] Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whats-new-guidelines. Accessed July 19, 2021.
[iii] Screening for Anal Dysplasia and Cancer in Patients with HIV. https://www.hivguidelines.org/hiv-care/anal-dysplasia-cancer/. Accessed July 19, 2021.
[iv] Sexually Transmitted Diseases Guidelines, 2015. June 5, 2015. MMWR 2015. vol. 64, no. 3. https://www.cdc.gov/std/tg2015/tg-2015-print.pdf. Accessed July 19, 2021.
[v] Clinical Practice Guideline for the Management of Chronic Kidney Disease in Patients Infect with HIV: 2014 Update by the HIV Medicine Association of the Infectious Disease Society of America. Clinical Infectious Disease, vol. 59, issue 9, November 2014, e96-e138.
[vi] American Diabetes Association. Diabetes Care. January 1, 2020. Vol. 43, Issue supplement 1. https://care.diabetesjournals.org/content/43/Supplement_1. Accessed July 21, 2021.
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[viii] Recommendations for Evaluation and Management of Bone Disease in HIV. Clinical Infectious Disease 2015:60; 1242-1251. https://pubmed.ncbi.nlm.nih.gov/25609682/. Accessed September 10, 2021.
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MIAMI-DADE HIV/AIDS PARTNERSHIP

Medical Care Subcommittee
Friday, October 22, 2021

9:30 a.m. – 11:30 a.m.

Behavioral Science Research
2121 Ponce de Leon Blvd.
Coral Gables, FL and Zoom

AGENDA

I.	Call to Order	Carlos Palacios
II.	Meeting Rules and Housekeeping	Carlos Palacios
III.	Roll Call and Introductions	Carlos Palacios
IV.	Floor Open to the Public	Carlos Palacios
V.	Review/Approve Agenda	All
VI.	Review/Approve Minutes of September 24, 2021	All
VII.	Reports	
	• Membership Vacancies	Marlen Meizoso
	• Partnership Report (informational)	Marlen Meizoso
	• Ryan White Program (no new report)	Ana Nieto
	• ADAP Program	Dr. Javier Romero
VIII.	Standing Business	
	• Conclusion of Cabenuva barriers discussion	All
	• ADAP formulary additions and RWP review	All
	• Primary Medical Care Standards	All
	• Service Descriptions -Outpatient Ambulatory and AIDS Pharma	All
IX.	New Business	
	• 2022 Meeting Dates	Marlen Meizoso
X.	Announcements	All
	• Anchor Study Release	Marlen Meizoso
XI.	Next Meeting: **November 19, 2021** at Main Library- **Auditorium**	Carlos Palacios
XII.	Adjournment	Carlos Palacios

Please turn off or mute cellular devices – Thank you

For more information, regarding the Miami-Dade HIV/AIDS Partnership's Medical Care Subcommittee please contact Marlen Meizoso at 305-445-1076 or marlen@behavioralscience.com

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AIDS PHARMACEUTICAL ASSISTANCE
(LOCAL PHARMACEUTICAL ASSISTANCE PROGRAM – LPAP)

(Year 32 Service Priority: #4 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 2021 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 his/her/their 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 HIV/AIDS 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

- o Medications, appetite stimulants, or vitamins that have been prescribed for the client by his/her/their 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 2021 Service Delivery Manual for copies of the Letters of Medical Necessity, as may be amended):

Medications:

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

Test:

- o **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.)

IMPORTANT NOTES: delete these for 2022

- **The LOMN for the following is discontinued, effective 3/1/2021:**
    - o **Testosterone**
- **The LOMNs or Physician Letter for the following are discontinued, effective 4/12/2021:**

- **Aptivus (Tipranavir)**
- **Fuzeon (Enfuvirtide)**
- **Sporanox (Itraconazole)**
- **Nutritional Supplements Referral – Physician Letter (2-page letter)**

- **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 2022 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.**

OUTPUTPATIENT/AMBULATORY HEALTH SERVICES

(Year 32 Service Priorities: #2 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 2022 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.

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 simply use either their designated Quest Diagnostic lab or LabCorp code for reimbursement directly from ViiV Healthcare. 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 Nurse, 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. <u>Outpatient Specialty Care</u>

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 people with HIV (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 2022 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**: <u>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.)</u>

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.

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.

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 December 16, 2019, 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/mm^3 *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.

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 people with HIV (clients) as part of substance abuse treatment services.

Although the selection of a Ryan White Program-funded service provider is based on client choice, whenever possible, pregnant women should be referred to the University of Miami OB/GYN Department (Ryan White Part D Program, etc.) due to its specialized care for this HIV population. Furthermore, 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 2022 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:
  - Core
  - All Ages
  - Adolescent/Adult
  - Children
  - HIV-Exposed Children
  - Medical Case Management (MCM)
  - Oral Health Care
  - AIDS Drug Assistance Program (ADAP)
  - Systems-Level
  - Frequently Asked Questions

- Minimum Primary Medical Care Standards

CI. **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 "2021 Florida Medicare Part B Physician Fee Schedule

(Participating, Locality/Area 04), revised December 31, 2020, modified January 5, 2021."

