Adult Anti-retroviral and Anti-tuberculosis Drugs Dosing Guidelines: RENAL
Jackson Memorial Hospital (JMH)

Renal Dosing Based on Creatinine Clearance and Dialysis

Mayela Castillo, PharmD, BCPS and Jacquelyn Lansing, PharmD, BCPS,
Nafeesa Chin-Beckford, PharmD

Antiretroviral GENERIC, (Abbreviation) - Brand®	**Usual Daily Dose**	**Dosing in Renal Insufficiency and Dialysis** Hemodialysis (HD), Chronic Ambulatory Peritoneal Dialysis (CAPD)
ABACAVIR/DOLUTEGRAVIR/ LAMIVUDINE, (ABC, DTG, 3TC) - Triumeq®	- 1 tablet: 600mg/50mg/300mg - Fixed dose: 1 tab PO q12h - Do NOT use in weight < 40 kg	- Fixed dose combination contraindicated in CrCl < 50mL/min
ABACAVIR/LAMIVUDINE/ ZIDOVUDINE, (ABC, 3TC, ZTC) - Trizivir®	- 1 tablet: 300mg/150mg/300mg - Fixed dose: 1 tab PO q12h - Do NOT use in weight < 40 kg	- Fixed dose combination contraindicated in CrCl < 50mL/min
ATAZANAVIR, (ATV) - Reyataz®	**Treatment naïve and ARV* experienced patients:** - 300mg PO q24h + 100mg Ritonavir (RTV) PO q24h **Treatment naïve and unable to tolerate RTV** - 400mg PO q24h - Avoid PPI, Give 2h before or 10h after H2RAs	- No dosage adjustment in renal insufficiency not on HD **ARV naïve on HD:** 300mg PO q24h + 100mg RTV PO q24h **ARV experienced on HD:** ATV or RTV-boosted ATV not recommended
DIDANOSINE, (ddI) - Videx®	≥ 60 kg / < 60 kg - Preferred: 200mg PO q12h / 125mg PO q12h - Once daily: 400mg PO q24h / 250mg PO q24h - Take on an empty stomach - Do not crush or break capsules	**CrCl (mL/min)** / **≥ 60 kg** / **< 60 kg** 30-59: 200mg PO q24h / 150mg PO q24h 100mg PO q12h / 75mg PO q12h 10-29: 150mg PO q24h / 100mg PO q24h < 10, HD, CAPD**: 100mg PO q24h / 75 mg PO q24h
EFAVIRENZ/EMTRICITABINE/ TENOFOVIR, (EFV, FTC, TDF) - Atripla®	- 1 tablet: 600mg/200mg/300mg - Fixed dose: 1 tab PO q24h	- Fixed dose combination contraindicated in CrCl < 50mL/min
ELVITEGRAVIR/COBICISTAT/ EMTRICITABINE/TENOFOVIR, (EVG, COBI, FTC, TDF) - Stribild®	- 1 tablet: 150mg/150mg/200mg/300mg - Fixed dose: 1 tab PO q24h - Separate from antacids by at least 2h	**CrCl (mL/min)** / **Dose** ≥ 70: No dosage adjustments recommended < 70 at initiation: Initial use is not recommended < 50 during therapy: Continued use is not recommended ESRD on HD: Use is not recommended
EMTRICITABINE, (FTC) - Emtriva®	- Capsule: 200mg PO q24h - Oral Solution (10mg/mL): 240mg PO q24h - Abrupt withdrawal may cause Hep B flares	**CrCl (mL/min)** / **Capsule** / **Oral Solution** 30-49: 200mg PO q48h / 120mg (12mL) PO q24h 15-29: 200mg PO q72h / 80mg (8mL) PO q24h < 15 or HD: 200mg PO q96h / 60mg (6mL) PO q24h Take dose after HD session on dialysis days
EMTRICITABINE/TENOFOVIR, (FTC, TDF) - Truvada®	- 1 tablet: 200mg/300mg - Fixed dose: 1 tab PO q24h	**CrCl (mL/min)** / **Dose** 30-49: 1 tablet PO q48h < 30 or HD: Combination not recommended/See individual drugs
ETHAMBUTOL - Myambutol®	- Tablets: 100, 400mg - Tuberculosis: 15mg/kg/dose PO q24h - Dosing by lean body weight (max of 1600mg/day) 40-55 kg: 800mg PO q24h 56-75 kg: 1200mg PO q24h 76-90 kg: 1600mg PO q24h - For DOT dosing refer to back of card	**CrCl (mL/min)** / **Dose** < 30 or HD: 15mg/kg/dose PO 3 x/week CVVH: Standard lean body weight dosing PO q24h - Take dose after HD session on dialysis days
