

Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Updated January 10, 2011)

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See reference section following tables for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Antiretrovirals Generic Name (abbreviation)/ Trade Name	Usual Daily Dose (Refer to Appendix B Tables 1-6 for additional dosing information)	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis [CAPD] and hemodialysis [HD])	Dosing in Hepatic Impairment
Nucleoside Reverse Transcriptase Inhibitors			
Use of fixed-dose combination NRTI (+/- NNRTI) of Atripla, Combivir, Trizivir, or Epzicom is not recommended in patients with CrCl <50 mL/min. Use of Truvada is not recommended in patients with CrCl <30 mL/min.			
Abacavir (ABC)/ Ziagen	300 mg PO BID	No dosage adjustment necessary	Child-Pugh Score 5–6 Dose 200 mg BID (use oral solution) > 6 Contraindicated
Didanosine enteric coated (ddl)/ Videx EC	Body weight ≥60 kg: 400 mg PO once daily Body weight <60 kg: 250 mg PO once daily	CrCl (mL/min) 30–59 10–29 <10, HD, CAPD Dose (once daily) ≥60 kg <60 kg 200 mg 125 mg 125 mg 125 mg 125 mg use oral solution	No dosage adjustment necessary
Didanosine oral solution (ddl)/ Videx	Body weight ≥60 kg: 200 mg PO BID or 400 mg PO once daily Body weight <60 kg: 250 mg PO once daily or 125 mg PO BID	CrCl (mL/min) 30–59 10–29 <10, HD, CAPD Dose (once daily) ≥60 kg <60 kg 200 mg 150 mg 150 mg 100 mg 100 mg 75 mg	No dosage adjustment necessary
Emtricitabine (FTC)/ Emtriva	200mg oral capsule PO once daily; or 240 mg (24 mL) oral solution PO once daily	CrCl (mL/min) 30–49 15–29 <15 or HD Take dose after HD session on dialysis days Dose Capsule Solution 200 mg q48h 120 mg q24h 200 mg q72h 80 mg q24h 200 mg q96h 60 mg q24h	No dosage recommendation
Lamivudine (3TC)/ Epivir	300 mg PO once daily; or 150 mg PO BID	CrCl (mL/min) 30–49 15–29 5–14 <5 or HD Take dose after HD session on dialysis days Dose 150 mg q24h 1 x 150 mg, then 100 mg q24h 1 x 150 mg, then 50 mg q24h 1 x 50 mg, then 25 mg q24h	No dosage adjustment necessary
Stavudine (D4T)/ Zerit	Body weight ≥60 kg: 40 mg PO BID Body weight <60 kg: 30 mg PO BID	CrCl (mL/min) 26–50 10–25 or HD Take dose after HD session on dialysis days Dose ≥60 kg <60 kg 20 mg q12h 15 mg q12h 20 mg q24h 15 mg q24h	No dosage recommendation
Tenofovir (TDF)/ Viread	300 mg PO once daily	CrCl (mL/min) 30–49 10–29 <10 not on HD HD Take dose after HD session on dialysis days Dose 300 mg q48h 300 mg twice weekly no recommendation 300 mg q7d	No dosage adjustment necessary
Emtricitabine (FTC) + Tenofovir (TDF)/ Truvada	1 tablet PO once daily	CrCl (mL/min) 30–49 <30 or HD Dose 1 tablet q48h not recommended	No dosage recommendation
Zidovudine (AZT, ZDV)/ Retrovir	300 mg PO BID	CrCl (mL/min) < 15 or HD Dose 100 mg TID or 300 mg once daily	No dosage recommendation