- Reimbursements for medical procedures performed at Ambulatory Surgical Centers (ASC) will be no higher than the rates found in the "2021 Florida Medicare Part B ASC Fee Schedule, by HCPCS Codes and Payment Rates, PDF dated December 30, 2020, electronic file modified January 7, 2021; 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 2021 (January 2021), corrected February 22, 2021 (note "b.02.22.2021" in file name)." (Applies only to organizations with on-site or affiliated outpatient hospital centers).

- 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.

- Reimbursements for lab tests and related procedures will be based on rates no higher than those found in the "2021 Medicare Clinical Diagnostic Laboratory Fee Schedule, for Florida (FL), Calendar Year (CY) 2021 Quarter 1 (Q1) Release, added for January 2021, updated January 25, 2021."

- If the client is eligible for ADAP, that program should be accessed for genotype and phenotype testing if available.

- A Letter of Medical Necessity 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.

- Reimbursements for injectables will be based on rates no higher than those found in the "2021 Medicare Part B Drug Average Sales Price (ASP) Drug Pricing Files, Payment Allowance Limits for Medicare Part B Drugs, updated March 4, 2021 (payment limit column)."

- 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 every six (6) months. 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. Available at: https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf; pp 1-451; last updated June 03, 2021. Accessed 8/5/2021

- Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PediatricGuidelines.pdf; pp 1-446; last updated April 07, 2021. Accessed 8/5/2021

- Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection *and* Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf; pp 1-478; last updated February 10, 2021. Accessed 8/5/2021

- Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations: from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at:

https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf. ; pp 1-483; last updated July 22, 2021.
Accessed 8/5/2021

- Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at:
  https://clinicalinfo.hiv.gov/sites/default/files/inline-files/oi_guidelines_pediatrics.pdf; pp 1-409; last updated December 9, 2019.
  Accessed 8/5/2021

- Interim Guidance for COVID-19 and Persons with HIV. Available at: https://clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv-interim-guidance/interim-guidance-covid-19-and-persons-hiv; pp 1-9; last updated February 26, 2021.
  Accessed 8/5/2021

- 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: A Guide to the Clinical Care of Women with HIV (2013), Guide for HIV/AIDS Clinical Care (2014), A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV (2011); and References Guides for Optimizing Care for People Aging with HIV. Available at:
  https://hab.hrsa.gov/clinical-quality-management/clinical-care-guidelines-and-resources.
  Accessed 8/5/2021

- 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 Mental Health, Nutrition and Food Safety, and Drug and Alcohol Use). Available at:
  https://hivinfo.nih.gov/understanding-hiv/fact-sheets
  Accessed 8/5/2021

- 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 RN/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.

MIAMI-DADE
HIV/AIDS PARTNERSHIP

Medical Care Subcommittee
Friday, October 22, 2021

9:30 a.m. – 11:30 a.m.

Behavioral Science Research
2121 Ponce de Leon Blvd.
Coral Gables, FL and Zoom

AGENDA

I.	Call to Order	Carlos Palacios
II.	Meeting Rules and Housekeeping	Carlos Palacios
III.	Roll Call and Introductions	Carlos Palacios
IV.	Floor Open to the Public	Carlos Palacios
V.	Review/Approve Agenda	All
VI.	Review/Approve Minutes of September 24, 2021	All
VII.	Reports	
	• Membership Vacancies	Marlen Meizoso
	• Partnership Report (informational)	Marlen Meizoso
	• Ryan White Program (no new report)	Ana Nieto
	• ADAP Program	Dr. Javier Romero
VIII.	Standing Business	
	• Conclusion of Cabenuva barriers discussion	All
	• ADAP formulary additions and RWP review	All
	• Primary Medical Care Standards	All
	• Service Descriptions -Outpatient Ambulatory and AIDS Pharma	All
IX.	New Business	
	• 2022 Meeting Dates	Marlen Meizoso
X.	Announcements	All
	• Anchor Study Release	Marlen Meizoso
XI.	Next Meeting: **November 19, 2021** at Main Library- **Auditorium**	Carlos Palacios
XII.	Adjournment	Carlos Palacios

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For more information, regarding the Miami-Dade HIV/AIDS Partnership's Medical Care Subcommittee please contact Marlen Meizoso at 305-445-1076 or marlen@behavioralscience.com

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2022 Meeting Dates

All Dates/Locations are subject to change

Medical Care Subcommittee

9:30 a.m. to 11:30 a.m.

