



## **Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents**

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**Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 1 of 5)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-Lives	Adverse Events (Also see Table 13.)
<p><b>Abacavir</b> (ABC)/ Ziagen</p> <p>Generic available in tablet formulation</p> <p>Also available as a component of fixed-dose combinations:</p>	<p><u>Ziagen</u></p> <ul style="list-style-type: none"> <li>• 300 mg tablets</li> <li>• 20 mg/mL oral solution</li> </ul>	<p><u>Ziagen</u></p> <p>300 mg BID or 600 mg once daily</p> <p>Take without regard to meals</p>	<p>Metabolized by alcohol dehydrogenase and glucuronyl transferase</p> <p>Renal excretion of metabolites 82%</p> <p>Dosage adjustment for ABC is recommended in patients with hepatic insufficiency (see Appendix B, Table 7)</p>	<p>1.5 hours/ 12–26 hours</p>	<ul style="list-style-type: none"> <li>• HSRs: Patients who test positive for HLA-B*5701 are at highest risk. HLA screening should be done before initiation of ABC. Re-challenge is not recommended.</li> <li>• Symptoms of HSR may include fever, rash, nausea, vomiting, diarrhea, abdominal pain, malaise, or fatigue or respiratory symptoms such as sore throat, cough, or shortness of breath.</li> </ul>
<p><u>Trizivir</u></p> <p>ABC with ZDV + 3TC</p>	<p><u>Trizivir</u></p> <p>(ABC 300 mg + ZDV 300 mg + 3TC 150 mg) tablet</p>	<p><u>Trizivir</u></p> <p>1 tablet BID</p>			<ul style="list-style-type: none"> <li>• Some cohort studies suggest increased risk of MI with recent or current use of ABC, but this risk is not substantiated in other studies.</li> </ul>
<p><u>Epzicom</u></p> <p>ABC with 3TC</p>	<p><u>Epzicom</u></p> <p>(ABC 600 mg + 3TC 300 mg) tablet</p>	<p><u>Epzicom</u></p> <p>1 tablet once daily</p>			
<p><b>Didanosine</b> (ddI)/ Videx EC</p> <p>Generic available; dose same as Videx EC</p>	<p><u>Videx EC</u></p> <p>125, 200, 250, and 400 mg capsules</p> <p><u>Videx</u></p> <p>10 mg/mL oral solution</p>	<p><b>Body weight ≥60kg:</b></p> <p>400 mg once daily</p> <p><i>With TDF:</i> 250 mg once daily</p> <p><b>Body weight &lt;60kg:</b></p> <p>250 mg once daily</p> <p><i>With TDF:</i> 200 mg once daily</p> <p>Take 1/2 hour before or 2 hours after a meal</p> <p>Note: Preferred dosing with oral solution is BID (total daily dose divided into 2 doses)</p>	<p>Renal excretion 50%</p> <p>Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table Z).</p>	<p>1.5 hours/ &gt;20 hours</p>	<ul style="list-style-type: none"> <li>• Pancreatitis</li> <li>• Peripheral neuropathy</li> <li>• Retinal changes, optic neuritis</li> <li>• Lactic acidosis with hepatic steatosis +/- pancreatitis (rare but potentially life-threatening toxicity)</li> <li>• Nausea, vomiting</li> <li>• Potential association with non-cirrhotic portal hypertension, in some cases, patients presented with esophageal varices</li> <li>• One cohort study suggested increased risk of MI with recent or current use of ddI, but this risk is not substantiated in other studies.</li> <li>• Insulin resistance/diabetes mellitus</li> </ul>

**Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 2 of 5)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-Lives	Adverse Events (Also see Table 13.)
<b>Emtricitabine</b> (FTC)/ Emtriva  <b>Also available as a component of fixed-dose combinations:</b>	<u>Emtriva</u> • 200 mg hard gelatin capsule  • 10 mg/mL oral solution	<u>Emtriva</u> <i>Capsule:</i> 200 mg once daily <i>Oral solution:</i> 240 mg (24 mL) once daily  Take without regard to meals	Renal excretion 86%  Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table Z).	10 hours/ >20 hours	<ul style="list-style-type: none"> <li>• Minimal toxicity</li> <li>• Hyperpigmentation/skin discoloration</li> <li>• Severe acute exacerbation of hepatitis may occur in HBV-co-infected patients who discontinue FTC.</li> </ul>
<u>Atripla</u> FTC with EFV + TDF	<u>Atripla</u> (FTC 200 mg + EFV 600 mg + TDF 300 mg) tablet	<u>Atripla</u> 1 tablet at or before bedtime  Take on an empty stomach to reduce side effects.			
<u>Complera</u> FTC with RPV+TDF	<u>Complera</u> (FTC 200 mg + RPV 25 mg + TDF 300 mg) tablet	<u>Complera</u> 1 tablet once daily with a meal			
<u>Stribild</u> FTC with EVG + COBI + TDF	<u>Stribild</u> (FTC 200 mg + EVG 150 mg + COBI 150 mg + TDF 300 mg) tablet	<u>Stribild</u> 1 tablet once daily with food			
<u>Truvada</u> FTC with TDF	<u>Truvada</u> (FTC 200 mg + TDF 300 mg) tablet	<u>Truvada</u> 1 tablet once daily			

**Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 3 of 5)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-Lives	Adverse Events (Also see Table 13.)
<p><b>Lamivudine</b> (3TC)/ Epivir</p> <p>Generic available in tablet formulation</p> <p><b>Also available as a component of fixed-dose combinations:</b></p>	<p><u>Epivir</u></p> <ul style="list-style-type: none"> <li>• 150 and 300 mg tablets</li> <li>• 10 mg/mL oral solution</li> </ul>	<p><u>Epivir</u></p> <p>150 mg BID or 300 mg once daily</p> <p>Take without regard to meals</p>	<p>Renal excretion 70%</p> <p>Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table Z).</p>	<p>5–7 hours/ 18–22 hours</p>	<ul style="list-style-type: none"> <li>• Minimal toxicity</li> <li>• Severe acute exacerbation of hepatitis may occur in HBV-co-infected patients who discontinue 3TC.</li> </ul>
<p><u>Combivir</u></p> <p>3TC with ZDV</p> <p>Generic available</p>	<p><u>Combivir</u></p> <p>(3TC 150 mg + ZDV 300 mg) tablet</p>	<p><u>Combivir</u></p> <p>1 tablet BID</p>			
<p><u>Epzicom</u></p> <p>3TC with ABC</p>	<p><u>Epzicom</u></p> <p>(3TC 300 mg + ABC 600 mg) tablet</p>	<p><u>Epzicom</u></p> <p>1 tablet once daily</p>			
<p><u>Trizivir</u></p> <p>3TC with ZDV+ABC</p>	<p><u>Trizivir</u></p> <p>(3TC 150 mg + ZDV 300 mg + ABC 300 mg) tablet</p>	<p><u>Trizivir</u></p> <p>1 tablet BID</p>			
<p><b>Stavudine</b> (d4T)/ Zerit</p> <p>Generic available</p>	<p><u>Zerit</u></p> <ul style="list-style-type: none"> <li>• 15, 20, 30, and 40 mg capsules</li> <li>• 1 mg/mL oral solution</li> </ul>	<p><b>Body weight ≥60 kg:</b> 40 mg BID</p> <p><b>Body weight &lt;60 kg:</b> 30 mg BID</p> <p>Take without regard to meals</p> <p>Note: WHO recommends 30 mg BID dosing regardless of body weight.</p>	<p>Renal excretion 50%</p> <p>Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table Z).</p>	<p>1 hours/ 7.5 hours</p>	<ul style="list-style-type: none"> <li>• Peripheral neuropathy</li> <li>• Lipoatrophy</li> <li>• Pancreatitis</li> <li>• Lactic acidosis/severe hepatomegaly with hepatic steatosis (rare but potentially life-threatening toxicity)</li> <li>• Hyperlipidemia</li> <li>• Insulin resistance/diabetes mellitus</li> <li>• Rapidly progressive ascending neuromuscular weakness (rare)</li> </ul>

Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 4 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-Lives	Adverse Events (Also see Table 13.)
<b>Tenofovir Disoproxil Fumarate</b> (TDF)/ Viread  <b>Also available as a component of fixed-dose combinations:</b>	<u>Viread</u> • 150, 200, 250, 300 mg tablets  • 40 mg/g oral powder	<u>Viread</u> 300 mg once daily or 7.5 scoops once daily  Take without regard to meals  Mix oral powder with 2–4 ounces of soft food that does not require chewing (e.g., applesauce, yogurt). <b>DO NOT MIX ORAL POWDER WITH LIQUID.</b>	Renal excretion  Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table 7).	17 hours/ >60 hours	<ul style="list-style-type: none"> <li>• Renal insufficiency, Fanconi syndrome, proximal tubulopathy</li> <li>• Osteomalacia, decrease in bone mineral density</li> <li>• Potential decrease in bone mineral density</li> <li>• Severe acute exacerbation of hepatitis may occur in HBV-co-infected patients who discontinue TDF.</li> <li>• Asthenia, headache, diarrhea, nausea, vomiting, and flatulence</li> </ul>
<u>Atripla</u> TDF with EFV+FTC	<u>Atripla</u> (TDF 300 mg + EFV 600 mg + FTC 200 mg) tablet	<u>Atripla</u> 1 tablet at or before bedtime  Take on an empty stomach to reduce side effects			
<u>Complera</u> TDF with RPV+FTC	<u>Complera</u> (TDF 300 mg + RPV 25 mg + FTC 200 mg) tablet	<u>Complera</u> 1 tablet once daily  Take with a meal			
<b>Stribild</b> TDF with EVG+COBI+ FTC	<b>Stribild</b> (TDF 300 mg + EVG 150 mg + COBI 150 mg + FTC 200 mg) tablet	<b>Stribild</b> 1 tablet once daily with food			
<u>Truvada</u> TDF with FTC	<u>Truvada</u> (TDF 300 mg + FTC 200 mg) tablet	<u>Truvada</u> 1 tablet once daily  Take without regard to meals			

**Appendix B, Table 1. Characteristics of Nucleoside Reverse Transcriptase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 5 of 5)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum/ Intracellular Half-Lives	Adverse Events (Also see Table 13.)
<b>Zidovudine</b> (ZDV)/ Retrovir  Generic available  <b>Also available as a component of fixed-dose combinations</b>	<u>Retrovir</u> <ul style="list-style-type: none"> <li>• 100 mg capsule</li> <li>• 300 mg tablet (generic only)</li> <li>• 10 mg/mL intravenous solution</li> <li>• 10 mg/mL oral solution</li> </ul>	<u>Retrovir</u> 300 mg BID or 200 mg TID  Take without regard to meals	Metabolized to GAZT Renal excretion of GAZT  Dosage adjustment in patients with renal insufficiency is recommended (see Appendix B, Table 7).	1.1 hours/ 7 hours	<ul style="list-style-type: none"> <li>• Bone marrow suppression: macrocytic anemia or neutropenia</li> <li>• Nausea, vomiting, headache, insomnia, asthenia</li> <li>• Nail pigmentation</li> <li>• Lactic acidosis/severe hepatomegaly with hepatic steatosis (rare but potentially life-threatening toxicity)</li> </ul>
<u>Combivir</u> ZDV with 3TC  Generic available	<u>Combivir</u> (ZDV 300 mg + 3TC 150 mg) tablet	<u>Combivir</u> 1 tablet BID			<ul style="list-style-type: none"> <li>• Hyperlipidemia</li> <li>• Insulin resistance/diabetes mellitus</li> </ul>
<u>Trizivir</u> ZDV with 3TC+ ABC	<u>Trizivir</u> (ZDV 300 mg + 3TC 150 mg + ABC 300 mg) tablet	<u>Trizivir</u> 1 tablet BID			<ul style="list-style-type: none"> <li>• Lipoatrophy</li> <li>• Myopathy</li> </ul>

**Key to Abbreviations:** 3TC = lamivudine, ABC = abacavir, BID = twice daily, **COBI = cobicistat**, d4T = stavudine, ddl = didanosine, EC = enteric coated, EFV = efavirenz, **EVG = elvitegravir**, FTC = emtricitabine, GAZT = azidothymidine glucuronide, HBV = hepatitis B virus, HLA = human leukocyte antigen, HSR = hypersensitivity reaction, MI = myocardial infarction, RPV = rilpivirine, TDF = tenofovir disoproxil fumarate, TID = three times a day, WHO = World Health Organization, ZDV = zidovudine

**Appendix B, Table 2. Characteristics of Non-Nucleoside Reverse Transcriptase Inhibitors\* (Last updated February 12, 2013; last reviewed February 12, 2013) (page 1 of 2)**

\* Delavirdine (DLV) is not included in this table. Please refer to the DLV FDA package insert for related information.

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Adverse Events (Also see Table 13.)
<b>Efavirenz</b> (EFV)/ Sustiva  <b>Also available as a component of fixed-dose combination:</b>	<ul style="list-style-type: none"> <li>• 50 and 200 mg capsules</li> <li>• 600 mg tablet</li> </ul>	600 mg once daily, at or before bedtime  Take on an empty stomach to reduce side effects.	Metabolized by CYPs 2B6 and 3A4  CYP3A4 mixed inducer/inhibitor (more an inducer than an inhibitor)	40–55 hours	<ul style="list-style-type: none"> <li>• Rash<sup>a</sup></li> <li>• Neuropsychiatric symptoms<sup>b</sup></li> <li>• Increased transaminase levels</li> <li>• Hyperlipidemia</li> <li>• False-positive results with some cannabinoid and benzodiazepine screening assays reported.</li> <li>• Teratogenic in non-human primates and potentially teratogenic in humans</li> </ul>
Atripla EFV with TDF + FTC	(EFV 600 mg + FTC 200 mg + TDF 300 mg) tablet	1 tablet once daily, at or before bedtime			
<b>Etravirine</b> (ETR)/ Intencele	<ul style="list-style-type: none"> <li>• 25, 100, and 200 mg tablets</li> </ul>	200 mg BID  Take following a meal.	CYP3A4, 2C9, and 2C19 substrate  3A4 inducer; 2C9 and 2C19 inhibitor	41 hours	<ul style="list-style-type: none"> <li>• Rash, including Stevens-Johnson syndrome<sup>a</sup></li> <li>• HSRs, characterized by rash, constitutional findings, and sometimes organ dysfunction, including hepatic failure, have been reported.</li> <li>• Nausea</li> </ul>
<b>Nevirapine</b> (NVP)/ Viramune or Viramine XR  Generic available for 200 mg tablets	<ul style="list-style-type: none"> <li>• 200 mg tablet</li> <li>• 400 mg XR tablet</li> <li>• 50 mg/5 mL oral suspension</li> </ul>	200 mg once daily for 14 days (lead-in period); thereafter, 200 mg BID, or 400 mg (Viramune XR tablet) once daily  Take without regard to meals  Repeat lead-in period if therapy is discontinued for more than 7 days  In patients who develop mild-to-moderate rash without constitutional symptoms, continue lead-in period until rash resolves but not longer than 28 days total.	CYP450 substrate, inducer of 3A4 and 2B6; 80% excreted in urine (glucuronidated metabolites, <5% unchanged); 10% in feces	25–30 hours	<ul style="list-style-type: none"> <li>• Rash, including Stevens-Johnson syndrome<sup>a</sup></li> <li>• Symptomatic hepatitis, including fatal hepatic necrosis, has been reported:                             <ul style="list-style-type: none"> <li>• Rash reported in approximately 50% of cases</li> <li>• Occurs at significantly higher frequency in ARV-naïve female patients with pre-NVP CD4 counts &gt;250 cells/mm<sup>3</sup> and in ARV-naïve male patients with pre-NVP CD4 counts &gt;400 cells/mm<sup>3</sup>. NVP should not be initiated in these patients unless the benefit clearly outweighs the risk.</li> </ul> </li> </ul>

**Appendix B, Table 2. Characteristics of Non-Nucleoside Reverse Transcriptase Inhibitors\* (Last updated February 12, 2013; last reviewed February 12, 2013) (page 2 of 2)**

\* Delavirdine (DLV) is not included in this table. Please refer to the DLV FDA package insert for related information.

