

Appendix B, Table 11. Antiretroviral Dosing Recommendations in Persons with Renal or Hepatic Insufficiency

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The older antiretroviral (ARV) drugs didanosine (ddI), stavudine (d4T), fosamprenavir (FPV), indinavir (IDV), nelfinavir (NFV), saquinavir (SQV), tipranavir (TPV), and zidovudine (ZDV) are no longer used commonly in clinical practice and have been removed from this table. Please refer to the Food and Drug Administration product labels for these drugs for recommendations on dosing in people with renal or hepatic insufficiency.

See the reference section at the end of this table for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
<p>Some FDC products are not recommended in persons with different degrees of renal insufficiency. The recommendations for individual FDCs based on CrCl level are outlined below.</p> <ul style="list-style-type: none"> • <i>CrCl</i> <70 mL/min: Initiation of Stribild is not recommended. • <i>CrCl</i> <50 mL/min: FDCs not recommended: Atripla, Cimduo, Complera, Delstrigo, Temyxis, Truvada, Symfi, Symfi-Lo • <i>CrCl</i> <30 mL/min: FDCs not recommended: Dovato, Epzicom, Triumeq • <i>CrCl</i> <30 mL/min and not on HD: FDCs not recommended: Biktarvy, Descovy, Genvoya, Odefsey, and Symtuza. <p>The component drugs in some of the FDC products listed above may be prescribed as individual formulations with dose adjustment based on CrCl level as indicated below in this table.</p>			
NRTIs			
Abacavir (ABC) Ziagen	ABC 300 mg PO twice daily or ABC 600 mg PO once daily	No dose adjustment necessary.	<i>Child-Pugh Class A:</i> ABC 200 mg PO twice daily (use oral solution) <i>Child-Pugh Class B or C: Contraindicated.</i>
Abacavir/Lamivudine (ABC/3TC) Epzicom	One tablet PO once daily	Not recommended if <i>CrCl</i> <30 mL/min. ^b Instead, use the individual component drugs and adjust 3TC dose according to <i>CrCl</i> .	<i>Child-Pugh Class A:</i> Patients with mild hepatic impairment require a dose reduction of ABC. Use the individual drugs instead of the FDC tablet in these patients. <i>Child-Pugh Class B or C: Contraindicated due to the ABC component.</i>

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency			Dosing in Persons with Hepatic Impairment
NRTIs, continued					
Emtricitabine (FTC) <i>Emtriva</i>	FTC 200-mg oral capsule once daily <i>or</i> FTC 240-mg (24-mL) oral solution once daily	Dose by Formulation			No dose recommendation.
		CrCl (mL/min)	Capsule	Solution	
		30–49	200 mg every 48 hours	120 mg every 24 hours	
		15–29	200 mg every 72 hours	80 mg every 24 hours	
		<15	200 mg every 96 hours	60 mg every 24 hours	
On HD ^c	200 mg every 24 hours	240 mg every 24 hours			
Lamivudine^b (3TC) <i>Epivir</i>	3TC 300-mg PO once daily <i>or</i> 3TC 150-mg PO twice daily	CrCl (mL/min)	Dose		No dose adjustment necessary.
		15–29	1 × 150 mg, then 100 mg every 24 hours		
		5–14	1 × 150 mg, then 50 mg every 24 hours		
		<5 or on HD ^c	1 × 50 mg, then 25 mg every 24 hours		
Tenofovir Alafenamide (TAF) <i>Vemlidy</i>	Vemlidy is available as a 25-mg tablet for the treatment of HBV.	CrCl (mL/min)	Dose		<i>Child-Pugh Class B or C: Not recommended</i>
		<15 and not on HD	Not recommended		
		On HD ^c	One tablet PO once daily.		

