

Table 8: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination Antiretroviral Medications in Patients With Hepatic or Renal Impairment

Fixed-Dose Combination	Hepatic Impairment Dose Adjustment [a]	Renal Impairment Dose Adjustment		
		Recommended Dose Adjustment[a]	Individual FDC Components and Recommended Dose Adjustment [a]	Clinical Comments
<i>Integrase Strand Transfer Inhibitors</i>				
Abacavir/dolutegravir/lamivudine (ABC/DTG/3TC; Triumeq)	Child-Pugh A, B, C: Do not use.	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • ABC: No renal dose adjustment is needed. • DTG: No renal dose adjustment is needed. • 3TC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 150 mg once daily – CrCl 15–29 mL/min: 150 mg first dose, then 100 mg once daily – CrCl 5–14 mL/min: 150 mg first dose, then 50 mg once daily – CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily 	<ul style="list-style-type: none"> • CrCl >30 mL/min: Limited data to support use of FDC; 21 patients with CrCl >30 mL/min received full dose 3TC with minimal increases in AUC. No elevations in lactate or other ADRs reported [Fischetti, et al. 2018]. • CrCl <30 mL/min, without HD: Renal adjustment should be based on individual components; 13 patients with CrCl <30 mL/min not on HD received 100–150 mg of 3TC with minimal increases in AUC. No elevations in lactate or other ADRs reported [Fischetti, et al. 2018]. • CrCl <30 mL/min, with HD: Limited data to support use of FDC. Case series evaluating safety and efficacy of FDC in 9 patients with end-stage renal disease on HD reported viral suppression achieved in all 9 patients. No change in immune function. FDC generally well tolerated; 1 patient complained of nausea, which resolved without drug discontinuation [Michienzi, et al. 2019]. • Note: DTG serum concentrations appear to be reduced in uninfected healthy controls with eGFR <30 mL/min/m² compared to those with normal kidney function. This may increase the risk of therapeutic failure among patients with HIV drug resistance to INSTIs [FDA 2024].

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Bictegravir/emtricitabine/tenofovir alafenamide [b] (BIC/FTC/TAF; Biktarvy)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: Do not use. 	<p>CrCl <30 mL/min: Use of FDC is not recommended.</p>	<ul style="list-style-type: none"> • BIC: No renal adjustment is needed. • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TAF: <ul style="list-style-type: none"> – CrCl <15 mL/min, without HD: Use is not recommended. – CrCl <15 mL/min, with HD: No renal dose adjustment is needed. 	<ul style="list-style-type: none"> • CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. • CrCl 15–29 mL/min: No BIC dose adjustment is needed. In a study of 10 patients with CrCl 15–29 mL/min compared to 8 patients with normal renal function who received a single dose of BIC 75 mg, severe renal impairment did not produce clinically relevant changes in BIC exposure [Zhang, et al. 2017].
Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/COBI/FTC/TDF; Stribild)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: No data; do not use. 	<ul style="list-style-type: none"> • CrCl <70 mL/min: Do not initiate therapy. • Drop in CrCl to <50 mL/min during treatment: Discontinue therapy. 	<ul style="list-style-type: none"> • EVG: No renal dose adjustment is needed. • EVG/COBI: No renal dose adjustment is needed. • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TDF: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 300 mg every 48 hours – CrCl 10–29 mL/min: 300 mg every 72–96 hours – CrCl <10 mL/min, without HD: No data available. – CrCl <10 mL/min, with HD: 300 mg every 7 days 	<ul style="list-style-type: none"> • CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components. • EVG/COBI: Dose adjustment not warranted. In 12 patients with eGFR <30 mL/min/m² (not on HD) and 12 controls with normal renal function given 7 days of EVG/COBI, lower EVG AUC, C_{max}, and C_{min} values and higher COBI AUC, C_{max}, and C_{min} values were observed in severe renal impairment, but values were not considered clinically relevant [German, et al. 2012].