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Non-Nucleoside Reverse Transcriptase Inhibitors			
Delavirdine (DLV)/ Rescriptor	400 mg PO TID	No dosage adjustment necessary	No dosage recommendation; use with caution in patients with hepatic impairment
Efavirenz (EFV)/ Sustiva	600 mg PO at or before bedtime	No dosage adjustment necessary	No dosage recommendation; use with caution in patients with hepatic impairment
Efavirenz (EFV) + Emtricitabine (FTC) + Tenofovir (TDF)/ Atripla	1 tablet PO once daily	Atripla not recommended if CrCl <50 mL/min	
Etravirine (ETR)/ Intelecle	200 mg PO BID	No dosage adjustment necessary	<u>Child-Pugh Class A or B</u> : no dosage adjustment <u>Child-Pugh Class C</u> : no dosage recommendation
Nevirapine (NVP)/ Viramune	200 mg PO BID	<u>HD patients</u> : limited data; no dosage recommendation	<u>Child-Pugh Class B or C</u> : contraindicated
Protease Inhibitors			
Atazanavir (ATV)/ Reyataz	400 mg PO once daily or (ATV 300 mg + RTV 100 mg) PO once daily	No dosage adjustment for patients with renal dysfunction not requiring HD <u>ARV-naïve patients on HD</u> : (ATV 300 mg + RTV 100 mg) once daily <u>ARV-experienced patients on HD</u> : ATV or RTV-boosted ATV not recommended	Child-Pugh Score Dose 7–9 300 mg once daily >9 not recommended RTV boosting is not recommended in patients with hepatic impairment (Child-Pugh Score ≥7).
Darunavir (DRV)/ Prezista	(DRV 800 mg + RTV 100 mg) PO once daily (ARV-naïve patients) or (DRV 600 mg + RTV 100 mg) PO BID	No dosage adjustment necessary	<u>Mild to moderate hepatic impairment</u> : no dosage adjustment <u>Severe hepatic impairment</u> : not recommended
Fosamprenavir (FPV)/ Lexiva	1,400 mg PO BID or (FPV 1,400 mg + RTV 100–200 mg) PO once daily or (FPV 700 mg + RTV 100 mg) PO BID	No dosage adjustment necessary	Child-Pugh Score Dose <u>PI-naïve patients only</u> : 5–9 700 mg BID 10–15 350 mg BID <u>PI-naïve or PI-experienced patients</u> : 5–6 700 mg BID + RTV 100 mg once daily 7–9 450 mg BID + RTV 100 mg once daily 10–15 300 mg BID + RTV 100 mg once daily
Indinavir (IDV)/ Crixivan	800 mg PO q8h	No dosage adjustment necessary	<u>Mild to moderate hepatic insufficiency because of cirrhosis</u> : 600 mg q8h
Lopinavir/ritonavir (LPV/r) Kaletra	400/100 mg PO BID or 800/200 mg PO once daily	Avoid once daily dosing in patients on HD	No dosage recommendation; use with caution in patients with hepatic impairment
Nelfinavir (NFV)/ Viracept	1,250 mg PO BID	No dosage adjustment necessary	<u>Mild hepatic impairment</u> : no dosage adjustment <u>Moderate to severe hepatic impairment</u> : do not use
Ritonavir (RTV)/ Norvir	<u>As a PI-boosting agent</u> : 100–400 mg per day	No dosage adjustment necessary	Refer to recommendations for the primary PI
Saquinavir (SQV)/ Invirase	(SQV 1,000 mg + RTV 100 mg) PO BID	No dosage adjustment necessary	<u>Mild to moderate hepatic impairment</u> : use with caution <u>Severe hepatic impairment</u> : contraindicated
Tipranavir (TPV)/ Aptivus	(TPV 500 mg + RTV 200 mg) PO BID	No dosage adjustment necessary	<u>Child-Pugh Class A</u> : use with caution <u>Child-Pugh Class B or C</u> : contraindicated

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Antiretrovirals Generic Name (abbreviation)/ Trade Name	Daily Dose	Dosing in Renal Insufficiency	Dosing in Hepatic Impairment
Fusion Inhibitor			
Enfuvirtide (T20)/ Fuzeon	90 mg subcutaneous BID	No dosage adjustment necessary	No dosage adjustment necessary
CCR5 Antagonist			
Maraviroc (MVC)/ Selzentry	The recommended dose differs based on concomitant medications because of drug interactions. See Appendix B, Table 6 for detailed dosing information.	CrCl <30 mL/min or HD Without potent CYP3A inhibitors or inducers: 300 mg BID; reduce to 150 mg BID if postural hypotension occurs With potent CYP3A inducers or inhibitors: not recommended	No dosage recommendations. Concentrations will likely be increased in patients with hepatic impairment.
Integrase Inhibitor			
Raltegravir (RAL)/ Isentress	400 mg BID	No dosage adjustment necessary	<u>Mild to moderate hepatic insufficiency:</u> no dosage adjustment necessary <u>Severe hepatic insufficiency:</u> no recommendation

Creatinine Clearance Calculation

Male: $\frac{(140 - \text{age in years}) \times \text{weight (kg)}}{72 \times \text{Serum Creatinine}}$

Female: $\frac{(140 - \text{age in years}) \times \text{weight (kg)} \times 0.85}{72 \times \text{Serum Creatinine}}$

Child-Pugh Score

Component	Points Scored		
	1	2	3
Encephalopathy*	None	Grade 1–2	Grade 3–4
Ascites	None	Mild or controlled by diuretics	Moderate or refractory despite diuretics
Albumin	>3.5 g/dL	2.8–3.5 g/dL	<2.8 g/dL
Total bilirubin or Modified total bilirubin†	<2 mg/dL (<34 μmol/L)	2–3 mg/dL (34 μmol/L to 50 μmol/L)	>3 mg/dL (>50 μmol/L)
Prothrombin time (seconds prolonged) or International normalized ratio (INR)	<4	4–6	>6
	<1.7	1.7–2.3	>2.3

* Encephalopathy Grades

Grade 1: Mild confusion, anxiety, restlessness, fine tremor, slowed coordination**Grade 2:** Drowsiness, disorientation, asterixis**Grade 3:** Somnolent but rousable, marked confusion, incomprehensible speech, incontinence, hyperventilation**Grade 4:** Coma, decerebrate posturing, flaccidity

† Modified total bilirubin used to score patients who have Gilbert's syndrome or who are taking indinavir or atazanavir

Child-Pugh Classification	Total Score*
Class A	5–6 points
Class B	7–9 points
Class C	>9 points

* Sum of points for each component