Michigan Department of Health and Human Services
Bureau of HIV and STI Programs

Michigan Rapid Start ART (MiStart)
Standard Operating Procedures (SOP)

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Introduction

Rapid Start ART is the recommended clinical practice model for providing care by U.S Federal Guidelines for people with new and existing HIV (PWH) diagnoses nation-wide, unless there are contraindications. As stated in the National HIV/AIDS Strategy (NHAS) 2022-2025 goal 2.1.1, providing rapid start equates to starting antiretroviral therapy (ART) the same day or within 7 days of diagnosis **AND** includes linkage to HIV health care within 30 days. The Strategy sets bold targets for ending the HIV epidemic in the United States by 2030, including a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. An additional component of the Ending the HIV Epidemic (EHE) plan is to rapidly treat PWH to reach sustained viral suppression (U=U).

Rationale for MiStart

Michigan Rapid Start ART (MiStart) is Michigan's implementation of Rapid Start ART. MiStart will result in earlier HIV viral suppression, improved retention in care and reduced HIV transmission. MiStart also improves equity and accessibility of ART for people who may otherwise be lost to follow-up after diagnosis and has proven community level benefits by reduced HIV transmission.

Purpose of Standard Operating Procedure

This Standard Operating Procedure (SOP) exists to promote and sustain rapid initiation of ART for people with new and existing HIV (PWH) diagnoses in the State of Michigan. The goal is to accelerate the uptake of MiStart as an evidence-based strategy to improve implementation of HIV care to reduce the time from HIV diagnosis to initiation of treatment, entry into care, re-engagement in care, and viral load suppression.

Persons Appropriate for MiStart

1. Nearly all persons with a **confirmed** new diagnosis of HIV (i.e., HIV Ag/Ab, and/or HIV RNA viral load).
2. Persons with high clinical and epidemiological suspicion of acute HIV, such as but not limited to known HIV exposure and flu-like symptoms, whose HIV diagnosis may not yet be confirmed (e.g., the HIV antigen or antibody test result may be negative at the time of evaluation) while confirmation is pending.
3. Persons with reactive results of rapid HIV tests, before confirmatory test results are available, if the likelihood for HIV infection is high (after counseling) can be offered immediate ART with the understanding that if confirmatory tests are negative, the patient would stop ART. In these instances, providers can utilize the HIV Provider Consult Line for further guidance.
4. Persons with a known or existing HIV diagnosis who are re-engaging in care and have no contraindications to starting ART at the initial appointment. If the ART and HIV resistance history is known or can be predicted (based on adherence and resistance history and HIV viral load while on ART), and if an appropriate ART regimen can be devised in the absence of current resistance test results.
    a. Persons who are re-engaging in care should receive enhanced clinical and wraparound support to optimize the likelihood of successful adherence to care and ART. Re-engaging patients who are not immediately restarted on ART (or who decline rapid restart) should be followed closely and restarted at the earliest appropriate time.

Persons Not Appropriate for MiStart

Special considerations for persons with certain untreated opportunistic infections must consult with experts/physicians/nurse practitioners.

1. Contraindications can include:
    a. A complex or unknown ART history with possibility of complicated acquired resistance.
    b. Persons with certain untreated opportunistic infections (OIs), particularly central nervous system (CNS) OIs such as cryptococcal meningitis and CNS tuberculosis for whom a short period of treatment for the OI is recommended before ART initiation, to reduce risk of dangerous IRIS (immune reconstitution inflammatory syndrome); note that this is very rare in the outpatient clinic setting.
    c. Persons with a preliminary reactive rapid HIV test result who have a low pretest probability of HIV infection. For persons who fit this description (e.g., those with no discernable individual or demographic risk factors for HIV), the preliminary result is likely to be a false positive, and clinicians should wait for a confirmed lab result before starting ART. ART can be started immediately if the confirmatory test is reactive.

Operations

MiStart indicates that patients will be initiated on ART within 7 days of diagnosis or before confirmed laboratory results are available (i.e. preliminary reactive), regardless of where the person is diagnosed. It is important to note that regimens can be modified if needed once lab results become available.

MiStart consists of several basic steps:

- Provider counseling inclusive of treatment options, education on MiStart, medication readiness assessment, and HIV Care assessment.
- If diagnosing provider has the ability, MiStart initiation should be same day. Otherwise, it is recommended that the testing provider assist in scheduling an appointment for Rapid Start initiation. Some clinics may have same day appointments available. A list of Michigan HIV Care Providers can be found in the HIV Care Resource Guide.
- Prioritization of MiStart is key. Sample starter packs of the selected ART are available throughout Michigan as needed. ART should be started, even if ongoing HIV primary care will be continued at another facility/provider. If MiStart and continued HIV Care sites are differing locations, a warm handoff is recommended to ensure continuity in care.