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in renal or hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Adverse Events (Also see Table 13.)
<b>Rilpivirine</b> (RPV)/ Edurant  <b>Also available as a component of fixed-dose combination:</b>	<ul style="list-style-type: none"> <li>• 25 mg tablet</li> </ul>	25 mg once daily  Take with a meal	CYP3A4 substrate	50 hours	<ul style="list-style-type: none"> <li>• Rash<sup>a</sup></li> <li>• Depression, insomnia, headache</li> <li>• Hepatotoxicity</li> </ul>
<b>Complera</b> RPV with TDF + FTC	<b>Complera</b> (RPV 25 mg + TDF 300 mg + FTC 200 mg) tablet	1 tablet once daily with a meal			

**Key to Abbreviations:** ARV = antiretroviral, BID = twice daily, CYP = cytochrome P, DLV = delavirdine, EFV = efavirenz, ETR = etravirine, FDA = Food and Drug Administration, FTC = emtricitabine, HSR = hypersensitivity reaction, NNRTI = non-nucleoside reverse transcriptase inhibitor, NVP = nevirapine, RPV = rilpivirine, TDF = tenofovir disoproxil fumarate, XR = extended release

<sup>a</sup> Rare cases of Stevens-Johnson syndrome have been reported with most NNRTIs; the highest incidence of rash was seen with NVP.

<sup>b</sup> Adverse events can include dizziness, somnolence, insomnia, abnormal dreams, confusion, abnormal thinking, impaired concentration, amnesia, agitation, depersonalization, hallucinations, and euphoria. Approximately 50% of patients receiving EFV may experience any of these symptoms. Symptoms usually subside spontaneously after 2 to 4 weeks but may necessitate discontinuation of EFV in a small percentage of patients.



Appendix B, Table 3. Characteristics of Protease Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 1 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Storage	Adverse Events (Also see Table 13.)
<b>Atazanavir</b> (ATV)/ Reyataz	100, 150, 200, and 300 mg capsules	<p>ARV-naïve patients: 400 mg once daily, or (ATV 300 mg + RTV 100 mg) once daily</p> <p>With TDF or in ARV-experienced patients: (ATV 300 mg + RTV 100 mg) once daily</p> <p>With EFV in ARV-naïve patients: (ATV 400 mg + RTV 100 mg) once daily</p> <p><b>For recommendations on dosing with H2 antagonists and PPIs, refer to Table 16a.</b></p> <p>Take with food</p>	<p>CYP3A4 inhibitor and substrate</p> <p>Dosage adjustment in patients with hepatic insufficiency is recommended. (see Appendix B, Table 7).</p>	7 hours	Room temperature (up to 25°C or 77°F)	<ul style="list-style-type: none"> <li>Indirect hyperbilirubinemia</li> <li>PR interval prolongation: First degree symptomatic AV block reported. Use with caution in patients with underlying conduction defects or on concomitant medications that can cause PR prolongation.</li> <li>Hyperglycemia</li> <li>Fat maldistribution</li> <li>Possible increased bleeding episodes in patients with hemophilia</li> <li><b>Cholelithiasis</b></li> <li>Nephrolithiasis</li> <li>Skin rash (20%)</li> <li>Serum transaminase elevations</li> <li>Hyperlipidemia (especially with RTV boosting)</li> </ul>
<b>Darunavir</b> (DRV)/ Prezista	75, 150, 300, 400, 600, and 800 mg tablets 100 mg/mL oral suspension	<p>ARV-naïve patients or ARV-experienced patients with no DRV mutations: (DRV 800 mg + RTV 100 mg) once daily</p> <p>ARV-experienced patients with at least one DRV mutation: (DRV 600 mg + RTV 100 mg) BID</p> <p>Unboosted DRV is <b>not</b> recommended.</p> <p>Take with food</p>	CYP3A4 inhibitor and substrate	15 hours (when combined with RTV)	Room temperature (up to 25°C or 77°F)	<ul style="list-style-type: none"> <li>Skin rash (10%): DRV has a sulfonamide moiety; Stevens-Johnson syndrome, <b>toxic epidermal necrolysis, acute generalized exanthematous pustulosis</b>, and erythema multiforme have been reported.</li> <li>Hepatotoxicity</li> <li>Diarrhea, nausea</li> <li>Headache</li> <li>Hyperlipidemia</li> <li>Serum transaminase elevation</li> <li>Hyperglycemia</li> <li>Fat maldistribution</li> <li>Possible increased bleeding episodes in patients with hemophilia</li> </ul>

Appendix B, Table 3. Characteristics of Protease Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 2 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Storage	Adverse Events (Also see Table 13.)
<b>Fosamprenavir</b> (FPV)/ Lexiva (a prodrug of amprenavir [APV])	<ul style="list-style-type: none"> <li>• 700 mg tablet</li> <li>• 50 mg/mL oral suspension</li> </ul>	<p>ARV-naive patients: FPV 1400 mg BID, or (FPV 1400 mg + RTV 100–200 mg) once daily, or (FPV 700 mg + RTV 100 mg) BID</p> <p>PI-experienced patients (once-daily dosing <b>not</b> recommended): (FPV 700 mg + RTV 100 mg) BID</p> <p>With EFV: (FPV 700 mg + RTV 100 mg) BID, or (FPV 1400 mg + RTV 300 mg) once daily</p> <p><i>Tablet:</i> Take without regard to meals (if not boosted with RTV tablet)</p> <p><i>Suspension:</i> Take without food</p> <p><i>FPV with RTV tablet:</i> Take with meals</p>	<p>APV is a CYP3A4 substrate, inhibitor, and inducer.</p> <p>Dosage adjustment in patients with hepatic insufficiency is recommended (see Appendix B, Table 7).</p>	7.7 hours (APV)	Room temperature (up to 25°C or 77°F)	<ul style="list-style-type: none"> <li>• Skin rash (12%–19%): FPV has a sulfonamide moiety.</li> <li>• Diarrhea, nausea, vomiting</li> <li>• Headache</li> <li>• Hyperlipidemia</li> <li>• Serum transaminase elevation</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> <li>• Nephrolithiasis</li> </ul>
<b>Indinavir</b> (IDV)/ Crixivan	100, 200, and 400 mg capsules	<p>800 mg every 8 hrs</p> <p>Take 1 hour before or 2 hours after meals; may take with skim milk or low-fat meal</p> <p>With RTV: (IDV 800 mg + RTV 100–200 mg) BID</p> <p>Take without regard to meals</p>	<p>CYP3A4 inhibitor and substrate</p> <p>Dosage adjustment in patients with hepatic insufficiency is recommended (see Appendix B, Table 7).</p>	1.5–2 hours	<p>Room temperature (15°–30°C/ 59°–86°F)</p> <p>Protect from moisture</p>	<ul style="list-style-type: none"> <li>• Nephrolithiasis</li> <li>• GI intolerance, nausea</li> <li>• Hepatitis</li> <li>• Indirect hyperbilirubinemia</li> <li>• Hyperlipidemia</li> <li>• Headache, asthenia, blurred vision, dizziness, rash, metallic taste, thrombocytopenia, alopecia, and hemolytic anemia</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> </ul>