LAMIVUDINE, (3TC) - Epivir®	- 150mg PO q12h **OR** - 300mg PO q24h	**CrCl (mL/min)** / **Dose** 30-49: 150mg PO q24h 15-29: 150mg PO x 1, then 100mg PO q24h 5-14: 150mg PO x 1, then 50mg PO q24h < 5 or HD: 50mg PO x 1, then 25mg PO q24h Take dose after HD session on dialysis days **CrCl < 50mL/min:** Some patients may be managed with 150mg PO q24h including HD patients
LAMIVUDINE/ZIDOVUDINE, (3TC, AZT) - Combivir®	- 1 tablet: 150mg/300mg - Fixed dose (weight ≥ 30 kg): 1 tab PO q12h	- Fixed dose combination contraindicated in CrCl < 50mL/min (Some patients may be managed on 1 tab PO q24h for CrCL<15 or HD)
LOPINAVIR/RITONAVIR, (LPV/r) - Kaletra®	- Tablets: 200mg/50mg or 100mg/25mg - Oral solution: 5mL = 400mg/100mg (with food) **Standard dosing:** 400mg/100mg PO q12h **Patients with < 3 LPV resistance associated substitutions:** 800mg/200mg PO q24h	- Avoid once daily dosing in patients on HD
PYRAZINAMIDE	**Daily Dosing (Lean Body Weight)** 40-55 kg: 1000mg PO q24h 56-75 kg: 1500mg PO q24h 76-90 kg: 2000mg PO q24h* **Thrice Weekly Dosing (Lean Body Weight)** 40-55 kg: 1500mg 3 x/week 56-75 kg: 2500mg 3 x/week 76-90 kg: 3000mg 3 x/week* **Twice Weekly Dosing (Lean Body Weight) **** 40-55 kg: 2000mg 2 x/week 56-75 kg: 3000mg 2 x/week 76-90 kg: 4000mg 2 x/week* * Max dose regardless of weight ** Do not use twice weekly dosing in patients coinfected with HIV	**CrCl (mL/min)** / **Dose** < 30 or HD: 40-55 kg: 1000mg PO 3 x/week 56-75 kg: 1500mg PO 3 x/week 76-90 kg: 2000mg PO 3 x/week
RALTEGRAVIR, (RAL) - Issentress®	- 400mg PO q12h - If rifampin co-administration: 800mg PO q12h	Mild, moderate and severe impairment: No adjustment necessary HD: Dose after dialysis on dialysis days
RIFABUTIN, (RFB), - Mycobutin®	**Disseminated MAC in advanced HIV infection:** **Prophylaxis:** 300mg PO q24h **Treatment:** 300mg PO q24h as optional add-on to primary therapy of clarithromycin and ethambutol **Latent TB Prophylaxis:** 300mg PO q24h **Active TB Treatment:** 300mg PO q24h **OR** 300mg PO 2-3x/week ****Doses vary depending on the antiretroviral agent being used**	**CrCl (mL/min)** < 30: Reduce dose by 50%
STAVUDINE, (d4t) - Zerit®	- < 60kg: 30mg q12h - ≥ 60kg: 40mg q12h	**CrCl (mL/min)** / **≥ 60 kg** / **< 60 kg** 26-50: 20mg PO q12h / 15mg PO q12h ≤ 25 or HD: 20mg PO q24h / 15mg PO q24h
STREPTOMYCIN	- 15mg/kg/day IM (max of 1000mg) **OR** - 25-30mg/kg/dose IM (max of 1500mg) 2-3x/week	**CrCl (mL/min)** / **Dose** 10-50 or CVVHD: 15mg/kg/day IM (max of 1000mg) q24-72h < 10: 15mg/kg/day IM (max of 1000mg) q72-96h HD: 7.5mg/kg/day IM after HD on dialysis days PD: Administer 20-40mg/L of PD fluid via PD fluid
TENOFOVIR, (TDF) - Viread®	- 300mg PO q24h - Abrupt withdrawal may cause Hep B flares	**CrCl (mL/min)** / **Dose** 30-49: 300mg PO q48h 10-29: 300mg PO q72h (twice weekly) < 10 not on HD: No recommendations HD: 300mg PO weekly or after ~12h of HD)
ZIDOVUDINE, (AZT, ZDV) - Retrovir®	- 300mg PO q12h	**CrCl (mL/min)** / **Dose** < 15 or HD: 100mg PO q6-8h **OR** 300mg PO q24h

