

MAGNET CLINICAL PROTOCOLS	Page 1 of
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Rapid HIV Treatment Initiation	

Providers: Rapid HIV Treatment Initiation will be limited to NP and MD.

Back ground: Clients with a newly diagnosed HIV infection benefit from rapid linkage and Antiretroviral Treatment (ART) initiation. Some clients are not able to access care after their diagnosis due to insurance or immigration difficulties. This protocol is to support the client during the gap in treatment allowing clients to immediately start on HIV treatment while waiting to be linked to care.

Client Eligibility for Services: All clients who have a new HIV diagnosis in clinic and would have difficulty being linked to care within 5 days or who prefer to initiate treatment at the time of diagnosis.

Healthy Clients: Due to the limited ability to provide full primary care at Magnet, Clients must be in stable health to be start HIV treatment in clinic. Certain health conditions as determined by the NP/MD may be referred to a primary care provider if the care and follow up needed beyond the capabilities at Magnet.

Scope of Care: Clients initiated on HIV treatment are not required to have a primary care provider. Magnet will provide the initial HIV evaluation and follow up for a maximum of two months or until the client has established care at their provider. Complex primary care issues as determined by the NP/MD and care that requires scheduled medications will be referred to a primary care provider.

Enrollment into Rapid HIV Treatment Initiation:

All parts of the enrollment process must be completed prior to ART initiation.

Rapid HIV Treatment Enrollment: The steps needed for the intake involve:

1. Eligibility
2. Health history
3. Medications
4. Physical exam
5. Laboratory tests
6. Sexual Health Screen
7. Clinician assessment
8. HIV counseling
9. Adherence counseling
10. Medication selection and prescription
11. Referring to Benefits Navigation
12. Referring to Health Navigation

Rapid HIV Treatment Initiation Eligibility:

Eligibility Criteria

- 1) Age 12 and over
- 2) Positive Geenius confirmatory test or HIV RNA

Exclusion Criteria

- 1) Pregnancy-Allowed with MD consult
- 2) Signs or symptoms consistent with an HIV-related opportunistic infection (OI). In the setting of certain OIs, immediate initiation of ART is contraindicated
 - a. New unexplained neurological symptoms
 - i. r/o cryptococcal meningitis
 - ii. r/o intracranial infections
- 3) Visceral (Pulmonary or Gastrointestinal) Kaposi Sarcoma
- 4) Any other conditions that are deemed contraindicated by the NP/MD

Health History: A complete health history will be documented in the client record

Medications: All medications currently prescribed to the client and over the counter (including supplements) will be recorded in the client record.

Physical Exam: An initial full physical exam will be completed with a focus on neuro exam to rule out meningitis.

Lab Tests:

1. HIV RNA
2. Genotype with Integrase resistance
3. CBC/Diff
4. CD4/CD8
5. Liver Function
6. Creatinine/eGFR
7. HLAB5701
8. Hepatitis B AB, AG, & Total Core,
9. HEP C AB
10. RPR
11. GC/CT Throat, Rectum, and Urine as indicated
12. Urine HCG test will be collected for clients of child bearing capacity.

Sexual Health Screen: Clients will have relevant sexual health tests collected per protocol.

Clinician Assessment: The final assessment of the appropriateness for the will be made by an NP/MD. The determination will be based on:

1. Eligibility
2. Health History
3. Medications
4. Laboratory results

HIV Counseling: Depending on the counseling state of the client, the provider will review HIV pathogenesis, HIV medications, side effects, viral response, goal of uninfected state in 6 months, discussing with partners, life expectancy when engaged in care, and availability of benefits. This may be covered at a later date if the client is not ready to engage.

Adherence Counseling: A brief interactive counseling session will be conducted to highlight possible side effects of the selected medication. One adherence strategy will be identified and recorded. Possible strategies to suggest include linking the dose with a daily activity that occurs every day, even when traveling or staying out late, such as brushing teeth or hair, a morning shower, or waking up. In general, people using daily medications in the morning tend to be more successful than dosing occurring later in the day. If people forget a dose, they should take the dose when they remember if it's the same day. If they do not recall whether they have taken a dose on a given day, they should take a dose.