Specific steps of the MiStart process may vary widely based on client residency, facility of diagnosis and proximity of Rapid Start providers. The key to making MiStart work is for receiving clinics to have a system in place that allows for rapid referrals. This could look like specialty blocks in provider schedules for last minute rapid start appointments.

Intake Appointment

It is recommended that patients who test at a clinic that provides HIV primary care should be prioritized for same day assessment and initiation of MiStart.

- ART counseling on the risks and benefits of immediate ART: A client centered approach should be emphasized during this process, including, but not limited to, building rapport, and ensure all questions and concerns are addressed in a timely manner. Discussion topics should include benefits and risks of immediate ART, the concept of treatment as prevention (U=U), monitoring HIV viral load, importance of ART adherence and goals, and informing person(s) of the importance of being in close contact with their provider(s) during the early months of treatment.
- Selection of antiretroviral therapy: The selection of a particular ART regimen for an individual will be guided by their preferences, comorbidities, potential drug interactions, and drug allergy history.
- Regimens can be modified, if indicated, based on the genotype results or other results.
- It is important to establish a sustainable long-term care plan by addressing other barriers. An initial assessment should consider needs for case management, housing, transportation, mental health services, health insurance, etc.

Baseline Laboratory Testing

For persons with a suspected diagnosis of HIV, ART will be started at the first clinic visit, before the results of baseline testing are available.

- The intake process will include the following baseline laboratory testing:
  - Confirmatory HIV testing (dual rapid or lab-based test).
  - HIV viral load.
  - HIV genotype assay with integrase genotype assay if available.
  - HLAB5701 polymorphism testing (if Ziagen/abacavir is being considered).
  - CD4+T cell count.
  - Comprehensive metabolic panel.
  - Appropriate three site testing for chlamydia and gonorrhea, syphilis.
  - Full Hepatitis panel (Total Hepatitis A, Hepatitis C antibody, Hepatitis Bs Antigen, Total Hepatitis B core antibody, Hepatitis Bs antibody).
  - Pregnancy test.
- Additional laboratory tests may be ordered based on provider.
- The same laboratory testing guidelines also apply for special populations.

Starter Packs

The goal of MiStart is to ensure persons diagnosed with HIV are provided with antiretroviral therapy (ART) the day of diagnosis or within 7 days (rapid start).

Please refer to Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV for choosing the best regimen based on the persons' current medications, co-morbidities and preference.

Regimens should always be individually tailored to increase adherence and support. Currently, most medications for rapid start are tablet based. For non-specialty providers requiring additional guidance on appropriate ART regimens, please consult with the HIV Provider Consult Line.

Sample starter packs containing a 3-to-5-day supply (can be up to 7 days) of the selected ART regimen can be helpful if they are available; they ensure that patients can take their first dose of ART on the day of the initial clinic visit, bypassing pharmacy and/or insurance delays.

When needed to fill in gaps, free sample starter packs can be accessed through the following resources *(Physicians will be required to fill out any necessary paperwork to receive sample starter packs from pharmaceutical representatives*): Michigan Pharmaceutical Representatives.

PrEP and PEP considerations

If person has taken pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) at the time of HIV exposure or acquisition:

- Take a careful history to determine the last time the person took PrEP or PEP medication.
- If there is concern that resistance to ARTs have developed, consider a reinforced ART regimen consisting of an integrase inhibitor (dolutegravir or bictegravir) + boosted darunavir + TAF/FTC (or TDF/FTC or TDF/3TC) while awaiting the results of the genotype assay. For additional guidance or to consult with an expert - HIV Provider Consult Line.

Utilizing MIDAP

Michigan Drug Assistance Program (MIDAP) covers HIV-specific and HIV-related prescription medications, as well as vaccines, for eligible Michigan residents with HIV.

- To be eligible for MIDAP, applicants must meet the following criteria:
  - Provide proof of HIV Status.
  - Be a resident of the State of Michigan.
  - Have a gross income between 138%-500% of the Federal Poverty Level (FPL)* FPL Guidelines.
  - Not be eligible for any other insurance programs. MIDAP is the payer of last resort.
- To apply:
  - Submit a MIDAP application Michigan Drug Assistance Program (MIDAP).
  - Check off ‘New Diagnosis’ (when added to application).
    - Expedited Criteria: New Diagnosis or Persons Returning to Care.
    - Note for case managers: Expedite all applications for persons returning to care and document in the MIDAP online application system if the client is returning to care. (For person entering application: Look for date of HIV diagnosis.)