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency		Dosing in Persons with Hepatic Impairment
NRTIs, continued				
Tenofovir Alafenamide/ Emtricitabine (TAF/FTC) <i>Descovy</i>	TAF for HIV treatment is only available as a component of FDC tablets (i.e., in Descovy, Genvoya, Odefsey, Biktarvy, and Symtuza). TAF 10 mg PO daily with EVG/c (Genvoya) or DRV/c (Symtuza) TAF 25 mg PO daily in other FDC tablets	CrCl (mL/min)	Dose	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> No dose recommendation
		<30 and not on HD	Not recommended	
		<30 and on HD ^c	One tablet once daily.	
Tenofovir Disoproxil Fumarate (TDF) <i>Viread</i>	TDF 300 mg PO once daily	CrCl (mL/min)	Dose	No dose adjustment necessary.
		30–49	300 mg every 48 hours	
		10–29	300 mg twice weekly (every 72–96 hours)	
		<10 and not on HD	No recommendation	
		On HD ^c	300 mg every 7 days	
Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC) <i>Truvada</i>	One tablet PO once daily	CrCl (mL/min)	Dose	No dose recommendation.
		30–49	One tablet every 48 hours	
		<30 or on HD	Not recommended	
Tenofovir Disoproxil Fumarate/Lamivudine (TDF/3TC) <i>Cimduo</i> or <i>Temixys</i>	One tablet PO once daily	CrCl (mL/min)	Dose	No dose recommendation.
		<50 or on HD	Not recommended	

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
NNRTIs			
Doravirine (DOR) <i>Pifeltro</i>	DOR 100 mg PO once daily	No dose adjustment required in mild, moderate, or severe renal impairment. Has not been studied in individuals with ESRD or on HD.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> Not studied
Doravirine/Tenofovir Disoproxil Fumarate/Lamivudine (DOR/TDF/3TC) <i>Delstrigo</i>	One tablet PO once daily	Not recommended if CrCl <50 mL/min.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> Not studied
Efavirenz (EFV) <i>Sustiva</i>	EFV 600 mg PO once daily on an empty stomach, preferably at bedtime	No dose adjustment necessary.	No dose recommendation; use with caution in patients with hepatic impairment.
Efavirenz/Tenofovir Disoproxil Fumarate/Emtricitabine (EFV/TDF/FTC) <i>Atripla</i>	One tablet PO once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min. Instead, use the individual component ARVs and adjust TDF and FTC doses according to CrCl level.	No dose recommendation; use with caution in patients with hepatic impairment.
Efavirenz 600 mg/Tenofovir Disoproxil Fumarate/Lamivudine (EFV/TDF/3TC) <i>Symfi</i>	One tablet PO once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min or if patient is on HD. Instead, use the individual component ARVs and adjust TDF and 3TC doses according to CrCl level.	Not recommended for patients with moderate or severe hepatic impairment. Use with caution in patients with mild hepatic impairment.
Efavirenz 400 mg/Tenofovir Disoproxil Fumarate/Lamivudine (EFV/TDF/3TC) <i>Symfi Lo</i>	One tablet PO once daily on an empty stomach, preferably at bedtime	Not recommended if CrCl <50 mL/min or if patient is on HD. Instead, use the individual component ARVs and adjust TDF and 3TC doses according to CrCl level.	Not recommended for patients with moderate or severe hepatic impairment. Use with caution in patients with mild hepatic impairment.
Etravirine (ETR) <i>Intence</i>	ETR 200 mg PO twice daily	No dose adjustment necessary.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> No dose recommendation