Appendix B, Table 3. Characteristics of Protease Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 3 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Storage	Adverse Events (Also see Table 13.)
<b>Lopinavir + Ritonavir</b> (LPV/r)/ Kaletra	<p><u>Tablets:</u> (LPV 200 mg + RTV 50 mg), or (LPV 100 mg + RTV 25 mg)</p> <p><u>Oral solution:</u> Each 5 mL contains (LPV 400 mg + RTV 100 mg)</p> <p>Oral solution contains 42% alcohol</p>	<p>LPV/r 400 mg/100 mg BID</p> <p>or</p> <p>LPV/r 800 mg/200 mg once daily</p> <p>Once-daily dosing is not recommended for patients with <math>\geq 3</math> LPV-associated mutations, pregnant women, or patients receiving EFV, NVP, FPV, NFV, carbamazepine, phenytoin, or phenobarbital.</p> <p><u>With EFV or NVP (PI-naive or PI-experienced patients):</u> LPV/r 500 mg/125 mg tablets BID (Use a combination of two LPV/r 200 mg/50 mg tablets + one LPV/r 100 mg/25 mg tablet to make a total dose of LPV/r 500 mg/125 mg.)</p> <p>or</p> <p>LPV/r 533 mg/133 mg oral solution BID</p> <p><i>Tablet:</i> Take without regard to meals</p> <p><i>Oral solution:</i> Take with food</p>	CYP3A4 inhibitor and substrate	5–6 hours	<p>Oral tablet is stable at room temperature.</p> <p>Oral solution is stable at 2°–8°C (36°–46°F) until date on label and is stable for up to 2 months when stored at room temperature (up to 25°C or 77°F).</p>	<ul style="list-style-type: none"> <li>• GI intolerance, nausea, vomiting, diarrhea</li> <li>• Pancreatitis</li> <li>• Asthenia</li> <li>• Hyperlipidemia (especially hypertriglyceridemia)</li> <li>• Serum transaminase elevation</li> <li>• Hyperglycemia</li> <li>• Insulin resistance/diabetes mellitus</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> <li>• PR interval prolongation</li> <li>• QT interval prolongation and torsades de pointes have been reported; however, causality could not be established.</li> </ul>
<b>Nelfinavir</b> (NFV)/ Viracept	<ul style="list-style-type: none"> <li>• 250 and 625 mg tablets</li> <li>• 50 mg/g oral powder</li> </ul>	<p>1250 mg BID or 750 mg TID</p> <p>Dissolve tablets in a small amount of water, mix admixture well, and consume immediately.</p> <p>Take with food</p>	CYP2C19 and 3A4 substrate—metabolized to active M8 metabolite; CYP 3A4 inhibitor	3.5–5 hours	Room temperature (15°–30°C/ 59°–86°F)	<ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Hyperlipidemia</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> <li>• Serum transaminase elevation</li> </ul>

Appendix B, Table 3. Characteristics of Protease Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 4 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Storage	Adverse Events (Also see Table 13.)
<b>Ritonavir</b> (RTV)/ Norvir	<ul style="list-style-type: none"> <li>• 100 mg tablet</li> <li>• 100 mg soft gel capsule</li> <li>• 80 mg/mL oral solution</li> </ul> <p>Oral solution contains 43% alcohol</p>	<p>As pharmacokinetic booster for other PIs: 100–400 mg per day in 1–2 divided doses (refer to other PIs for specific dosing recommendations)</p> <p><i>Tablet.</i> Take with food</p> <p><i>Capsule and oral solution:</i> To improve tolerability, take with food if possible.</p>	CYP3A4 >2D6 substrate; potent 3A4, 2D6 inhibitor	3–5 hours	<p>Tablets do not require refrigeration.</p> <p>Refrigerate capsules.</p> <p>Capsules can be left at room temperature (up to 25°C or 77°F) for up to 30 days.</p> <p>Oral solution should <b>not</b> be refrigerated; store at room temperature (20°–25°C/ 68°–77°F).</p>	<ul style="list-style-type: none"> <li>• GI intolerance, nausea, vomiting, diarrhea</li> <li>• Paresthesias (circumoral and extremities)</li> <li>• Hyperlipidemia (especially hypertriglyceridemia)</li> <li>• Hepatitis</li> <li>• Asthenia</li> <li>• Taste perversion</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> </ul>
<b>Saquinavir</b> (SQV)/ Invirase	<ul style="list-style-type: none"> <li>• 500 mg tablet</li> <li>• 200 mg hard gel capsule</li> </ul>	<p>(SQV 1000 mg + RTV 100 mg) BID</p> <p>Unboosted SQV is <b>not</b> recommended.</p> <p>Take with meals or within 2 hours after a meal</p>	CYP3A4 inhibitor and substrate	1–2 hours	Room temperature (15°–30°C/ 59°–86°F)	<ul style="list-style-type: none"> <li>• GI intolerance, nausea, and diarrhea</li> <li>• Headache</li> <li>• Serum transaminase elevation</li> <li>• Hyperlipidemia</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> <li>• PR interval prolongation</li> <li>• QT interval prolongation, torsades de pointes have been reported. Patients with pre-SQV QT interval &gt;450 msec should not receive SQV (see Table 5b).</li> </ul>

Appendix B, Table 3. Characteristics of Protease Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013) (page 5 of 5)

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Elimination	Serum Half-Life	Storage	Adverse Events (Also see Table 13.)
Tipranavir (TPV)/ Aptivus	<ul style="list-style-type: none"> <li>• 250 mg capsule</li> <li>• 100 mg/mL oral solution</li> </ul>	<p>(TPV 500 mg + RTV 200 mg) BID</p> <p>Unboosted TPV is <b>not</b> recommended.</p> <p><i>TPV taken with RTV tablets:</i> Take with meals</p> <p><i>TPV taken with RTV capsules or solution:</i> Take without regard to meals</p>	<p>CYP P450 3A4 inducer and substrate</p> <p>Net effect when combined with RTV (CYP 3A4, 2D6 inhibitor)</p>	6 hours after single dose of TPV/r	<p>Refrigerate capsules.</p> <p>Capsules can be stored at room temperature (25°C or 77°F) for up to 60 days.</p> <p>Oral solution should <b>not</b> be refrigerated or frozen and should be used within 60 days after bottle is opened.</p>	<ul style="list-style-type: none"> <li>• Hepatotoxicity: Clinical hepatitis (including hepatic decompensation and hepatitis-associated fatalities) has been reported; monitor patients closely, especially those with underlying liver diseases.</li> <li>• Skin rash (3%–21%): TPV has a sulfonamide moiety; use with caution in patients with known sulfonamide allergy.</li> <li>• Rare cases of fatal and nonfatal intracranial hemorrhages have been reported. Risks include brain lesion, head trauma, recent neurosurgery, coagulopathy, hypertension, alcoholism, use of anti-coagulant or anti-platelet agents (including vitamin E).</li> <li>• Hyperlipidemia</li> <li>• Hyperglycemia</li> <li>• Fat maldistribution</li> <li>• Possible increased bleeding episodes in patients with hemophilia</li> </ul>

**Key to Abbreviations:** APV = amprenavir, ARV = antiretroviral, ATV = atazanavir, AV = atrioventricular, BID = twice daily, CYP = cytochrome P, DRV = darunavir, EFV = efavirenz, FPV = fosamprenavir, GI = gastrointestinal, IDV = indinavir, LPV = lopinavir, LPV/r = lopinavir + ritonavir, msec = millisecond, NFV = nelfinavir, NVP = nevirapine, PI = protease inhibitor, PPI = proton pump inhibitor, RTV = ritonavir, SQV = saquinavir, TDF = tenofovir disoproxil fumarate, TID = three times a day, TPV = tipranavir