MIDAP MiStart Eligibility Process

The following process will suffice for MiStart:

- MIDAP Declaration of Status by physician/physician designee (30 days temp coverage until proof of labs are submitted to MIDAP or until MIDAP can verify HIV proof of status in LMS).
- Evidence of reactive HIV test or other laboratory testing indicative of HIV available in LMS eHARS system. If eHARS data is not available, MIDAP will accept a statement from a doctor, testing facility or laboratory result sheet with CD4 viral load examination.
- Laboratory Generated (computer generated): Western Blot, Nucleic Acid Amplification Test (NAAT), Multi-spot or Immunoassay (IA) test with a reactive result.

Monitoring and Measurement

All clinical care settings should be prepared to either initiate MiStart on-site or provide a confirmed referral to support patients in initiating ART as rapidly as possible after diagnosis. It is recommended that agencies conduct their own internal evaluations of MiStart integration to monitor gaps in care, disparities, opportunities for program improvement, and outcome measures.

Outcome measures reflect the impact of the intervention on the health status of the person. By monitoring retention to care, providers can more easily spot and address when a person may be falling out of care or require re-engagement. Outcomes are measured by the number of persons who achieved viral suppression after being prescribed ART. This data is further broken down by the number of days it took to achieve and maintain viral suppression.

Monitoring dates is an important tool to help providers determine the length of time between diagnosis, clinician appointment as well as ART prescription and pick up. Based on this time range, they can determine how effective MiStart was in contributing to viral suppression. For program evaluation it is suggested to include the following data points:

- Demographic data (age, gender identity, sexual orientation, race, ethnicity, % of poverty limit, zip code, housing status, socioeconomic information).
- Exposure factors.
- Initial HIV lab results and initial viral load.
- Dates of: referral, linkage to care, first intake appointment, ART prescription written, and ART prescription picked up by client.

Reporting Requirements

- A Michigan Adult HIV Confidential Case Report Form should be completed and faxed within 24 hours. For patients under the age of 13 utilize the Michigan Pediatric HIV/AIDS Confidential Case Report Form. In addition, it is recommended that the testing provider also contact their local Disease Intervention Specialist (DIS), Communicable Disease Investigator, or Partner Services Worker to assist with the linkage process and ensure that Partner Services are conducted.
    - If you are unsure who your local Disease Intervention Specialist is, please call (313) 410-1695.