*ARV: Antiretroviral **CAPD: Continuous Ambulatory Peritoneal Dialysis

Anti-retroviral and Anti-tuberculosis Drugs WITHOUT Renal Adjustment

Drug	General Dose
ABACAVIR, (ABC) - Ziagen®	- 300mg PO q12h **OR** 600mg q24h - Use with caution in coronary heart disease - EtOH decreases elimination and may increase levels by 41%
DARUNAVIR, (DRV) - Prezista®	**Treatment-naïve or with no DRV resistance:** - 800mg PO q24h + RTV 100mg PO q24h **≥ 1 DRV resistance-associated substitutions:** - 600mg PO q12h + RTV 100mg PO q12h - CrCl < 30mL/min: Not studied
DOLUTEGRAVIR, (DTG) - Tivicay®	**Treatment naïve or INSTI-naïve patients:** - 50mg PO q24h **Coadministration with efavirenz, fosamprenavir/ritonavir or rifampin or when INSTI*** resistance or mutations are clinically suspected:** - 50 mg PO q12h - Take 2h before or 6h after cation containing meds (Mg, Al, Fe, Ca)
EFAVIRENZ, (EVF) - Sustiva®	**Standard dosing:** 600mg PO q24h **Concomitant use of rifampin and wt ≥ 50 kg:** 800mg PO q24h **Concomitant use of voriconazole:** 300mg PO q24h and increase voriconazole dose - Take at bedtime without food to decrease CNS effects (hallucinations, abnormal dreams) - Evaluate risk vs benefit us in patients with unstable psych disorders - Use 2 forms of contraception; teratogenic
ELVITEGRAVIR, (EVG) - Vitekta®	**Coadministration with atazanavir or lopinavir + ritonavir:** 85mg PO q24h **Coadministration with darunavir, fosamprenavir, or tipranavir + ritonavir:** 150mg PO q24h
FOSAMPRENAVIR, (FPV) - Lexiva®	- 700mg PO q12h **OR** 1400mg PO q24h - If patient requires PPIs/H2RAs, PPIs are preferred - Do not coadminister with oral contraceptives: Decrease FPV levels
ISONIAZID, (INH)	- Active TB: 5mg/kg PO q24h (max 300mg) or 15mg/kg PO 2-3x/week (max 900mg) - Latent TB: 300mg q24h or 900mg 2x/week
RIFAMPIN, (RIF)	- Active TB: 10mg/kg PO q24h (max of 600/day) or 10mg/kg PO 2-3x/week (max of 600mg) - Latent TB: 10mg/kg PO q24h (max of 600/day)
RITONAVIR, (RTV) - Norvir®	**Varies depending on the protease inhibitor used:** 100-200mg PO q12-24h

***INSTI: Integrase Strand Transfer Inhibitor

Adult Anti-retroviral and Anti-tuberculosis Drugs Dosing Guidelines: HEPATIC
Jackson Memorial Hospital (JMH)

Mayela Castillo, PharmD, BCPS, Jacquelyn Lansing, PharmD, BCPS
and Nafeesa Chin-Beckford, PharmD

