**Immediate AntiRetroviral Therapy (iART) Protocol:**

\*immediate antiretroviral therapy has been shown to improve patient outcomes in health and adherence.

| **Who is eligible for iART?** | **Who is not eligible for iART?** |
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| NO previously treated HIV &* Two positive HIV rapid tests -**or**-
* Positive 4th gen HIV test by blood -**or**-
* Detectable HIV RNA “viral load” -**and**-
* > 18 years of age
* Medically & psychologically stable
* Substance use is NOT a contraindication to iART

(Those previously on PrEP are okay to start iART, if concerns around resistance to PrEP, consider combo regimen below) | * Previously treated HIV
* Known kidney failure
* Confirmed pregnancy
* Appears medically or psychologically unstable: specifically signs of TB or cryptococcal meningitis. iART should be delayed in any person with signs or symptoms suggestive of meningitis, including headache, nausea or vomiting, light sensitivity, and changes in mental status (clinical discretion).
* <18 yrs of age

Refer to HIV Specialist: https://providers.aahivm.org/referral-link-search |

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| **Counseling/Assessment:**  |
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| * Provide HIV counseling:
	+ HIV basics: viral loads, CD4, transmission, prevention, etc.
	+ Risks of not treating HIV
	+ Potential risks of starting HIV medicine today:
		- Immune reconstitution syndrome (rare, usually CD4<100). Create a plan should they feel worse: ER, Office Visit, TeleMedicine Visit, etc.
	+ Side Effects - now rare, but if any side effects develop, create a plan to communicate with clinic. Some GI upset is normal, can take with food or before bedtime to reduce symptoms. A side effect free regimen should be possible for most patients..
	+ Undetectable = Untransmittable: condoms should be used until undetectable
	+ Partner notification
	+ Adherence Counseling
		- Identify any barriers to adherence: housing, transportation, etc.
		- Connect with HIV community organization to help decrease barriers
	+ Ever been on PrEP/PEP? If so, when?
* Assess interest in iART
	+ If not interested, refer to HIV Specialist
	+ If interested, proceed as below:
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| **Wrap Around Services:** |
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| * Insurance:
	+ Confirm medical insurance status
		- Uninsured → Contact pharmacy for iART script + local HIV patient navigation services for retroactive coverage (depending on state)
		- Insured → Contact pharmacy to begin expedited prior authorization, or provide “starter pack” if available
* Additional Needs
	+ If needed, refer to mental health, social work, HIV patient navigation, community case workers, substance use treatment, syringe exchange referral, etc.
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| **Labs drawn today: No need to wait for labs to come back before prescribing iART** |
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| * HIV-1/2 antigen/antibody assay (if not already done)
* HIV quantitative viral load
* Baseline HIV genotypic resistance profile (PR-RT resistance and integrase resistance)
* Baseline CD4 cell count
* Testing for hepatitis A, B, and C viruses
* Comprehensive metabolic panel (creatinine clearance, hepatic profile)
* Sexually transmitted infection screening: urine, pharyngeal, and/or rectal + syphilis screening
* Urinalysis
* Pregnancy test for individuals of childbearing potential
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| **Provide iART:** |
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| Prescribe ONE of the below medication regimens. Prescriptions can be for 30 days, or a shorter “starter pack” may be used, if available: |
| **Biktarvy** (Tenofovir alafenamide/emtricitabine/bictegravir(TAF 25 mg/FTC/BIC)* **If recently on PrEP:** *and concerned* about resistance, consider adding in Prezcobix (darunavir + cobicistat). 2 pills once a day. Check for drug to drug interactions with cobicistat containing regimen (statins, etc.)

***Biktarvy+ Prezcobix once a day with food.*** If no resistance on genotype, stop the Prezcobix. -Salama E, Hill L, Patel N, et al. Pharmacokinetics of bictegravir and tenofovir in combination with darunavir/cobicistat in treatment-experienced persons with HIV. J Acquir Immune Defic Syndr. 2021 Jul 19. doi: 10.1097/QAI.0000000000002765. PMID: 34285156.  | * ***Single-tablet***, taken once daily, w or w/o food
* should not be used in patients with a creatinine clearance (CrCl) <30 mL/min; re-evaluate after baseline laboratory testing results are available.
* Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after BIC; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
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| **Tivicay + Descovy** (dolutegravir and Tenofovir alafenamide/Emtricitabine; DTG & TAF 25mg/FTC) | * ***Two pills***, taken together once a day, w/ or w/o food
* Should not be used in patients with CrCl <30 mL/min; re-evaluate after baseline laboratory testing results are available.
* Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.
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| **Symtuza** (darunavir/cobicistat/tenofovir alafenamide/emtricitabine TAF 10 mg/FTC/DRV/COBI) | * ***Single-tablet***, taken once a day with food
* should not be used in patients with a creatinine clearance (CrCl) <30 mL/min; re-evaluate after baseline laboratory testing results are available.
* Interaction with certain statins, inhaled steroids, oral steroids and other cyp3a4 inhibited meds. (Avoid in polypharmacy) hiv-druginteractions.org
* May boost recreational substances
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| **Follow-Up:** |
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| Once iART initiated:* *IF* iART provider is not managing long-term follow up, schedule with new provider before iART prescription runs out (recommend 7 days)
	+ Scheduled before pt leaves clinic during iART initiation
		- Visit can be in-person or TeleMedicine
* 48 hr check in by nursing, patient navigator, social worker, etc
	+ Side Effects?
	+ Psycho-social support needed?
	+ Clarify any questions about iART/HIV
* Lab Results: provided either via phone, teleMedicine, office visit, or through electronic medical record messenager
	+ If CD4 < 200 start Bactrim DS 1 pill PO QD or Bactrim SS 1 pill PO QD
	+ If CD4 < 100 consider referral to HIV Specialist for consult
	+ Genotype: If M184V is noted, above regimens do **not** need to be altered.
	+ Genotype: If K65R is noted, refer to HIV Specialist and stop iART (Exception: Biktarvy + Prezcobix does not need to be stopped) . New regimen will be needed.
	+ Genotype: if integrase resistance to bictegravir or dolutegravir, stop iART and refer to HIV Specialist. New regimen will be needed. (Very unlikely to occur)
	+ If eGFR <30, stop iART and refer to HIV Specialist.
* 30 day follow up for next labs, check:
	+ HIV RNA “viral load”; CMP; asses adherence and any barriers
* Once undetectable, follow up q 3 months for the first year for:
	+ HIV RNA “viral load”; CD4 count; CMP
	+ STI screening as appropriate
	+ Prescribe 90 days worth of medication to improve adherence
* If not undetectable, follow up monthly and identify any barriers to adherence and refer appropriately
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* HIV Guidelines: https://www.hivguidelines.org/antiretroviral-therapy/when-to-start-plus-rapid-start