**Appendix B, Table 4. Characteristics of Integrase Inhibitors (Last updated February 12, 2013; last reviewed February 12, 2013)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see <a href="#">Appendix B, Table 7.</a> )	Serum Half-Life	Route of Metabolism	Adverse Events (Also see <a href="#">Table 13.</a> )
<b>Raltegravir</b> (RAL)/ Isentress	400 mg tablet  25 and 100 mg chewable tablets	400 mg BID  <u>With rifampin:</u> 800 mg BID  Take without regard to meals	~9 hours	UGT1A1-mediated glucuronidation	<ul style="list-style-type: none"> <li>• Rash, including Stevens-Johnson syndrome, HSR, and toxic epidermal necrolysis</li> <li>• Nausea</li> <li>• Headache</li> <li>• Diarrhea</li> <li>• Pyrexia</li> <li>• CPK elevation, muscle weakness, and rhabdomyolysis</li> </ul>
<b>Elvitegravir</b> (EVG) Currently only available as a co-formulated product with:  <b>Cobicistat</b> (COBI)/ TDF/FTC  Stribild	(EVG 150 mg + COBI 150 mg + TDF 300 mg + FTC 200 mg) tablet	1 tablet once daily with food  <b>Not recommended</b> for patients with baseline CrCl < 70 mL/min. See <a href="#">Appendix B, Table 7</a> for the equation for calculating CrCl.  <b>Not recommended for use with other antiretroviral drugs</b>	~13 hours	EVG: CYP3A, UGT1A1/3  COBI: CYP3A, CYP2D6 (minor)	<ul style="list-style-type: none"> <li>• Nausea</li> <li>• Diarrhea</li> <li>• New onset or worsening renal impairment</li> <li>• Potential decrease in bone mineral density</li> <li>• Severe acute exacerbation of hepatitis may occur in HBV-coinfected patients who discontinue FTC and TDF.</li> </ul>

**Key to Abbreviations:** BID = twice daily, **COBI = cobicistat**, CPK = creatine phosphokinase, **CrCl = creatinine clearance**, **EVG = elvitegravir**, FTC = emtricitabine, HSR = hypersensitivity reaction, RAL = raltegravir, TDF = tenofovir, UGT = uridine diphosphate gluconyltransferase

**Appendix B, Table 5. Characteristics of Fusion Inhibitor (Last updated January 29, 2008; last reviewed February 12, 2013)**

Generic Name (Abbreviation)/ Trade Name	Formulations	Dosing Recommendations	Serum Half-Life	Elimination	Storage	Adverse Events (Also see Table 13.)
<b>Enfuvirtide</b> (T20)/ Fuzeon	<ul style="list-style-type: none"> <li>Injectable; supplied as lyophilized powder</li> <li>Each vial contains 108 mg of T20; reconstitute with 1.1 mL of sterile water for injection for delivery of approximately 90 mg/1 mL.</li> </ul>	90 mg (1 mL) subcutaneously BID	3.8 hours	Expected to undergo catabolism to its constituent amino acids, with subsequent recycling of the amino acids in the body pool	Store at room temperature (up to 25°C or 77°F). Reconstituted solution should be refrigerated at 2°C–8°C (36°F–46°F) and used within 24 hours.	<ul style="list-style-type: none"> <li>Local injection site reactions (e.g., pain, erythema, induration, nodules and cysts, pruritus, ecchymosis) in almost 100% of patients</li> <li>Increased incidence of bacterial pneumonia</li> <li>HSR (&lt;1% of patients): Symptoms may include rash, fever, nausea, vomiting, chills, rigors, hypotension, or elevated serum transaminases. Re-challenge is not recommended.</li> </ul>

**Key to Abbreviations:** BID = twice daily, HSR = hypersensitivity reaction, T20 = enfuvirtide

**Appendix B, Table 6. Characteristics of CCR5 Antagonist (Last updated March 27, 2012; last reviewed February 12, 2013)**

Generic Name (Abbreviation)/ Trade Name	Formulation	Dosing Recommendations (For dosage adjustment in hepatic insufficiency, see Appendix B, Table 7.)	Serum Half-Life	Elimination	Adverse Events (Also see Table 13.)
<b>Maraviroc</b> (MVC)/ Selzentry	150 and 300 mg tablets	<p><b>150 mg BID</b> when given with drugs that are strong CYP3A inhibitors (with or without CYP3A inducers) including PIs (except TPV/r)</p> <p><b>300 mg BID</b> when given with NRTIs, T20, TPV/r, NVP, RAL, and other drugs that are not strong CYP3A inhibitors or inducers</p> <p><b>600 mg BID</b> when given with drugs that are CYP3A inducers, including EFV, ETR, etc. (without a CYP3A inhibitor)</p> <p>Take without regard to meals</p>	14–18 hours	CYP3A4 substrate	<ul style="list-style-type: none"> <li>Abdominal pain</li> <li>Cough</li> <li>Dizziness</li> <li>Musculoskeletal symptoms</li> <li>Pyrexia</li> <li>Rash</li> <li>Upper respiratory tract infections</li> <li>Hepatotoxicity, which may be preceded by severe rash or other signs of systemic allergic reactions</li> <li>Orthostatic hypotension, especially in patients with severe renal insufficiency</li> </ul>

**Key to Abbreviations:** BID = twice daily, CYP = cytochrome P, EFV = efavirenz, ETR = etravirine, MVC = maraviroc, NRTI = nucleoside reverse transcriptase inhibitor, NVP = nevirapine, PI = protease inhibitor, RAL = raltegravir, T20 = enfuvirtide, TPV/r = tipranavir + ritonavir

**Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Last updated February 12, 2013; last reviewed February 12, 2013) (page 1 of 5)**