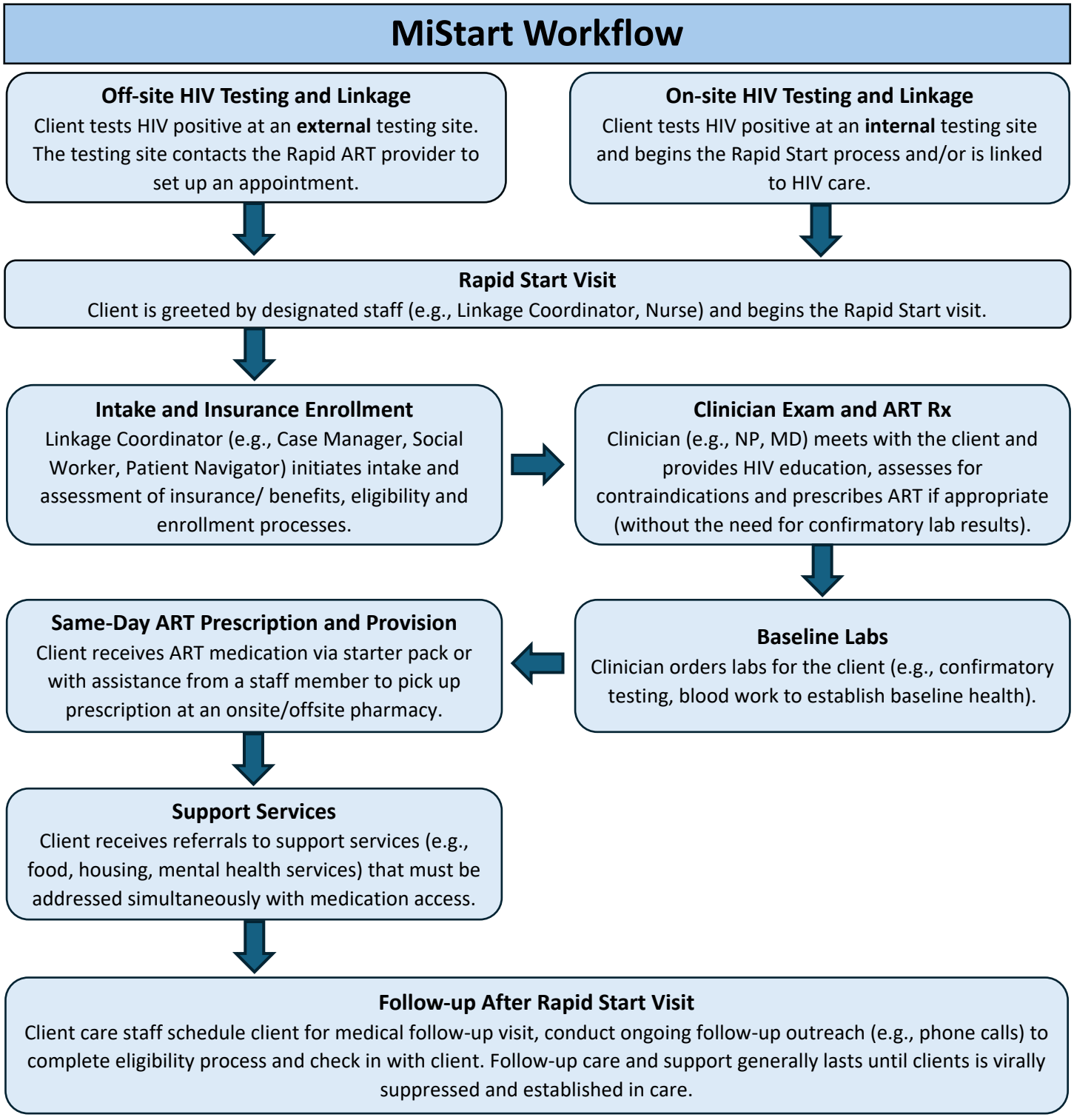
- Funded agencies should continue following reporting requirements for APHIRM and CareWare
    - Document all services provided into CAREWare under the Services and Case Notes tabs that correspond with the services and units provided.
        - MDHHS Ryan White Program Service Standards
        - MDHHS Ryan White SOC Parts B and D - Appendix A
    - Documentation in APHIRM should include date of first HIV care appointment and ART start date.
- Non-funded agencies will report all new HIV diagnoses through the Michigan Adult HIV Confidential Case Report Form and indicate ART start date in *Section XII – History of Antiretroviral Treatment (ARV) Use*. If Rapid Start is not implemented at the time of diagnosis, agencies are to use the Comment Section to describe the reason ART was not initiated, the referral process and anticipated date of first appointment. For cases being reported through the Michigan Pediatric HIV/AIDS Confidential Case Report Form treatment start date should be documented in Section XI – Treatment/Services Referrals. If treatment is not initiated, reason should be explained in the Comment Section – XII with a detailed referral process.

How to Request Technical Assistance for MiStart Implementation

For assistance implementing MiStart at your practice, please utilize the following resources:

- Midwest AIDS Training and Education Center/MATEC: matecmichigan@wayne.edu and 313-962-2000
    - Can provide TA, provider education, educational materials, access to resources, and Rapid Start guidance.
- Henry Ford Provider HIV Consult Line: 313-575-0332 or www.Henryford.com/HIVConsult
    - 24-hour Provider Consult line, can provide immediate clinical TA.
- Funded agencies can request technical assistance by submitting a SHOARS request.

Appendix



Source: *Adopted from "Compendium of Best Practices in Provision of Rapid Start Services for People with HIV for Ryan White HIV/AIDS Program Funded Providers", CAI Global, 2023.*

MiStart to PrEP Workflow

Negative HIV Results Received
Clinic receives negative lab-based HIV test (e.g., HIV confirmation from initial MiStart labs).

Inform Client of Test Results
Clinician and/or support staff inform client of negative HIV results

PrEP Conversation
Clinician and/or support staff screen client for PrEP eligibility, provide PrEP information (e.g., options available to the client) and assess readiness (e.g., address concerns) for PrEP initiation.

Internal PrEP Initiation
PrEP initiation stays within clinic. Discontinue MiStart and initiate PrEP.

Assessment of Labs and Medication
Clinician determines if additional HIV test is needed based on time lapse between previous negative result and PrEP initiation. Appropriate PrEP regimen discussed and prescribed.

Continuity of PrEP
Clinician continues prescribing PrEP. Schedule follow-up visit(s).

External PrEP Initiation via Referral
Clinician evaluates current MiStart regimen and informs client to cease medication and/or transition to PrEP.

Discontinue MiStart–refer out for PrEP initiation. Warm handoff and risk reduction counseling recommended to ensure continuity in care.