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
NNRTIs, continued			
Nevirapine (NVP) <i>Viramune</i> or <i>Viramune XR</i>	NVP 200 mg PO twice daily or NVP 400 mg PO once daily (using <i>Viramune XR</i> formulation)	No dose adjustment for patients with renal impairment. Patients on HD should receive an additional dose of NVP 200 mg following each dialysis treatment.	<i>Child-Pugh Class A</i> : No dose adjustment <i>Child-Pugh Class B or C</i> : Contraindicated
Rilpivirine (RPV PO) <i>Edurant</i>	RPV 25 mg PO once daily	No dose adjustment necessary.	<i>Child-Pugh Class A or B</i> : No dose adjustment <i>Child-Pugh Class C</i> : No dose recommendation
Rilpivirine IM plus Cabotegravir IM (RPV IM and CAB IM) <i>Cabenuva</i>	Loading dose: RPV 900 mg/3 mL IM × 1 dose and CAB 600 mg/3mL IM × 1 dose Continuation phase: RPV 600 mg/2 mL IM every 4 weeks and CAB 400 mg/2mL IM every 4 weeks	No dose adjustment necessary for mild or moderate renal impairment. For patients with severe renal impairment or on HD, increase monitoring for adverse events.	<i>Child-Pugh Class A or B</i> : No dose adjustment <i>Child-Pugh Class C</i> : No recommendation
Rilpivirine/Tenofovir Alafenamide/Emtricitabine (RPV/TAF/FTC) <i>Odefsey</i>	One tablet PO once daily	In Patients on Chronic HD: • One tablet once daily. On HD days, administer after dialysis. Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.	<i>Child-Pugh Class A or B</i> : No dose adjustment <i>Child-Pugh Class C</i> : No dose recommendation
Rilpivirine/Tenofovir Disoproxil Fumarate/Emtricitabine (RPV/TDF/FTC) <i>Complera</i>	One tablet PO once daily	Not recommended if CrCl <50 mL/min. Instead, use the individual component ARVs and adjust TDF and FTC doses according to CrCl level.	<i>Child-Pugh Class A or B</i> : No dose adjustment <i>Child-Pugh Class C</i> : No dose recommendation
Rilpivirine/Dolutegravir (RPV/DTG) <i>Juluca</i>	One tablet PO once daily with food	No dose adjustment necessary. In patients with CrCl <30 mL/min, monitor closely for adverse effects.	<i>Child-Pugh Class A or B</i> : No dose adjustment <i>Child-Pugh Class C</i> : No dose recommendation

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
PIs			
Atazanavir (ATV) <i>Reyataz</i>	ATV 400 mg PO once daily <i>or</i> (ATV 300 mg plus RTV 100 mg) PO once daily	No dose adjustment for patients with renal dysfunction who do not require HD. In ARV-Naive Patients on HD: <ul style="list-style-type: none"> (ATV 300 mg plus RTV 100 mg) once daily In ARV-Experienced Patients on HD: <ul style="list-style-type: none"> ATV and ATV/r are not recommended 	<i>Child-Pugh Class A:</i> No dose adjustment <i>Child-Pugh Class B:</i> ATV 300 mg once daily (unboosted) for ARV-naive patients only <i>Child-Pugh Class C: Not recommended</i> RTV boosting is not recommended in patients with hepatic impairment.
Atazanavir/Cobicistat (ATV/c) <i>Evotaz</i>	One tablet PO once daily	If Used with TDF: <ul style="list-style-type: none"> Not recommended if CrCl <70 mL/min 	Not recommended in patients with hepatic impairment.
Darunavir (DRV) <i>Prezista</i>	In ARV-Naive Patients and ARV-Experienced Patients with No DRV Resistance Mutations: <ul style="list-style-type: none"> (DRV 800 mg plus RTV 100 mg) PO once daily with food In ARV-Experienced Patients with at Least One DRV Resistance Mutation: <ul style="list-style-type: none"> (DRV 600 mg plus RTV 100 mg) PO twice daily 	No dose adjustment necessary.	<i>In Patients with Mild-to-Moderate Hepatic Impairment:</i> No dose adjustment <i>In Patients with Severe Hepatic Impairment:</i> Not recommended