Miami-Dade County Main Library

101 West Flagler Street, Auditorium

Miami, FL 33130

January	28	2022
February	25	2022
March	25	2022
April	22	2022
May	27	2022
June	24	2022
July	22	2022
August	26	2022
September	23	2022
October	28	2022
November	18	2022

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FOR IMMEDIATE RELEASE
Thursday, October 7, 2021

Source: Elizabeth Fernandez (415) 502-6397
Elizabeth.Fernandez@UCSF.edu | @EFernandezUCSF

Treating Anal Cancer Precursor Lesions Reduces Cancer Risk for People With HIV

Groundbreaking National Clinical Trial Halted Due to Therapy's High Success Rates

Treating precursor anal cancer lesions can significantly reduce the risk of progression to full blown anal cancer among people living with HIV, according to results of a large, phase 3 study led by researchers at UC San Francisco.

In a randomized clinical trial with 4,446 participants, known as the Anal Cancer/HSIL Outcomes Research (ANCHOR) study, researchers found that by removing high-grade squamous intraepithelial lesions (HSIL), chances of progression to anal cancer were significantly reduced.

The trial is the first to show such findings and was performed at 21 clinical sites around the United States. Results are being prepared for peer-reviewed publication and are being shared now because of the public health importance of the findings.

The study caps decades of research into the history, prevention and treatment of anal cancer and its precursors. It also provides important information for developing standard of care guidelines for people at high risk of anal cancer, including screening for and treatment of anal HSIL, said lead investigator Joel Palefsky, MD, a professor of medicine at UCSF.

"ANCHOR data show for the first time that, like cervical cancer, anal cancer can be prevented even in high-risk populations, such as people living with HIV, who often have HSIL that can be difficult to treat," Palefsky said. "Although the study was performed in people living with HIV, the results suggest that anal cancer prevention could be similarly possible in other groups known to be at increased risk of anal cancer, including women with a history of vulvar or cervical cancer, men who have sex with men who are HIV-negative, and men and women who have immunosuppression for reasons other than HIV infection."

Palefsky established the world's first clinic devoted to anal cancer prevention in 1991 at UCSF. Now known as the UCSF Anal Neoplasia Clinic Research and Education Center, it is currently based at the UCSF Medical Cancer at Mount Zion.

In the study, people living with HIV aged 35 years and older who had the precursor lesion were randomized into two groups: treatment of the lesion or active monitoring of the lesion without treatment.

Most often, treatment consisted of a technique performed in physician offices called hyfrecation (electrocautery), in which an electric current was targeted directly to areas of the HSIL to remove them. Participants were re-evaluated every three to six months, and rates of anal cancer were compared between the two groups.

The incidence of anal cancer is very high among people with HIV and is similar to cervical cancer: both have a strong association with human papillomavirus and are preceded by HSIL.

Cervical cancer prevention programs to find and treat cervical HSIL are the standard of care and highly effective in reducing the risk of developing cervical cancer. The investigators noted that the principal reason to consider HSIL treatment is to reduce the risk of developing anal cancer. The ANCHOR study will provide key information in guiding recommendations to make anal cancer prevention programs the standard of care for people at high risk of anal cancer.

The study was conducted through the National Cancer Institute's (NCI's) AIDS Malignancy Consortium, led by Palefsky and his team at UCSF. The University of Arkansas for Medical Sciences provided statistical support and contract research organization support was provided by The Emmes Company, LLC.

Funding: The trial was sponsored by the National Cancer Institute's Office of HIV and AIDS Malignancy (Grant number U01 CA121947).

About UCSF Health: UCSF Health is recognized worldwide for its innovative patient care, reflecting the latest medical knowledge, advanced technologies and pioneering research. It includes the flagship UCSF Medical Center, which is ranked among the top 10 hospitals nationwide, as well as UCSF Benioff Children's Hospitals, with campuses in San Francisco and Oakland, Langley Porter Psychiatric Hospital and Clinics, UCSF Benioff Children's Physicians and the UCSF Faculty Practice. These hospitals serve as the academic medical center of the University of California, San Francisco, which is world-renowned for its graduate-level health sciences education and biomedical research. UCSF Health has affiliations with hospitals and health organizations throughout the Bay Area. Visit http://www.ucsfhealth.org/. Follow UCSF Health on Facebook or on Twitter.

About the AIDS Malignancy Consortium: AMC is a membership-based scientific organization supported by the National Cancer Institute, part of the National Institutes of Health, that designs and conducts cancer research among PLWH who have or are at risk of developing cancer. For more information please visit www.amcoperations.com.

About the National Cancer Institute (NCI): NCI leads the National Cancer Program and NIH's efforts to dramatically reduce the prevalence of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI website at cancer.gov or call NCI's Contact Center (formerly known as the Cancer Information Service) at 1-800-4-CANCER (1-800-422-6237).

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit nih.gov.

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