See the reference section following Table 7 for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Antiretrovirals Generic Name (Abbreviation)/ Trade Name	Usual Daily Dose (Refer to <a href="#">Appendix B, Tables 1–6</a> for additional dosing information.)	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis and hemodialysis)	Dosing in Hepatic Impairment															
<b>Nucleoside Reverse Transcriptase Inhibitors</b>																		
<b>Stribild should not be initiated in patients with CrCl &lt;70 mL/min. Use of the following fixed-dose combinations is not recommended in patients with CrCl &lt;50 mL/min: Atripla, Combivir, Stribild, Trizivir, or Epzicom. Use of Truvada is not recommended in patients with CrCl &lt;30 mL/min.</b>																		
<b>Abacavir</b> (ABC)/ Ziagen	300 mg PO BID	No dosage adjustment necessary	<table border="0"> <tr> <td><b>Child-Pugh Score</b></td> <td><b>Dose</b></td> </tr> <tr> <td>5–6</td> <td>200 mg PO BID (use oral solution)</td> </tr> <tr> <td>&gt;6</td> <td>Contraindicated</td> </tr> </table>	<b>Child-Pugh Score</b>	<b>Dose</b>	5–6	200 mg PO BID (use oral solution)	>6	Contraindicated									
<b>Child-Pugh Score</b>	<b>Dose</b>																	
5–6	200 mg PO BID (use oral solution)																	
>6	Contraindicated																	
<b>Didanosine EC</b> (ddl)/ Videx EC	<b>Body weight ≥60 kg:</b> 400 mg PO once daily  <b>Body weight &lt;60 kg:</b> 250 mg PO once daily	<table border="0"> <tr> <td colspan="3"><b>Dose (once daily)</b></td> </tr> <tr> <td><b>CrCl (mL/min)</b></td> <td><b>≥60 kg</b></td> <td><b>&lt;60 kg</b></td> </tr> <tr> <td>30–59</td> <td>200 mg</td> <td>125 mg</td> </tr> <tr> <td>10–29</td> <td>125 mg</td> <td>125 mg</td> </tr> <tr> <td>&lt;10, HD, CAPD</td> <td>125 mg</td> <td>use ddl oral solution</td> </tr> </table>	<b>Dose (once daily)</b>			<b>CrCl (mL/min)</b>	<b>≥60 kg</b>	<b>&lt;60 kg</b>	30–59	200 mg	125 mg	10–29	125 mg	125 mg	<10, HD, CAPD	125 mg	use ddl oral solution	No dosage adjustment necessary
<b>Dose (once daily)</b>																		
<b>CrCl (mL/min)</b>	<b>≥60 kg</b>	<b>&lt;60 kg</b>																
30–59	200 mg	125 mg																
10–29	125 mg	125 mg																
<10, HD, CAPD	125 mg	use ddl oral solution																
<b>Didanosine oral solution</b> (ddl)/ Videx	<b>Body weight ≥60 kg:</b> 200 mg PO BID or 400 mg PO once daily  <b>Body weight &lt;60 kg:</b> 250 mg PO once daily or 125 mg PO BID	<table border="0"> <tr> <td colspan="3"><b>Dose (once daily)</b></td> </tr> <tr> <td><b>CrCl (mL/min)</b></td> <td><b>≥60 kg</b></td> <td><b>&lt;60 kg</b></td> </tr> <tr> <td>30–59</td> <td>200 mg</td> <td>150 mg</td> </tr> <tr> <td>10–29</td> <td>150 mg</td> <td>100 mg</td> </tr> <tr> <td>&lt;10, HD, CAPD</td> <td>100 mg</td> <td>75 mg</td> </tr> </table>	<b>Dose (once daily)</b>			<b>CrCl (mL/min)</b>	<b>≥60 kg</b>	<b>&lt;60 kg</b>	30–59	200 mg	150 mg	10–29	150 mg	100 mg	<10, HD, CAPD	100 mg	75 mg	No dosage adjustment necessary
<b>Dose (once daily)</b>																		
<b>CrCl (mL/min)</b>	<b>≥60 kg</b>	<b>&lt;60 kg</b>																
30–59	200 mg	150 mg																
10–29	150 mg	100 mg																
<10, HD, CAPD	100 mg	75 mg																
<b>Emtricitabine</b> (FTC)/ Emtriva	200 mg oral capsule once daily or 240 mg (24 mL) oral solution once daily	<table border="0"> <tr> <td colspan="3"><b>Dose</b></td> </tr> <tr> <td><b>CrCl (mL/min)</b></td> <td><b>Capsule</b></td> <td><b>Solution</b></td> </tr> <tr> <td>30–49</td> <td>200 mg q48h</td> <td>120 mg q24h</td> </tr> <tr> <td>15–29</td> <td>200 mg q72h</td> <td>80 mg q24h</td> </tr> <tr> <td>&lt;15 or on HD*</td> <td>200 mg q96h</td> <td>60 mg q24h</td> </tr> </table> <p>*On dialysis days, take dose after HD session.</p>	<b>Dose</b>			<b>CrCl (mL/min)</b>	<b>Capsule</b>	<b>Solution</b>	30–49	200 mg q48h	120 mg q24h	15–29	200 mg q72h	80 mg q24h	<15 or on HD*	200 mg q96h	60 mg q24h	No dosage recommendation
<b>Dose</b>																		
<b>CrCl (mL/min)</b>	<b>Capsule</b>	<b>Solution</b>																
30–49	200 mg q48h	120 mg q24h																
15–29	200 mg q72h	80 mg q24h																
<15 or on HD*	200 mg q96h	60 mg q24h																
<b>Lamivudine</b> (3TC)/ Epivir	300 mg PO once daily or 150 mg PO BID	<table border="0"> <tr> <td><b>CrCl (mL/min)</b></td> <td><b>Dose</b></td> </tr> <tr> <td>30–49</td> <td>150 mg q24h</td> </tr> <tr> <td>15–29</td> <td>1 x 150 mg, then 100 mg q24h</td> </tr> <tr> <td>5–14</td> <td>1 x 150 mg, then 50 mg q24h</td> </tr> <tr> <td>&lt;5 or on HD*</td> <td>1 x 50 mg, then 25 mg q24h</td> </tr> </table> <p>*On dialysis days, take dose after HD session.</p>	<b>CrCl (mL/min)</b>	<b>Dose</b>	30–49	150 mg q24h	15–29	1 x 150 mg, then 100 mg q24h	5–14	1 x 150 mg, then 50 mg q24h	<5 or on HD*	1 x 50 mg, then 25 mg q24h	No dosage adjustment necessary					
<b>CrCl (mL/min)</b>	<b>Dose</b>																	
30–49	150 mg q24h																	
15–29	1 x 150 mg, then 100 mg q24h																	
5–14	1 x 150 mg, then 50 mg q24h																	
<5 or on HD*	1 x 50 mg, then 25 mg q24h																	



**Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Last updated February 12, 2013; last reviewed February 12, 2013) (page 2 of 5)**

See the reference section following Table 7 for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

<b>Antiretrovirals Generic Name (Abbreviation)/ Trade Name</b>	<b>Usual Daily Dose (Refer to Appendix B, Tables 1–6 for additional dosing information.)</b>	<b>Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis and hemodialysis)</b>	<b>Dosing in Hepatic Impairment</b>
<b>Stavudine</b> (d4T)/ Zerit	<b>Body weight ≥60 kg:</b> 40 mg PO BID  <b>Body weight &lt;60 kg:</b> 30 mg PO BID	<b>Dose</b> <b>CrCl (mL/min)</b> ≥60 kg      <60 kg 26–50      20 mg q12h    15 mg q12h 10–25 or on HD*    20 mg q24h    15 mg q24h  *On dialysis days, take dose after HD session.	No dosage recommendation
<b>Tenofovir</b> (TDF)/ Viread	300 mg PO once daily	<b>CrCl (mL/min)</b> 30–49      300 mg q48h 10–29      300 mg twice weekly (every 72–96 hours) <10 and not on HD    Not recommended On HD*      300 mg q7d  *On dialysis days, take dose after HD session.	No dosage adjustment necessary
<b>Emtricitabine</b> (FTC) + <b>Tenofovir</b> (TDF)/ Truvada	1 tablet PO once daily	<b>CrCl (mL/min)</b> 30–49      1 tablet q48h <30 or on HD      Not recommended	No dosage recommendation
<b>Zidovudine</b> (AZT, ZDV)/ Retrovir	300 mg PO BID	<b>CrCl (mL/min)</b> <15 or HD*      100 mg TID or 300 mg once daily  *On dialysis days, take dose after HD session.	No dosage recommendation
<b>Non-Nucleoside Reverse Transcriptase Inhibitors</b>			
<b>Delavirdine</b> (DLV)/ Rescriptor	400 mg PO TID	No dosage adjustment necessary	No dosage recommendation; use with caution in patients with hepatic impairment.
<b>Efavirenz</b> (EFV)/ Sustiva	600 mg PO once daily, at or before bedtime	No dosage adjustment necessary	No dosage recommendation; use with caution in patients with hepatic impairment.
<b>Efavirenz (EFV) + Tenofovir (TDF) + Emtricitabine</b> (FTC)/ Atripla	1 tablet PO once daily	Not recommended for use in patients with CrCl <50 mL/min. Instead use the individual drugs of the fixed-dose combination and adjust TDF and FTC doses according to CrCl level.	
<b>Etravirine</b> (ETR)/ Intelence	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

**Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Last updated February 12, 2013; last reviewed February 12, 2013) (page 3 of 5)**

