Antivirals – HIV Combinations

WA.PHAR.97 Antivirals- HIV Combinations

Effective Date: August 1, 2020

Related medical policies:

- WA.PHAR.120 Antivirals- HIV: rilpivirine (Edurant)
- WA.PHAR.98 Antivirals- HIV : emtricitabine alafenamide-tenofovir (Descovy)
- WA.PHAR.112 Antivirals- HIV: cabotegravir/rilpivirine (Cabenuva)

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

Background:

Human immunodeficiency virus (HIV) is a single-stranded RNA retrovirus that attacks the immune system, specifically CD4+ T-helper cells, causing a progressive decrease in CD4+ T cell count and increased susceptibility of a person to infections. If left untreated, HIV can lead to acquired immunodeficiency syndrome (AIDS) which is the most severe phase of HIV infection. Approximately 1.1 million people in the U.S. live with HIV and about 14% of those living with HIV are unaware of their status. Although no cure for HIV currently exists, the use of antiretroviral therapy (ART) can help suppress the HIV virus and stop progression of the disease. ART therapy is recommended for all patients diagnosed with HIV to help protect the immune system and reduce the risk of serious health complications.

Medical necessity

Drug	Medical Necessity
Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Lamivudine/tenofovir disoproxil (**Cimduo, Temixys**) Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**) Abacavir/dolutegravir/Lamivudine (**Triumeq)**	Fixed-dose combination ART therapy may be considered medically necessary for the treatment of HIV-1 infection in patients who meet the criteria described in the clinical policy below. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) <u>*Preferred Alternatives:*</u> Emtricitabine/tenofovir disoproxil (Truvada) + Dolutegravir (Tivicay) OR Emtricitabine/tenofovir disoproxil (Truvada) +Raltegravir (Isentress)	**Biktarvy** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Body weight is greater than or equal to 25 kg; **AND** 3. Patient is: *a.* Treatment naïve; **OR** *b.* Virologically suppressed with HIV-1 RNA < 50 copies/mL and has been adherent to an ART regimen for at least 6 months; with no history of treatment failure, and no known substitutions associated with resistance to the individual components of Biktarvy; **AND** 4. Documentation that patient is not a candidate for a tenofovir disoproxil based regimen due to contraindication or intolerance defined as any **ONE** of the following**:** a. Requires renal hemodialysis; **OR** b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; **OR** c. Stabilized CrCL between 60 – 89 mL/min **AND** the patient has hypertension plus **ONE** of the following: i. Diabetes; ii. Hepatitis C; iii. African American with family history of kidney disease; **OR** d. Stabilized CrCL greater than 60mL/min **AND** high risk for bone complications as determined by a history of **ONE** of the following: i. Vertebral compression fracture; ii. Arm or hip fracture with minimal trauma; iii. T-score ≤ -2.0 (DXA) at the femoral neck or spine; iv. Taking glucocorticosteroids for more than 2 months – must include documentation of the following: 1. diagnosis requiring chronic glucocorticoid regimen; **AND** 2. current glucocorticoid regimen; 3. expected duration of therapy; **OR** **e.** Stabilized CrCl between 60-89 mL/min **AND** the patient has chronic kidney disease with proteinuria, low phosphate or is grade 3 or worse; **OR** **f.** CrCl has decreased ≥ 25% from baseline; **OR** 5. Patient has documentation of **ONE** of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR**

	b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** 6. Biktarvy will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Lamivudine/tenofovir disoproxil (**Cimduo, Temixys**) *Preferred Alternatives:* Lamivudine +Tenofovir Disoproxil (Viread)	**Cimduo or Temixys** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Body weight is greater than or equal to 35 kg; **AND** 3. Creatinine clearance greater than or equal to 50 mL/min; **AND** 4. Patient has documentation of one of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR** b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** 5. Cimduo or Temixys will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Dolutegravir/lamivudine (**Dovato**) *Preferred Alternatives:* Dolutegravir (Tivicay) + Lamivudine Dolutegravir/rilpivirine **(Juluca**) *Preferred Alternatives:* Dolutegravir (Tivicay) + Rilpivirine (Edurant)	**Dovato** and **Juluca** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Patient is: **a.** HIV-1 treatment naïve (DOVATO only); **OR** b. Patient is virologically suppressed with HIV-1 RNA < 50 copies/mL, and has been adherent to an ART regimen for at least 6 months; with no history of treatment failure, and no known substitutions associated with resistance to the individual components of Juluca or Dovato (JULUCA and DOVATO); **AND** 3. Absence of severe hepatic impairment (Child-Pugh Class C); **AND** 4. Creatinine clearance greater than or equal to 50 mL/min; **AND** 5. Patient has documentation of one of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR**

	b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** 6. Dovato and Juluca will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) <u>*Preferred Alternatives:*</u> Efavirenz + Lamivudine + Tenofovir disoproxil	**Symfi** or **Symfi Lo** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Patient is: a. Treatment naïve; **OR** b. Virologically suppressed with HIV-1 RNA < 50 copies/mL and has been adherent to an ART regimen for at least 6 months, with no history of treatment failure, and no known substitutions associated with resistance to the individual components of Symfi or Symfi Lo; **AND** 3. Body weight is greater than or equal to 40 kg for Symfi or greater than or equal to 35 kg for Symfi Lo; **AND** 4. Creatinine clearance greater than or equal to 50 mL/min; **AND** 5. Absence of severe hepatic impairment (Child-Pugh Class B or C); **AND** 6. Efavirenz/lamivudine/tenofovir disoproxil is not administered with Elbasvir/grazoprevir (Zepatier); **AND** 7. Patient has documentation of one of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR** b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** 7. Symfi or Symfi Lo will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza)**	**Symtuza** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND**