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Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide [b] (EVG/COBI/FTC/TAF; Genvoya)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: Do not use. 	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • EVG: No renal dose adjustment is needed. • EVG/COBI: No renal dose adjustment is needed. • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TAF: <ul style="list-style-type: none"> – CrCl <15 mL/min, without HD: Use is not recommended. – CrCl <15 mL/min, with HD: No renal dose adjustment is needed. – ESRD, with HD: 1 tablet once daily; administer after HD on HD days. 	<ul style="list-style-type: none"> • CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. • CrCl <15 mL/min, with HD: In a study of 55 patients on FDC for up to 96 weeks, 18 (33%) had grade 3 or higher ADR during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that, at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018].
Dolutegravir/lamivudine (DTG/3TC; Dovato)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: Do not use. 	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • DTG: No renal dose adjustment is needed. • 3TC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 150 mg once daily – CrCl 15–29 mL/min: 150 mg first dose, then 100 mg once daily – CrCl 5–14 mL/min: 150 mg first dose, then 50 mg once daily – CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily 	CrCl <50mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components.
Dolutegravir/rilpivirine (DTG/RPV; Juluca)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: No data; do not use. 	CrCl <30 mL/min or ESRD: No dose adjustment is needed; increased monitoring is recommended.	—	—

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		Recommended Dose Adjustment[a]	Individual FDC Components and Recommended Dose Adjustment [a]	Clinical Comments
<i>Non-Nucleoside Reverse Transcriptase Inhibitor</i>				
Emtricitabine/rilpivirine/tenofovir alafenamide (FTC/RPV/TAF; Odefsey) [b]	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: No data. 	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • RPV: No renal dose adjustment needed. • TAF: <ul style="list-style-type: none"> – CrCl <15 mL/min, without HD: Use is not recommended. – CrCl <15 mL/min, with HD: No renal dose adjustment is needed. 	<ul style="list-style-type: none"> • CrCl <30 mL/min, without HD: No data to support use of FDC. Renal dose adjustment should be based on individual components. • CrCl <30 mL/min, with HD: 1 FDC tablet once daily. On HD days, administer after dialysis [DHHS 2024]. • Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD. In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that, at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018].
Doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF; Delstrigo)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: No data. 	CrCl <50 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • DOR: No renal dose adjustment is needed. • 3TC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 150 mg once daily – CrCl 15–29 mL/min: 150 mg first dose, then 100 mg once daily – CrCl 5–14 mL/min: 150 mg first dose, then 50 mg once daily – CrCl <5 mL/min: 50 mg first dose, then 25 mg once daily • TDF: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 300 mg every 48 hours – CrCl 10–29 mL/min: 300 mg every 72–96 hours – CrCl <10 mL/min, without HD: No data available. – CrCl <10 mL/min, with HD: 300 mg every 7 days 	CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components.

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		Recommended Dose Adjustment[a]	Individual FDC Components and Recommended Dose Adjustment [a]	Clinical Comments
Efavirenz/lamivudine/tenofovir disoproxil fumarate (EFV/3TC/TDF; Symfi Lo)	<ul style="list-style-type: none"> • Child-Pugh A: No dose adjustment is needed. • Child-Pugh B, C: No data; do not use. 	CrCl <50 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • EFV: No renal dose adjustment is needed. • 3TC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 150 mg once daily – CrCl 15–29 mL/min: 150 mg first dose, then 100 mg once daily – CrCl 5–14 mL/min: 150 mg first dose, then 50 mg once daily • TDF: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 300 mg every 48 hours – CrCl 10–29 mL/min: 300 mg every 72–96 hours – CrCl <10 mL/min, without HD: No data available. – CrCl <10 mL/min, with HD: 300 mg every 7 days 	CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components.
Efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF; Atripla)	<ul style="list-style-type: none"> • Child-Pugh A: No dose adjustment is needed. • Child-Pugh B, C: No data; do not use. 	CrCl <50 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • EFV: No renal dose adjustment is needed. • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TDF: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 300 mg every 48 hours – CrCl 10–29 mL/min: 300 mg every 72–96 hours – CrCl <10 mL/min, without HD: No data available. – CrCl <10 mL/min, with HD: 300 mg every 7 days 	CrCl <50 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components.