Primary Care: Magnet does not provide full primary care. Certain primary care issues may be managed if they are deemed feasible for the clinic and there are no benefits/cost issues for the client.

Prescription: The client will receive a prescription for 3 months.

Bictegravir 50mg, emtricitabine 200mg & tenofovir alafenamide 25mg is the preferred regimen for ART naïve clients.

Clients who are currently on PrEP or failed nPEP should have a regimen intensification of bictegravir 50mg, emtricitabine 200mg & tenofovir alafenamide with darunavir 800mg/cobicistat 150mg until the results of a genotype are available to optimize the treatment.

Benefits Counselor: The benefits counselor will enroll the client into the appropriate benefits program to cover the cost of the medications and lab work.

Health Navigation: The client will meet with the Health Navigator who will link the client to care.

Follow-up visits:

Day 1: Phone call to assess side effects, adherence counseling, and HIV counseling

Week 1: Adherence and HIV counseling

Month 1: Labs, adherence and HIV counseling

Laboratory

1. CBC/Diff
2. CD4/CD8

3. HIV RNA
4. Glucose
5. Liver Function
6. Creatinine eGFR
7. QuantiFeron

Month 2: Adherence and HIV counseling

The client must be with a new PCP after 2 months. Any additional follow up may be done if the client would remain out of care. The MD will be consulted.

Adverse Events

Detectable Viral load: If the month 1 viral load unchanged from baseline, adherence and baseline drug resistance is evaluated. Adherence support is provided if the client reports missing doses. Clients reporting high levels of adherence may have had an undetected baseline resistance mutation. A genotype while on the current ARV regimen is collected and evaluated.

Elevated creatinine: If abnormally elevated or elevated more than 50% above baseline, creatinine testing should be repeated on a separate specimen. If the elevation in serum creatinine is confirmed, contact MD for consult. The client may be changed to abacavir 600mg/lamivudine 300mg pending the HLA-B5701 result.

Nausea or vomiting or headaches: Gastrointestinal side effects and head aches have been reported with all ARVs. These side effects are generally self-limiting and resolve within 2 weeks initiating the regimen. If a client reports nausea or vomiting the client will be encouraged to take the medication with non-spicy food. If the nausea, vomiting, or headaches persists after 2 weeks, the ARV may be reevaluated with MD consult.

Hepatitis B: Clients who test positive for chronic Hep B require an MD consult for follow up.

Immune Reconstitution Syndrome (IRIS): Clients with immune suppression (CD4<50 or VL >100,000 copies/ml) may experience IRIS 4 to 8 weeks after starting ART. IRIS may occur during immune reconstitution even without an increase in CD4. Clients experiencing IRIS have a higher mortality. Symptoms of IRIS will vary depending on the infection. Any inflammatory response should be reviewed with an MD to assess treatment. Clients with suspected IRIS should be sent to the ER for evaluation and treatment.

Pregnancy: Clients of child bearing potential will be given a urine pregnancy test at baseline and at the 1 month follow up. If the urine pregnancy test is positive, the client should be referred to an OB/GYN.

Established New PCP: Once the client has established care, all relevant labs and progress notes are to be sent to the PCP. The NP may call the PCP to discuss the transfer of care.

Time and Events:

	Enrollment	Day 1	Week 1	Month 1	Month 2
Age	X				
Address	X			X	X
Gender Identity	X				
Physical Exam	X				
Health History	X			X	X
Medications	X			X	X
Geenius Confirmatory	X				
CBC/Diff	X			X	
CD4/CD8	X			X	
HIV RNA	X			X	
HIV Genotype with Integrase Resistance	X				
HCV AB	X				
HBV AB/AG/T Core	X				
Glucose	X			X	
GFR/Creatinine/Bun	X			X	
AST/ALT/ALP	X			X	
HLAB5701	X				
QuantiFERON				X	
RPR	X				
GC/CT T, R, U	X				
Urine Pregnancy	X			X	
HIV Counseling	X	X	X	X	X
Adherence Counseling	X	X	X	X	X
Health Navigation	X			X	
Benefits Coordination	X				
Phone check in		X			