See the reference section following Table 7 for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Antiretrovirals Generic Name (Abbreviation)/ Trade Name	Daily Dose (Refer to <a href="#">Appendix B, Tables 1–6</a> for additional dosing information.)	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis and hemodialysis)	Dosing in Hepatic Impairment														
<b>Non-Nucleoside Reverse Transcriptase Inhibitors, continued</b>																	
<b>Nevirapine</b> (NVP)/ Viramune or Viramune XR	200 mg PO BID or 400 mg PO once daily (using Viramune XR formulation)	Patients on HD: limited data; no dosage recommendation	Child-Pugh Class A: No dosage adjustment  Child-Pugh Class B or C: Contraindicated														
<b>Rilpivirine</b> (RPV)/ Edurant	25 mg PO once daily	No dosage adjustment necessary	Child-Pugh Class A or B: No dosage adjustment  Child-Pugh Class C: No dosage recommendation														
<b>Rilpivirine (RPV) + Tenofovir (TDF) + Emtricitabine</b> (FTC)/ Complera	1 tablet PO once daily	Not recommended for use in patients with CrCl <50 mL/min. Instead use the individual drugs of the fixed-dose combination and adjust TDF and FTC doses levels according to CrCl level.	Child-Pugh Class A or B: No dosage adjustment  Child-Pugh Class C: No dosage recommendation														
<b>Protease Inhibitors</b>																	
<b>Atazanavir</b> (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  ARV-naïve patients on HD: (ATV 300 mg + RTV 100 mg) once daily  ARV-experienced patients on HD: ATV or RTV-boosted ATV not recommended	<table border="0"> <thead> <tr> <th>Child-Pugh Class</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>B</td> <td>300 mg once daily</td> </tr> <tr> <td>C</td> <td>Not recommended</td> </tr> </tbody> </table> RTV boosting is <b>not</b> recommended in patients with hepatic impairment (Child-Pugh Class B or C).	Child-Pugh Class	Dose	B	300 mg once daily	C	Not recommended								
Child-Pugh Class	Dose																
B	300 mg once daily																
C	Not recommended																
<b>Darunavir</b> (DRV)/ Prezista	(DRV 800 mg + RTV 100 mg) PO once daily (ARV- naïve patients only) or (DRV 600 mg + RTV 100 mg) PO BID	No dosage adjustment necessary	Mild-to-moderate hepatic impairment: No dosage adjustment  Severe hepatic impairment: Not recommended														
<b>Fosamprenavir</b> (FPV)/ Lexiva	1400 mg PO BID or (FPV 1400 mg + RTV 100–200 mg) PO once daily or (FPV 700 mg + RTV 100 mg) PO BID	No dosage adjustment necessary	PI-naïve patients only: <table border="0"> <thead> <tr> <th>Child-Pugh Score</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>5–9</td> <td>700 mg BID</td> </tr> <tr> <td>10–15</td> <td>350 mg BID</td> </tr> </tbody> </table> PI-naïve or PI-experienced patients: <table border="0"> <thead> <tr> <th>Child-Pugh Score</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>5–6</td> <td>700 mg BID + RTV 100 mg once daily</td> </tr> <tr> <td>7–9</td> <td>450 mg BID + RTV 100 mg once daily</td> </tr> <tr> <td>10–15</td> <td>300 mg BID + RTV 100 mg once daily</td> </tr> </tbody> </table>	Child-Pugh Score	Dose	5–9	700 mg BID	10–15	350 mg BID	Child-Pugh Score	Dose	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
Child-Pugh Score	Dose																
5–9	700 mg BID																
10–15	350 mg BID																
Child-Pugh Score	Dose																
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																

**Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Last updated February 12, 2013; last reviewed February 12, 2013) (page 4 of 5)**

See the reference section following Table 7 for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

<b>Antiretrovirals Generic Name (Abbreviation)/ Trade Name</b>	<b>Daily Dose (Refer to Appendix B, Tables 1–6 for additional dosing information.)</b>	<b>Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis and hemodialysis)</b>	<b>Dosing in Hepatic Impairment</b>
<b>Protease Inhibitors, continued</b>			
<b>Indinavir</b> (IDV)/ Crixivan	800 mg PO q8h	No dosage adjustment necessary	<u>Mild-to-moderate hepatic insufficiency because of cirrhosis:</u> 600 mg q8h
<b>Lopinavir/ritonavir</b> (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.
<b>Nelfinavir</b> (NFV)/ Viracept	1250 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
<b>Ritonavir</b> (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.
<b>Saquinavir</b> (SQV)/ Invirase	(SQV 1000 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
<b>Tipranavir</b> (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
<b>Integrase Inhibitors</b>			
<b>Raltegravir</b> (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
<b>Elvitegravir (EVG)/ Cobicistat (COBI)/ Tenofovir (TDF)/ Emtricitabine (FTC)/ Stribild (only available as a co-formulated product)</b>	1 tablet once daily	<b>EVG/COBI/TDF/FTC should not be initiated</b> in patients with CrCl <70 mL/min.  Discontinue EVG/COBI/TDF/FTC if CrCl declines to <50 mL/min while patient is on therapy.	<u>Mild-to-moderate hepatic insufficiency:</u> No dosage adjustment necessary <u>Severe hepatic insufficiency:</u> Not recommended

**Appendix B, Table 7. Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency (Last updated February 12, 2013; last reviewed February 12, 2013) (page 5 of 5)**

See the reference section following Table 7 for creatinine clearance (CrCl) calculation formulas and criteria for Child-Pugh classification.

Antiretrovirals Generic Name (Abbreviation)/ Trade Name	Daily Dose (Refer to Appendix B, Tables 1–6 for additional dosing information.)	Dosing in Renal Insufficiency (Including with chronic ambulatory peritoneal dialysis and hemodialysis)	Dosing in Hepatic Impairment
<b>Fusion Inhibitor</b>			
<b>Enfuvirtide</b> (T20)/ Fuzeon	90 mg subcutaneous BID	No dosage adjustment necessary	No dosage adjustment necessary
<b>CCR5 Antagonist</b>			
<b>Maraviroc</b> (MVC)/ Selzentry	The recommended dose differs based on concomitant medications and potential for drug-drug interactions. See Appendix B, Table 6 for detailed dosing information.	<b>CrCl &lt;30 mL/min or on HD</b>  <u>Without potent CYP3A inhibitors or inducers:</u> 300 mg BID; reduce to 150 mg BID if postural hypotension occurs  <u>With potent CYP3A inducers or inhibitors:</u> Not recommended	No dosage recommendations. Concentrations will likely be increased in patients with hepatic impairment.

**Key to Abbreviations:** 3TC = lamivudine, ABC = abacavir, ARV = antiretroviral, ATV = atazanavir, AZT = zidovudine, BID = twice daily, CAPD = chronic ambulatory peritoneal dialysis, COBI = cobicistat, CrCl = creatinine clearance, CYP = cytochrome P, d4T = stavudine, ddi = didanosine, DLV = delavirdine, DRV = darunavir, EC = enteric coated, EFV = efavirenz, ETR = etravirine, EVG= elvitegravir, FPV = fosamprenavir, FTC = emtricitabine, HD = hemodialysis, IDV = indinavir, LPV/r = lopinavir/ritonavir, MVC = maraviroc, NFV = nelfinavir, NNRTI = non-nucleoside reverse transcriptase inhibitor, NRTI = nucleoside reverse transcriptase inhibitor, NVP = nevirapine, PI = protease inhibitor, PO = orally, RAL = raltegravir, RPV = rilpivirine, RTV = ritonavir, SQV = saquinavir, T20 = enfuvirtide, TDF = tenofovir, TID = three times daily, TPV = tipranavir, XR = extended release, ZVD = zidovudine

### 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 <sup>a</sup>	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	<2 mg/dL (<34 μmol/L)	2–3 mg/dL (34 μmol/L to 50 μmol/L)	>3 mg/dL (>50 μmol/L)
Modified total bilirubin <sup>b</sup>	<4 mg/dL	4–7 mg/dL	>7 mg/dL
Prothrombin time (seconds prolonged) or	<4	4–6	>6
International normalized ratio (INR)	<1.7	1.7–2.3	>2.3