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<i>Protease Inhibitor</i>				
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/COBI/FTC/TAF; Symtuza) [b]	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: Do not use. 	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • DRV; DRV/COBI: No renal dose adjustment required unless when combined with TDF. Renal dose adjustment for CrCl <70 mL/min is recommended when combined with TDF. • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TAF: <ul style="list-style-type: none"> – CrCl <15 mL/min, without HD: Use is not recommended. – CrCl <15 mL/min, with HD: No renal dose adjustment is needed. 	<ul style="list-style-type: none"> • CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. • CrCl <30mL/min, with HD: 1 FDC tablet once daily. On HD days, administer after dialysis [DHHS 2024]. • Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD. In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that, at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018].
<i>Nucleoside/Nucleotide Reverse Transcriptase Inhibitors</i>				
Emtricitabine/tenofovir alafenamide (FTC/TAF; Descovy)	<ul style="list-style-type: none"> • Child-Pugh A, B: No dose adjustment is needed. • Child-Pugh C: No data. 	CrCl <30 mL/min: Use of FDC is not recommended.	<ul style="list-style-type: none"> • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TAF: <ul style="list-style-type: none"> – CrCl <15 mL/min, without HD: Use is not recommended. – CrCl <15 mL/min, with HD: No renal dose adjustment is needed. 	<ul style="list-style-type: none"> • CrCl <30 mL/min, without HD: No data to support use of FDC. Renal adjustment should be based on individual components. • CrCl <30 mL/min, with HD: 1 FDC once daily. On HD days, administer after HD [DHHS 2024]. • Note: Dose recommended based on data using FTC/TAF as part of FDC with EVG/COBI in patients on HD. In a study of 55 patients on EVG/COBI/FTC/TAF for up to 96 weeks, 18 (33%) had grade 3 or higher ADRs during treatment, and 3 patients discontinued treatment due to adverse effects. The authors concluded that, at 48 weeks, the FDC regimen was well tolerated in patients on HD [Eron, et al. 2018].

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Emtricitabine/tenofovir disoproxil fumarate (FTC/TDF; Truvada)	Child-Pugh A, B, C: No dose adjustment is needed.	<ul style="list-style-type: none"> • CrCl 30–49 mL/min: FTC 200 mg/TDF 300 mg every 48 hours • CrCl <30 mL/min: Use of FDC is not recommended. 	<ul style="list-style-type: none"> • FTC: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 200 mg every 48 hours – CrCl 15–29 mL/min: 200 mg every 72 hours – CrCl <15 mL/min: 200 mg every 96 hours • TDF: <ul style="list-style-type: none"> – CrCl 30–49 mL/min: 300 mg every 48 hours – CrCl 10–29 mL/min: 300 mg every 72 to 96 hours – CrCl <10 mL/min, without HD: No data available. – CrCl <10 mL/min, with HD: 300 mg every 7 days 	CrCl <30 mL/min: No data to support use of FDC. Renal dose adjustment should be based on individual components.

Abbreviations: ADR, adverse drug reaction; AUC, area under the curve; C_{max} , maximum plasma concentration; C_{min} , minimum plasma concentration; CrCl, creatinine clearance; FDC, fixed-dose combination; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; HD, hemodialysis; INSTI, integrase strand transfer inhibitor.

Notes:

- a. Per package inserts; see links.
- b. Per package inserts, FTC can be used at standard dose in FDCs that contain FTC/TAF when CrCl is >30 mL/min. FTC as an individual component requires renal dose adjustment when CrCl is <50 mL/min.

