CLINICAL GUIDELINES PROGRAM

Flowchart 3: Initial Visit: New Patient, HIV Confirmed, NOT Taking ART

First visit with a new patient who has a confirmed HIV diagnosis and is NOT taking ART

Note: Treat or refer for emergency care when a patient has red flag symptoms, e.g., fevers, dyspnea, severe headaches, mental status changes.

ART-experienced:

- Assess patient's reasons for discontinuing ART, including any challenges with adherence, accessibility, adverse effects, and drug-drug interactions
- Consultation with an experienced HIV care provider may be helpful if the patient stopped ART due to viremia or adverse effects, including unmanageable drug-drug interactions
- Assess HIV treatment readiness; facilitate shared decision-making regarding ART (see NYSDOH AI guideline Rapid ART Initiation > Benefits and Risks of ART)

If the patient is ready and able to re-start ART:

- Resume the most recent well-tolerated regimen; if the previous ART regimen is not known, initiate an INSTI-based regimen
- If the patient has had previous virologic failure, consider resistance testing, including on proviral DNA (or archive genotype) at 2 to 4 weeks
- If the previous ART regimen failed or was not well-tolerated, including due to drug-drug interactions, construct a new regimen and order resistance testing; note that archived genotype may have a role in identifying RAMs when standard genotype testing may not yield results, i.e., in patients with prior treatment experience who have stopped taking ARVs for >4 weeks or have a viral load <1,000 copies/mL (see NYSDOH AI guideline Second-Line ART After Treatment Failure or for Regimen Simplification > Table 1: Types of HIV Resistance Tests)

If the patient is not ready to re-start ART:

- Engage the patient in motivational interviewing and address challenges related to comorbidities and psychosocial factors
- Schedule a return visit within 1 to 2 weeks to review test results and encourage ART initiation

ART-naive:

- Assess HIV treatment readiness and facilitate shared decision-making regarding ART initiation (see Benefits and Risks of ART)
- Strongly recommend and offer same-day or rapid ART

If the patient is not ready to initiate ART:

- Engage patient in motivational interviewing
- Address challenges related to comorbidities and psychosocial factors
- Provide education and counseling regarding HIV transmission prevention, condom use, and STI prevention, including doxy-PEP
- Schedule a return visit within 1 to 2 weeks to review test results and encourage ART initiation

All patients:

Obtain:

- Pronoun(s) and gender identity
- Patient concerns and goals
- Comprehensive HIV history (see Checklist 1)
- Standard and HIV-specific medical, surgical, and family histories [a]
- Standard and HIV-specific ROS and physical exam, including sex organ inventory
- Current medications; note potential drug-drug interactions
- Immunization status

Provide counseling and patient education:

- Benefits of ART, including rapid start and U=U
- HIV transmission prevention [c]
- HIV disclosure status
- Age-, sex-, and risk-based screening and preventive care recommendations, including immunizations
- Adherence requirements and support resources
- Substance use treatment and harm reduction options
- Sexual health, including condom use, STI prevention, and other harm reduction options (e.g., doxy-PEP) [d]

Assess (also see Checklist 1):

- Comorbidities [a]
- Symptoms of common opportunistic infections (PJP, TB, CMV, CM); initiate OI prophylaxis if the patient's CD4 count is <200 cells/mm^3
- Substance use, including tobacco [b]; if high-risk, engage in shared decision-making regarding SUD treatment
- Harm reduction needs
- Functional status
- Urgent psychosocial or behavioral needs
- Trauma experience, including medical trauma

Order:

- Baseline laboratory testing (note: HBV status will inform ART regimen)
- Seasonal and other priority vaccines, e.g., influenza, COVID-19, mpox, pneumococcal; avoid live vaccines in patients with CD4 count <200 cells/mm^3
- STI and indicated age-, sex-, and risk-based screening and preventive care if not available on site

Refer as indicated for:

- Imaging
- Urgent specialty care
- Assistance with urgent psychosocial needs
- Screening and preventive care that cannot be provided on site

Follow-up for patient starting ART:

- **2 weeks after ART initiation, in-person, telephone, or telemedicine visit:** Confirm that the patient has filled the prescription and initiated ART; review laboratory test results; confirm patient's understanding of adherence requirements and adverse effect management; initiate OI prophylaxis if the patient has a CD4 count <200 cells/mm^3
- **4 weeks after ART initiation in-person visit:** Assess and manage adverse effects and adherence challenges; assess for symptoms of IRIS; identify drug-drug interactions
  - Order viral load testing and CMP; if the patient is restarting ART, consider genotype testing if there are significant concerns about baseline resistance
  - Continue immunizations until the patient has received all indicated vaccines; avoid live vaccines until CD4 count is >200 cells/mm^3
  - Assess [d]: Comorbidity management, preventive and specialty care needs, psychosocial status, and urgent psychosocial needs
  - Provide counseling, as above

Follow-up if patient is not ready to start or re-start ART:

- **Schedule monthly, in-person visits to:**
  - Review laboratory test results; reassess treatment readiness, barriers, and options
  - Assess and address any challenges related to comorbidities and behavioral or psychosocial factors
  - Perform or order STI and other indicated age-, sex-, and risk-based screening and preventive care
  - Provide education and counseling regarding HIV transmission prevention, condom use, and STI prevention, including doxy-PEP
  - Address treatment readiness and engage the patient in motivational interviewing
- **Adjust the visit schedule**: Schedule visits at a frequency that respects the patient's autonomy and tolerance

Abbreviations: ART, antiretroviral therapy; ARV, antiretroviral; CM, cryptococcal meningitis; CMP, comprehensive metabolic panel; CMV, cytomegalovirus; doxy-PEP, doxycycline post-exposure prophylaxis; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; INSTI, integrase strand transfer inhibitor; IRIS, immune reconstitution inflammatory syndrome; OI, opportunistic infection; PEP, post-exposure prophylaxis; PJP, *pneumocystis jirovecii* pneumonia; PrEP, pre-exposure prophylaxis; RAM, resistance-associated mutation; ROS, review of systems; STI, sexually transmitted infection; SUD, substance use disorder; TB, tuberculosis; U=U, undetectable=untransmittable.

Notes:

a. Monitor for potential long-term effects of HIV and ART (e.g., bone density changes, dyslipidemia, weight gain, and renal dysfunction) and comorbidities.
b. Smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors such as CD4 cell count or viral load [Althoff, et al. 2019].
c. Ongoing discussion and patient education regarding HIV disclosure, principles of U=U, PrEP and PEP for sex partners, and harm reduction is recommended.
d. Ongoing surveillance for diseases transmitted through the same routes as HIV, including HCV, HBV, HPV, and other STIs, is recommended.

Reference

Althoff KN, Gebo KA, Moore RD, et al. Contributions of traditional and HIV-related risk factors on non-AIDS-defining cancer, myocardial infarction, and end-stage liver and renal diseases in adults with HIV in the USA and Canada: a collaboration of cohort studies. *Lancet HIV* 2019;6(2):e93-104. [PMID: 30683625] https://pubmed.ncbi.nlm.nih.gov/30683625