Discontinue MiStart–provide initial PrEP prescription and refer out. Warm handoff recommended to ensure continuity in care.

Follow-up
Clinic staff confirm client has successfully initiated PrEP at referral clinic.

Definitions

- **Acute HIV infection:** Acute HIV infection is the earliest stage of HIV infection, and it generally develops within 2 to 4 weeks after infection with HIV. During this time, some people have flu-like symptoms, such as fever, headache and rash. In the acute stage of infection, HIV multiplies rapidly and spreads throughout the body.
- **APHIRM:** HIV prevention reporting database which includes HIV testing, PrEP, Interventions, and Partner Services data. To request access, submit a SHOARS request.
- **ART:** HIV medicine is called antiretroviral therapy, or ART. If taken as prescribed, HIV medicine reduces the amount of HIV in the body (viral load) to a very low level, which keeps the immune system working and prevents illness.
- **CAREWare:** CAREWare is a free, electronic health and social support services information system for Ryan White HIV/AIDS Program grant recipients and their providers. To request access, submit a SHOARS request.
- **False positive:** When a person does not have HIV but receives a reactive test result, that result is considered a false positive.
- **Genotype:** A blood sample is taken from the patient, and the HIV is analyzed for the presence of specific genetic mutations that are known to cause resistance to specific drugs.
- **In Care:** Patients who have initiated outpatient HIV care, have been taking ART, and continue to stay engaged with follow-up visits and services at a minimum of 6 months post diagnosis. Outpatient HIV care and treatment includes diagnostic and therapeutic services provided directly to a client by a licensed healthcare provider in an outpatient medical setting.
- **MiStart:** MiStart is the recommended clinical practice model for providing care for people with a new and existing HIV (PWH) diagnosis in the State of Michigan involving same-day or rapid (within 7 days) start of antiretroviral therapy (ART) for persons who are able in order to increase linkage to HIV health care within 30 days for all persons who have been confirmed to have HIV. Rapid Start ART by U.S Federal Guidelines for people with new and existing HIV (PWH) diagnoses nation-wide, unless there are contraindications. As stated in the National HIV/AIDS Strategy (NHAS) 2022-2025 goal 2.1.1, providing rapid start equates to starting antiretroviral therapy (ART) the same day or within 7 days of diagnosis **AND** includes linkage to HIV health care within 30 days.
- **Out of Care:** A person with HIV (PWH) who has not received HIV care in the past 15 months**.**
- **Pre-exposure prophylaxis (PrEP):** is medicine that can be taken to reduce a person's chances of getting HIV from sex or sharing drug injection equipment. PrEP is for people who do not have HIV but have the chance of getting it. When someone taking PrEP is exposed to HIV through sex or sharing drug injection equipment, the medicines can keep the virus from establishing a permanent infection.
- **Post-exposure prophylaxis (PEP):** is a preventive treatment that can reduce the chance that a person who is exposed to HIV will get HIV.
- **Re-engaged in Care/Linked to Care:** A PWH who has accepted linkage to HIV care/support services.
- **Undetectable = Untransmittable (U=U)**: a person with HIV who is on treatment (antiretroviral therapy or ART), has achieved an undetectable viral load and maintains it for six months and thereafter, cannot transmit HIV through sex.

- **Warm Hand Off:** is a referral that is conducted in person, between two members of the health care team, in front of the person allowing them to be included in their care plan.

Provider Resources:

- Midwest AIDS Training and Education Center/MATEC: matecmichigan@wayne.edu and 313-962-2000
    - Can provide TA, provider education, educational materials, access to resources, and Rapid Start guidance.
- Henry Ford Provider HIV Consult Line: 313-575-0332 or www.Henryford.com/HIVConsult
    - Direct consultation with an ID provider.
- PrEP
    - Find a PrEP Provider or Navigator
    - Learn more about PrEP
    - Resources
    - Provider Resources
    - Clinicians' Quick Guide
- Free sample starter packs can be accessed through the following resources *(Physicians will be required to fill out any necessary paperwork to receive sample starter packs from pharmaceutical representatives*): Michigan Pharmaceutical Representatives.

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MDHHS Resources:

- Michigan Rapid Start ART (MiStart)
- Michigan Pharmaceutical Representatives
- Michigan Drug Assistance Program (MIDAP)

- Michigan Adult HIV Confidential Case Report Form
- Link-Up Michigan Providers
- HIV Care Resource Guide
- Ryan White HIV/AIDS Program (including CAREWare)
- MDHHS Ryan White Program Service Standards
- MDHHS Ryan White SOC Parts B and D - Appendix A
- Medicaid assistance: MI Bridges