Antiretroviral Auto-Substitution

Antiretrovirals continue to be developed at a relatively rapid pace. Combination products that provide a patient the ability to complete a day of therapy with a single dose have also proliferated. Traditionally, all antiretrovirals have been added to the NMH formulary with a restriction to the Infectious Diseases Consultation Service.

A number of antiretroviral combinations require storage in the original container and may lose potency over a 30-day period when packaged in unit dose containers. This requirement increases the risk of decreased potency and increased waste associated with unit dose packaging.

The utilization of a patient's outpatient medication supply while they are hospitalized, while routinely discouraged, is required when a patient being treated for hepatitis C or is receiving an oral investigational medication. This process, which provides for safe continuation of care and avoids unnecessary risk and expense for the patient while hospitalized, should be expanded to include some of the newer HIV medications to reduce logistical issues related to potency and waste.

Auto-substitution of Antiretroviral Therapy in Hospitalized Patients

Currently, although the majority of patients on antiretroviral therapy who are hospitalized bring in their own medications, situations arise when the patient is not able to bring in their own supply. In these situations, the following protocol will be followed for auto-substitution to avoid any delays or gaps in therapy:

1. Patient's home antiretroviral regimen will be ordered.
    a. If home antiretroviral medication is on formulary → dispense from NMH supply
    b. If the home medication is NOT on formulary → pharmacist asks patient or family to present home supply of medication for dispensing
    c. If patient on a non-formulary antiretroviral AND unable to bring in from home → pharmacist to auto-substitute following the criteria charted below:
2. If auto-substitution is taking place, an FYI page will be sent by clinical pharmacist to the ordering physician (e.g., "FYI: Pharmacist substitution based on formulary, patient meets criteria approved by Antibiotic Subcommittee, will substitute Genvoya™ for Stribild™ ")
3. If a non-formulary medication is needed but appropriate criteria are not met (i.e., renal insufficiency), the clinical pharmacist will page the ID Clinic pharmacist (8-4:30pm, M-F; 1-7289) or the on call ID pharmacist (5-5955) for recommendations.

Appendix A: Formulary Status of Antiretroviral Medications

1. All ARVs are on formulary with the exception of those listed below. New antiretroviral regimens or changes in antiretroviral regimens require ID consultation.
2. Non-formulary:
    a. Stribild™ (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)
    b. Complera™ (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
3. Not yet reviewed (and therefore non-formulary):
    b. Prezcobix™ (darunavir/cobicistat)
    c. Evotaz™ (atazanavir/cobicistat)
    d. Juluca™ (dolutegravir/rilpivirine)

Non-formulary ARV	Auto-substitute with the following:
Stribild™ (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)	Genvoya™ (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide) If CrCl > 30 mL/min **AND** Not on concurrent P-glycoprotein inducers or inhibitors* **AND** Not on concurrent atazanavir
Complera™ (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)	Odefsey™ (emtricitabine/rilpivirine/tenofovir alafenamide) If CrCl >30 mL/min **AND** Not on concurrent P-glycoprotein inducers or inhibitors*
Prezcobix™ (darunavir/cobicistat)	Prezista™ (darunavir) 800mg plus Tybost™ (cobicistat) 150mg If CrCl is > 50mL/min†
Evotaz™ (atazanavir/cobicistat)	Reyataz™ (atazanavir) 300mg plus Tybost™ (cobicistat) 150mg
Formulary ARV Substitution	**Substitution required as individual component (bictegraivr) not available**
Biktarvy™ (bictegravir/emtricitabine/tenofovir alafenamide)	Consult Infectious Diseases for recommendations on switching to alternative therapy if followed by NM ID Center Biktarvy **cannot** be crushed Can consider Dolutegravir (Tivicay) and Emtricitabine/Tenofovir disoproxil fumarate (Truvada) as a short-term alternative if patient is: • Critically ill with no oral access • Does not have history of resistance, failure, or intolerance/adverse effects to DTG or 3TC/TDF • Anticipated duration of intubation is >2 days • If above information in unknown or unattainable, please page NM ID Clinic Pharmacist (17289) or obtain an ID consult

* Link to table of CYP and P-Glycoprotein inducers and inhibitors: https://secure.medicalletter.org/downloads/CYP_PGP_Tables.pdf

† This recommendation is per the package insert. In clinical practice, though, patients tolerated Prezcobix with CrCl <50 ml/min.

Approved by NMH P&T Executive Committee April 12, 2018 Updated 9.17.19

Approved by NMH P&T Executive Committee April 12, 2018 Updated 6.21.18