Drug	Mild Insufficiency (Child-Pugh class A)	Moderate Insufficiency (Child-Pugh class B)	Moderate Insufficiency (Child-Pugh class B)
ABACAVIR, (ABC) - Ziagen®	- 200mg q12h (oral solution recommended)	Contraindicated (has not been studied)	
ABACAVIR/DOLUTEGRAVIR/ LAMIVUDINE, (ABC, DTG, 3TC) - Triumeq®	Not recommended (use dose-adjusted individual components)	Contraindicated	
ABACAVIR/LAMIVUDINE/ ZIDOVUDINE, (ABC, 3TC, ZTC) - Trizivir®	Contraindicated; no specific recommendations		
ATAZANAVIR, (ATV) - Reyataz®	Use with caution	Use with caution; if no prior virologic failure, reduce dose to 300mg PO q24h	Not recommended
	Concomitant hepatitis B or C: May be at increased risk of hepatic decompensation		
DIDANOSINE, (ddI) - Videx®	No dosage adjustment necessary		
DOLUTEGRAVIR, (DTG) - Tivicay®	No dosage adjustment necessary		Not recommended (has not been studied)
EFAVIRENZ/EMTRICITABINE/ TENOFOVIR, (EFV, FTC, TDF) - Atripla®	Use with caution	Not recommended	
ELVITEGRAVIR, (EVG) - Vitekta®	No dosage adjustment necessary		Not recommended (has not been studied)
ELVITEGRAVIR/COBICISTAT/ EMTRICITABINE/TENOFOVIR, (EVG, COBI, FTC, TDF) Stribild®	No dosage adjustment necessary		Not recommended (has not been studied)
EMTRICITABINE, (FTC) - Emtriva®	No dosage adjustment necessary		
EMTRICITABINE/TENOFOVIR, (FTC, TDF) - Truvada®	No dosage adjustment necessary		
ETHAMBUTOL - Myambutol®	No dosage adjustment provided; use with caution		
FOSAMPRENAVIR, (FPV) - Lexiva®	**Treatment naïve:** 700mg PO q12h without concurrent ritonavir **Treatment naïve or PI experienced:** 700mg PO q12h plus ritonavir	**Treatment naïve:** 700mg PO q12h without concurrent ritonavir **Treatment naïve or PI experienced:** 450mg PO q12h plus ritonavir	**Treatment naïve:** 350mg PO q12h without concurrent ritonavir **Treatment naïve or PI experienced:** 300mg PO q12h plus ritonavir
ISONIAZID, (INH)	**Use with caution**; May accumulate in preexisting hepatic disease **Contraindications**: Acute hepatic disease or previous isoniazid-associated hepatic injury For ALT or AST >3x ULN: Discontinue or temporarily withhold treatment		
LAMIVUDINE, (3TC) - Epivir®	- No dosage adjustment necessary in compensated hepatic disease - Has not been studied in decompensated hepatic disease		
LAMIVUDINE/ZIDOVUDINE, (3TC, AZT) - Combivir®	Fixed-dose combination not recommended; use individual components		
LOPINAVIR/RITONAVIR, (LPV/r) - Kaletra®	Use with caution; lopinavir AUC may be increased by ~30%		Use with caution: No data available
PYRAZINAMIDE	No dosage adjustment provided		Contraindicated
RALTEGRAVIR, (RAL) **-** Issentress®	No dosage adjustment necessary		No dosage adjustment provided; has not been studied
RIFABUTIN, (RFB) - Mycobutin®	No dosage adjustment necessary	No dosage adjustment provided	
RIFAMPIN, (RIF)	No dosage adjustment provided		
RITONAVIR, (RTV) - Norvir®	No dosage adjustment necessary	No dosage adjustment necessary; however, levels may be decreased, monitor patient response	Not recommended (has not been studied)
STAVUDINE, (d4t) - Zerit®	Use with caution; no dosage adjustment provided		
STREPTOMYCIN	No dosage adjustment provided		
TENOFOVIR, (TDF) - Viread®	No dosage adjustment necessary		
ZIDOVUDINE, (AZT, ZDV) - Retrovir®	No dosage adjustment provided (has not been studied) Adjustment may be necessary due to extensive hepatic metabolism		

Tuberculosis Treatment Regimens

Dosing Regimens	Non-HIV Patients	Duration	Coinfected with HIV	Duration
Latent TB - Preferred	INH* 300mg q24h **OR** 900mg 2x/week	**Preferred:** 9-12 months **Alternative:** 6 months	INH* 5mg/kg PO q24h (max 300mg)	9-12 months
Latent TB - INH Resistance	RIF 10mg/kg PO q24h (max 600mg/day)	4 months	**DOT******;** INH* 15mg/kg 2x/week (max 900mg/dose)	9 months
ACTIVE TB DOSING REGIMENS				
Initial 4 Drug Regimen	INH* + RIF + PZA + EMB Followed by INH + RIF	2 months then 4 months	INH* + RIF + PZA + EMB Followed by INH + RIF	2 months 4-7 months
Frequency	Daily, 2x, 3x, OR 5x/week	6 months total	Daily, 3x or 5x/week	6-9 months total
For any variations in therapy, intolerance to the above regimen, or known resistance, please consult an ID specialist				

INH*: Requires coadministration with pyridoxine 25-50mg PO q24h to prevent neuropathy DOT**: Directly Observed Therapy