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PIs, continued			
Darunavir/Cobicistat (DRV/c) <i>Prezcobix</i>	One tablet PO once daily	If Used with TDF: <ul style="list-style-type: none"> Not recommended if CrCl <70 mL/min 	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C: Not recommended</i>
Darunavir/Cobicistat/ Tenofovir Alafenamide/ Emtricitabine (DRV/c/TAF/FTC) <i>Symtuza</i>	One tablet PO once daily	In Patients on Chronic HD: <ul style="list-style-type: none"> One tablet once daily. On HD days, administer after dialysis. <p>Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.</p>	Not recommended for patients with severe hepatic impairment.
Lopinavir/Ritonavir (LPV/r) <i>Kaletra</i>	(LPV/r 400 mg/100 mg) PO twice daily <i>or</i> (LPV/r 800 mg/200 mg) PO once daily	Avoid once-daily dosing in patients on HD.	No dose recommendation; use with caution in patients with hepatic impairment.
Ritonavir (RTV) <i>Norvir</i>	As a PI-Boosting Agent: <ul style="list-style-type: none"> RTV 100–400 mg PO per day 	No dose adjustment necessary.	Refer to recommendations for the primary (i.e., boosted) PI.
INSTIs			
Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/TAF/FTC) <i>Biktarvy</i>	One tablet PO once daily	In Patients on Chronic HD: <ul style="list-style-type: none"> One tablet once daily. On HD days, administer after dialysis. Patients receiving chronic HD should be virologically suppressed before Biktarvy is initiated. <p>Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.</p>	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C: Not recommended</i>

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<i>INSTIs, continued</i>			
Cabotegravir (CAB PO) <i>Vocabria</i>	CAB 30 mg PO once daily, given with RPV 25 mg PO, with food, for oral lead-in before switching to CAB IM and RPV IM, or for oral bridging	No dose adjustment necessary.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> No recommendation
Cabotegravir IM/ Ralpivirine IM (CAB IM/RPV IM) <i>Cabenuva</i>	Loading dose: CAB 600 mg/3mL IM × 1 dose and RPV 900 mg/3 mL IM × 1 dose Continuation phase: CAB 400 mg/2mL IM every 4 weeks and RPV 600 mg/2 mL IM every 4 weeks	No dose adjustment necessary for mild or moderate renal impairment. For patients with severe renal impairment or on HD, increase monitoring for adverse events.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> No recommendation
Dolutegravir (DTG) <i>Tivicay</i>	DTG 50 mg PO once daily or DTG 50 mg PO twice daily	No dose adjustment necessary.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> Not recommended
Dolutegravir/Abacavir/ Lamivudine (DTG/ABC/3TC) <i>Triumeq</i>	One tablet PO once daily	Not recommended if CrCl <30 mL/min. Instead, use the individual component drugs and adjust 3TC dose according to CrCl.	<i>Child-Pugh Class A:</i> Patients with mild hepatic impairment require a dose reduction of ABC. Use the individual drugs instead of the FDC tablet in these patients. <i>Child-Pugh Class B or C:</i> Contraindicated due to the ABC component
Dolutegravir/Emtricitabine (DTG/3TC) <i>Dovato</i>	One tablet PO once daily	Not recommended if CrCl <30 mL/min. Instead, use the individual component drugs and adjust 3TC dose according to CrCl.	<i>Child-Pugh Class C:</i> Not recommended
Dolutegravir/Rilpivirine (DTG/RPV) <i>Juluca</i>	One tablet PO once daily with food	No dose adjustment necessary. In patients with CrCl <30 mL/min, monitor closely for adverse effects.	<i>Child-Pugh Class A or B:</i> No dose adjustment <i>Child-Pugh Class C:</i> No dose recommendation