Other ARVs, not included above:

- Tenofovir disoproxil fumarate/emtricitabine/rilpivirine (TDF/FTC/RPV; [Complera](#)):
 - Renal dose adjustment: CrCl <50 mL/min: Do not use.
 - Hepatic dose adjustment: Child-Pugh A, B—no adjustment; Child-Pugh C—no data.
- Atazanavir (ATV; [Reyataz](#)):
 - Renal dose adjustment: No adjustment, but use only 300 mg dose with 100 mg RTV; do not use in treatment-experienced patients on HD.
 - Hepatic dose adjustment: Child-Pugh A, B—no adjustment; Child-Pugh C—no data.
- Atazanavir/cobicistat (ATV/COBI; [Evotaz](#)):
 - Renal dose adjustment: Do not use in patients with CrCl <70 mL/min taking a TDF-containing regimen; do not use in treatment-experienced patients on HD.
 - Hepatic dose adjustment: No data; not recommended.
- Raltegravir (RAL; [Isentress](#)):
 - Renal dose adjustment: None.
 - Hepatic dose adjustment: 400 mg twice daily: Child-Pugh A, B—no adjustment; Child-Pugh C—no data. 600 mg once daily: No data; use with caution.

DRUG MANUFACTURER PACKAGE INSERTS

- Atripla:** FDA. Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate) tablets, for oral use. 2019 Oct. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021937s044lbl.pdf [accessed 2024 Oct 15]
- Biktarvy:** FDA. Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2024 Oct. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210251Orig1s020lbl.pdf [accessed 2024 Oct 15]
- Complera:** FDA. Complera (emtricitabine, rilpivirine, tenofovir disoproxil fumarate) tablets, for oral use. 2019 Nov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202123s031lbl.pdf [accessed 2024 Oct 15]
- Delstrigo:** FDA. Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use. 2024 Nov. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210807s013lbl.pdf [accessed 2024 Oct 15]
- Descovy:** FDA. Descovy (emtricitabine and tenofovir alafenamide) tablets, for oral use. 2022 Jan. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208215s020lbl.pdf [accessed 2024 Oct 15]
- Dovato:** FDA. Dovato (dolutegravir and lamivudine) tablets, for oral use. 2024 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211994s021lbl.pdf [accessed 2024 Oct 15]
- Evotaz:** FDA. Evotaz (atazanavir and cobicistat) tablets, for oral use. 2023 May. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206353s008lbl.pdf [accessed 2024 Oct 15]
- Genvoya:** FDA. Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2022 Jan. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207561s029lbl.pdf [accessed 2024 Oct 15]
- Isentress:** FDA. Isentress (raltegravir) tablets, for oral use. 2021 May. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022145s044,203045s017,205786s009lbl.pdf [accessed 2024 Oct 15]
- Juluca:** FDA. Juluca (dolutegravir and rilpivirine) tablets, for oral use. 2024 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210192s014lbl.pdf [accessed 2024 Oct 15]
- Odefsey:** FDA. Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide) tablets, for oral use. 2025 Feb. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/208351s014s015lbl.pdf [accessed 2024 Oct 15]
- Reyataz:** FDA. Reyataz (atazanavir) capsules, for oral use. 2024 Dec. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021567s049,206352s011lbl.pdf [accessed 2024 Oct 15]
- Stribild:** FDA. Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) tablets, for oral use. 2021 Sep. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203100s036lblet.pdf [accessed 2024 Oct 15]
- Symfi Lo:** FDA. Symfi lo (efavirenz, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use. 2019 Oct. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208255s008lbl.pdf [accessed 2024 Oct 15]
- Symtuza:** FDA. Symtuza (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) tablets, for oral use. 2023 Mar. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/210455s023lbl.pdf [accessed 2024 Oct 15]
- Tivicay:** FDA. Tivicay (dolutegravir) tablets, for oral use. 2024 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/204790s031,213983s004lbl.pdf [accessed 2024 Oct 15]
- Triumeq:** FDA. Triumeq (abacavir, dolutegravir, and lamivudine) tablets, for oral use. 2024 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/205551s032,215413s003lbl.pdf [accessed 2024 Oct 15]
- Truvada:** FDA. Truvada (emtricitabine and tenofovir disoproxil fumarate) tablets, for oral use. 2024 Apr. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021752s064lbl.pdf [accessed 2024 Oct 15]

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