Anti-tuberculosis Medication Considerations

Dosing Regimens	RIFAMPIN (RIF)	ISONIAZID (INH)	PYRAZINAMIDE (PZA)	ETHAMBUTOL (EMB)
Formulations	Capsules: 150mg, 300mg Inj: 600mg/10mL	Tablets: 100mg, 300mg Syrup: 50mg/mL Inj: 100mg/mL	Tablet: 500mg	Tablets: 100mg, 400mg
Latent TB	- 10mg/kg/dose (max 600mg) PO q24h	- 5mg/kg/dose (max 300mg) PO q24h **DOT******:** 15mg/kg/dose (max 900mg) PO 2x/week	Not recommended in combination with RIF	
Active TB	- 10mg/kg/dose (max 600mg) PO q24h **DOT:** 10mg/kg/dose (max 600mg) PO 2-3x/week (Confirm HIV negative)	- 5mg/kg/dose (max of 300mg) PO q24h **DOT:** 15mg/kg/dose (max 900mg) PO 2-3x/week	**Dosing based on LBW (mg/dose)** **Daily** 40-55kg: 1000mg 56-75kg: 1500mg 76-90kg: 2000mg **DOT: 3x/week 2x/week** 40-55kg: 1500mg 2000mg 56-75kg: 2500mg 3000mg 76-90kg: 3000mg 4000mg	**Dosing based on LBW (mg/dose)** **Daily** 40-55kg: 800mg 56-75kg: 1200mg 76-90mg: 1600mg **DOT: 3x/week 2x/week** 40-55kg: 1200mg 2000mg 56-75kg: 2000mg 2800mg 76-90kg: 2400mg 4000mg
Adverse Effects	Orange discoloration of bodily fluids, flu-like symptoms, hepatotoxicity, hematologic reactions, hypersensitivity reactions	Hepatotoxicity, peripheral neuropathy, optic neuritis, hematologic reactions	GI symptoms (improve within a few weeks), polyarthralgia, Rare: Hyperuricemia, hepatotoxicity	GI symptoms, optic neuritis (decreased acuity, visual defects, color blindness), peripheral neuropathy, cutaneous reactions
Administration Points (10:00AM preferred)	Empty stomach (1h prior or 2h after a meal)	Empty stomach (30mins prior or 2h after a meal) Avoid antacids 2h before and after INH	Without regard to meals	With food, decreases GI upset
Clinical Peals	Potent CYP-P450 inducer. Do not use with etravirine, nevirapine, rilpivirine, PI-containing HAART regimens, Stribild®	CYP-P450 inhibitor, Autoinducer - CYP2E1. Recommend pyridoxine (vitamin B6) 25-50mg PO daily to prevent neuropathy.	May use in patients with gout; consider adding allopurinol at initiation. May use low dose NSAIDS or colchicine for pain relief as needed	Visual toxicity is dose related and less common with intermittent therapy (2 or 3x/week) and at lower doses (15mg/kg/day)
At Treatment Initiation	Baseline labs: LFTs, total bilirubin, uric acid, BUN, SCr, and CBC with differential, eye exam for EMB Educate patient on signs and symptoms of hepatitis and encourage them to report symptoms of hepatitis or change in vision immediately			
Monthly Monitoring By Agent	LFTs, Total bilirubin. Continue treatment unless: AST > 3x ULN and symptomatic, AST > 5x ULN and asymptomatic, Significant increase in bilirubin ± alkaline phosphatase Consult TB expert for management			Eye exam; If decreased, check dose, renal function, and drug levels. Refer patient to ophthalmologist and consult a TB expert for regimen changes
Other Considerations	Aggressively treat vomiting as it increases risk of drug resistance (Counsel patient to eat 2h prior to taking TB meds, use antiemetics such as ondansetron or metoclopramide 30min before TB meds)			

DOT**: Directly Observed Therapy

Contact Numbers		
For Approvals: ASP		**For Formal Consult: ID Fellow On-Call**
		JMH Team A (General ID): (305) 881 - 3165
JMH ASP: (786) 586 - 0607	**Hours: 7:00 am – 11:00 pm**	JMH Team B (Oncology/Transplant): (305) 996 - 0007

For more information, please visit: www.ugotabug.med.miami.edu

Last Revised and Approved by the JMH Anti-Infective Subcommittee and P&T October 2015