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Generic Name (Abbreviations) Trade Name	Usual Dose ^a	Dosing in Persons with Renal Insufficiency	Dosing in Persons with Hepatic Impairment
INSTIs, continued			
Elvitegravir/Cobicistat/ Tenofovir Alafenamide/ Emtricitabine (EVG/c/TAF/FTC) <i>Genvoya</i>	One tablet PO once daily	In Patients on Chronic HD: <ul style="list-style-type: none"> One tablet once daily. On HD days, administer after dialysis. Not recommended in patients with CrCl <30 mL/min who are not receiving chronic HD.	<i>In Patients with Mild-to-Moderate Hepatic Insufficiency:</i> No dose adjustment necessary <i>In Patients with Severe Hepatic Insufficiency:</i> Not recommended
Elvitegravir/Cobicistat/ Tenofovir Disoproxil Fumarate/Emtricitabine (EVG/c/TDF/FTC) <i>Stribild</i>	One tablet PO once daily	EVG/c/TDF/FTC should not be initiated in patients with CrCl <70 mL/min. Discontinue EVG/c/TDF/FTC if CrCl declines to <50 mL/min while patient is on therapy.	<i>In Patients with Mild-to-Moderate Hepatic Insufficiency:</i> No dose adjustment necessary <i>In Patients with Severe Hepatic Insufficiency:</i> Not recommended
Raltegravir (RAL) <i>Isentress</i> <i>Isentress HD</i>	RAL 400 mg PO twice daily (using Isentress formulation) <i>or</i> RAL 1,200 mg PO once daily (using Isentress HD formulation only)	No dose adjustment necessary.	<i>In Patients with Mild-to-Moderate Hepatic Insufficiency:</i> No dose adjustment necessary <i>In Patients with Severe Hepatic Insufficiency:</i> No recommendation
Fusion Inhibitor			
Enfuvirtide (T-20) <i>Fuzeon</i>	T-20 90 mg SQ twice daily	No dose adjustment necessary.	No dose adjustment necessary.
CCR5 Antagonist			
Maraviroc (MVC) <i>Selzentry</i>	The recommended dose differs based on concomitant medications and potential for drug-drug interactions. See Appendix B, Table 8 for detailed dosing information.	In Patients with CrCl <30 mL/min or Patients Who Are on HD <i>Without Potent CYP3A Inhibitors or Inducers:</i> <ul style="list-style-type: none"> MVC 300 mg twice daily; if postural hypotension occurs, reduce to MVC 150 mg twice daily <i>With Potent CYP3A Inducers or Inhibitors:</i> <ul style="list-style-type: none"> Not recommended 	No dose recommendations. MVC concentrations will likely be increased in patients with hepatic impairment.

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CD4 Post-Attachment Inhibitor			
Ibalizumab (IBA) <i>Trogarzo</i>	Loading dose: IBA 2,000 mg IV Maintenance dose: IBA 800 mg IV every 2 weeks	No dose adjustment recommended.	No recommendation.
gp120 Attachment Inhibitor			
Fostemsavir (FTR) <i>Rukobia</i>	FTR 600 mg PO twice daily	No dose adjustment recommended.	No dose adjustment recommended.

^a Refer to **Appendix B, Tables 1–10** for additional dosing information.

^b Based on prescribing information of **Triumeq**

^c Renal dosing varies amongst prescribing information for products containing this drug. On dialysis days, the patient should take the dose after the HD session.

Key: 3TC = lamivudine; ABC = abacavir; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; **CAB = cabotegravir**; COBI = cobicistat; CrCl = creatinine clearance; CYP = cytochrome P; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DTG = dolutegravir; EFV = efavirenz; ESRD = end stage renal disease; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDC = fixed-dose combination; FTC = emtricitabine; **FTR = Fostemsavir**; HBV = hepatitis B virus; HD = hemodialysis; IBA = ibalizumab; **IM = intramuscular**; INSTI = integrase strand transfer inhibitor; IV = intravenous; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PO = orally; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQ = subcutaneous; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; XR = extended release

Creatinine Clearance Calculation

Male: $\frac{(140 - \text{age in years}) \times (\text{weight in kg})}{72 \times (\text{serum creatinine})}$	Female: $\frac{(140 - \text{age in years}) \times (\text{weight in kg}) \times (0.85)}{72 \times (\text{serum creatinine})}$
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Child-Pugh Score

Component	Points Scored		
	1	2	3
Encephalopathy ^a	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, <i>or</i>	<2 mg/dL (<34 μmol/L)	2–3 mg/dL (34–50 μmol/L)	>3 mg/dL (>50 μmol/L)
Modified Total Bilirubin ^b	<4 mg/dL	4–7 mg/dL	>7 mg/dL
Prothrombin Time (Seconds Prolonged), <i>or</i>	<4	4–6	>6
International Normalized Ratio (INR)	<1.7	1.7–2.3	>2.3

^a 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

^b Modified total bilirubin is used for patients who have Gilbert’s syndrome or who are taking indinavir or atazanavir.

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

^a Sum of points for each component of the Child-Pugh Score.