<sup>a</sup> 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

<sup>b</sup> Modified total bilirubin used for patients who have Gilbert's syndrome or who are taking indinavir or atazanavir

Child-Pugh Classification	Total Child-Pugh Score <sup>c</sup>
Class A	5–6 points
Class B	7–9 points
Class C	>9 points

<sup>c</sup> Sum of points for each component

**Appendix B Table 8: Monthly Suggested Wholesale Price (SWP)<sup>a</sup> of Antiretroviral Drugs (Last updated February 12, 2013; last reviewed February 12, 2013) (page 1 of 3)**

Antiretroviral Drug (Generic and Brand Names)	Strength	Dosing	Tabs/Capsules/mLs per Month	SWP <sup>a</sup> (Monthly)
<b>Nucleoside Reverse Transcriptase Inhibitors (NRTIs)</b>				
abacavir • generic	300 mg tab	2 tabs daily	60 tabs	\$602.66
• Ziagen	300 mg tab	2 tabs daily	60 tabs	\$670.37
• Ziagen	20 mg/mL soln	30 mL daily	900 mL	\$674.60
didanosine delayed-release • generic	400 mg cap	1 cap daily	30 caps	\$368.72
• Videx EC	400 mg cap	1 cap daily	30 caps	\$478.08
emtricitabine • Emtriva	200 mg cap	1 cap daily	30 tabs	\$574.14
• Emtriva	10 mg/mL soln	24 mL daily	680 mL (28-day supply)	\$542.32
lamivudine • generic	300 mg tab	1 tab daily	30 tabs	\$429.66
• Epivir	300 mg tab	1 tab daily	30 tabs	\$498.89
• Epivir	10 mg/mL soln	30 mL daily	900 mL	\$498.90
stavudine • generic	40 mg cap	1 cap twice daily	60 caps	\$403.70
• Zerit	40 mg cap	1 cap twice daily	60 caps	\$512.62
tenofovir • Viread	300 mg tab	1 tab daily	30 tabs	\$998.80
zidovudine • generic	300 mg tab	1 tab twice daily	60 tabs	\$360.97
• Retrovir	300 mg tab	1 tab twice daily	60 tabs	\$557.83
<b>Combination NRTI Products</b>				
abacavir/lamivudine • Epzicom	600/300 mg tab	1 tab daily	30 tabs	\$1,118.90
tenofovir/emtricitabine • Truvada	300/150 mg tab	1 tab daily	30 tabs	\$1,467.97
zidovudine/lamivudine • generic	300/150 mg tab	1 tab twice daily	60 tabs	\$931.61
• Combivir	300/150 mg tab	1 tab twice daily	60 tabs	\$1,081.70
abacavir/zidovudine/ lamivudine • Trizivir	300/300/150 mg tab	1 tab twice daily	60 tabs	\$1,839.66

**Appendix B Table 8: Monthly Suggested Wholesale Price (SWP)<sup>a</sup> of Antiretroviral Drugs (Last updated February 12, 2013; last reviewed February 12, 2013) (page 2 of 3)**

Antiretroviral Drug (Generic and Brand Names)	Strength	Dosing	Tabs/Capsules/mLs per Month	SWP <sup>a</sup> (Monthly)
<b>Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)</b>				
efavirenz • Sustiva	600 mg tab	1 tab daily	30 tabs	\$785.90
etravirine • Intelence	200 mg tab	1 tab twice daily	60 tabs	\$978.64
nevirapine • generic	200 mg tab	1 tab twice daily	60 tabs	\$650.48
• Viramune	200 mg tab	1 tab twice daily	60 tabs	\$723.08
• Viramune XR (nevirapine extended release)	400 mg tab	1 tab daily	30 tabs	\$670.63
rilpivirine • Endurant	25 mg tab	1 tab daily	30 tabs	\$804.38
<b>Protease Inhibitors (PIs)</b>				
atazanavir • Reyataz	150 mg cap <sup>b</sup>	2 caps daily	60 caps	\$1,222.10
• Reyataz	200 mg cap	2 caps daily	60 caps	\$1,222.10
• Reyataz	300 mg cap <sup>b</sup>	1 cap daily	30 caps	\$1,210.56
darunavir • Prezista	400 mg tab <sup>b</sup>	2 tabs daily	60 tabs	\$1,230.20
• Prezista	600 mg tab <sup>b</sup>	1 tab twice daily	60 tabs	\$1,230.20
fosamprenavir • Lexiva	700 mg tab	2 tabs twice daily	120 tabs	\$1,988.96
• Lexiva	700 mg tab	1 tab twice daily <sup>b</sup>	60 tabs	\$994.48
• Lexiva	700 mg tab	2 tabs once daily <sup>b</sup>	60 tabs	\$994.48
lopinavir/ritonavir • Kaletra	200 mg/50 mg tab	2 tabs twice daily or 4 tabs once daily	120 tabs	\$871.36
• Kaletra	400 mg/100 mg per 5 mL soln	5 mL twice daily	300 mL	\$871.34
ritonavir (total daily dose depends on concomitant PI)				
• Norvir	100 mg tab	1 tab once daily	30 tabs	\$308.60
• Norvir	100 mg tab	1 tab twice daily	60 tabs	\$617.20
• Norvir	100 mg tab	2 tabs twice daily	120 tabs	\$1,234.40
saquinavir • Invirase	500 mg tab <sup>b</sup>	2 tabs twice daily	120 tabs	\$1,088.84
tipranavir • Aptivus	250 mg cap <sup>b</sup>	2 caps twice daily	120 caps	\$1,335.14

**Appendix B Table 8: Monthly Suggested Wholesale Price (SWP)<sup>a</sup> of Antiretroviral Drugs (Last updated February 12, 2013; last reviewed February 12, 2013) (page 3 of 3)**

Antiretroviral Drug (Generic and Brand Names)	Strength	Dosing	Tabs/Capsules/mLs per Month	SWP <sup>a</sup> (Monthly)
<b>Integrase Strand Transfer Inhibitor (INSTI)</b>				
(Please refer to Co-formulated Combination Antiretroviral Drugs for cost of elvitegravir/cobicistat/tenofovir/emtricitabine [Stribild])				
raltegravir • Isentress	400 mg tab	1 tab twice daily	60 tabs	\$1,228.69
<b>Fusion Inhibitor</b>				
enfuvirtide • Fuzeon	90 mg injection kit	1 injection twice daily	60 doses (1 kit)	\$3,248.72
<b>CR5 Antagonist</b>				
maraviroc • Selzentry	150 mg tab	1 tab twice daily	60 tabs	\$1,259.82
• Selzentry	300 mg tab	1 tab twice daily	60 tabs	\$1,259.82
<b>Co-formulated Combination Products as Complete Antiretroviral Regimens</b>				
efavirenz/tenofovir/ emtricitabine • Atripla	600/300/200 mg tab	1 tab daily	30 tabs	\$2,253.88
rilpivirine/tenofovir/ emtricitabine • Complera	25/300/200 mg tab	1 tab daily	30 tabs	\$2,195.83
elvitegravir/cobicistat/ tenofovir/emtricitabine • Stribild	150/150/300/200 mg tab	1 tab daily	30 tabs	\$2,810.96

<sup>a</sup> SWP = Suggested Wholesale Price (source: AmerisourceBergen, accessed December 2012/January 2013) Note that this price may not represent the pharmacy acquisition price or the price paid by consumers.

<sup>b</sup> Should be used in combination with ritonavir. Please refer to [Appendix B, Table 3](#) for ritonavir doses.

**Key to Abbreviations:** cap = capsule, DR = delayed release, EC = enteric coated, soln = solution, SWP = suggested wholesale price, tab = tablet, XR = extended release