Preferred Alternatives: Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir/Cobicistat (Prezcobix) OR Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir (Prezista) + Cobicistat (Tybost)	2. Absence of severe hepatic impairment (Child-Pugh Class C); **AND** 3. Body weight is greater than or equal to 40 kg; **AND** 4. Creatinine clearance greater than 30 mL/min; **AND** 5. Patient is: a. Treatment naïve **OR** b. Virologically suppressed with HIV-1 RNA < 50 copies/mL and has been adherent adherent to an ART regimen for at least 6 months, with no history of treatment failure, and no known substitutions associated with resistance to the individual components of Symtuza; **AND** 6. Documentation that patient is not a candidate for a tenofovir disoproxil based regimen due to contraindication or intolerance defined as any **ONE** of the following**:** a. Requires renal hemodialysis; **OR** b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; **OR** c. Stabilized creatinine clearance (CrCL) between 60 – 89 mL/min **AND** the patient has hypertension plus **ONE** of the following: i. Diabetes; ii. Hepatitis C; iii. African American with family history of kidney disease; **OR** d. Stabilized CrCl greater than 60 mL/min **AND** high risk for bone complications as determined by a history of **ONE** of the following: i. Vertebral compression fracture; ii. Arm or hip fracture with minimal trauma; iii. T-score ≤ -2.0 (DXA) at the femoral neck or spine; iv. Taking glucocorticosteroids for more than 2 months – must include documentation of the following: 1. Diagnosis requiring chronic glucocorticoid regimen; 2. Current glucocorticoid regimen; 3. Expected duration of therapy; **OR** e. Stabilized CrCl between 60-89 mL/min **AND** the patient has chronic kidney disease with proteinuria, low phosphate or is grade 3 or worse; **OR** **f.** CrCl has decreased ≥ 25% from baseline; **OR** 7. Patient has documentation of one of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR**

	b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** **8.** Symtuza will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Abacavir/dolutegravir/Lamivudine (**Triumeq)** *Preferred Alternatives:* Abacavir + Dolutegravir (Tivicay) + Lamivudine	**Triumeq** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 2. Absence of moderate or severe hepatic impairment (Child-Pugh Class B or C); **AND** 3. Body weight is greater than or equal to 40 kg; **AND** 4. Creatinine clearance greater than or equal to 30 mL/min; **AND** 5. Patient has documentation of one of the following: a. Allergy to inactive ingredients contained in commercially separate agents; **OR** b. Neurodiversity or a behavioral health condition which impairs the patient's ability to manage multiple medications; **OR** c. Severe substance use disorder; **OR** d. Diagnosed swallowing disorder; **OR** e. Cognitive impairment requiring assistance with activities of daily living; **AND** 6. Patient is negative for the HLA-B*5701 allele; **AND** 7. Triumeq will not be co-administered with any products listed in Table 1 (below) If **ALL** criteria are met, the request will be **approved for 12 months**
Drug Name	**Criteria (Reauthorization)**
Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Lamivudine/tenofovir disoproxil (**Cimduo, Temixys**) Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**)	Fixed-dose combination ART therapy may be reauthorized if the patient shows previous history of medication use within the last 6 months. The request will be **approved for 12 months** or the pharmacy may submit the claim with Expedited Authorization (EA) 85000000007: Continuation of antiviral treatment.

Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**) Abacavir/dolutegravir/Lamivudine (**Triumeq)**	

Dosage and quantity limits

Drug Name	Strength	Quantity Limit
Biktarvy	Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg	30 tablets per 30 day supply
Cimduo Temixys	Lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Dovato	Dolutegravir 50 mg/lamivudine 300 mg	30 tablets per 30 day supply
Juluca	Dolutegravir 50 mg/rilpivirine 25 mg	30 tablets per 30 day supply
Symfi	Efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Symfi Lo	Efavirenz 400 mg/lamivuidine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Symtuza	Darunavir 800 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg	30 tablets per 30 day supply
Triumeq	Abacavic 600 mg/dolutegravir 50 mg/lamivudine 300 mg	30 tablets per 30 day supply

Appendix

Table 1: Contraindications

	Biktarvy	Cimduo Temixys	Dovato	Juluca	Symfi, Symfi Lo	Symtuza	Triumeq
Alfuzosin						X	
Carbamazepine				X		X	
Colchicine						X	
Dexamethasone (more than single dose treatment)				X			
Dofetilide	X		X	X			X
Enzalutamide							
Esomeprazole				X			
Lansoprazole				X			
Lurasidone						X	
Mitotane							
Omeprazole				X			
Oxcarbazepine				X			
Pantoprazole				X			
Phenobarbital				X		X	
Phenytoin				X		X	
Pimozide						X	
Rabeprazole				X			
Rifampin	X			X		X	
Rifapentine				X			
St. John's Wort				X			
Zeptier (elbasvir/grazoprevir)					X		

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History

Date	Action and Summary of Changes
04/13/2020	New policy created
07/15/2020	Updated note section from "TWO preferred agents" to "ONE preferred regimen"
12/03/2020	Updated clinical and reauthorization criteria
12/16/2020	Approved by DUR Board
01/04/2021	Added renal function decline criteria and updated Dovato criteria
05/18/2021	• Added Triumeq to policy • Updated listed of related medical policies • Removed Delstrigo • Added Cimduo
10/25/2021	• Removed statement from note section “Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least ONE preferred regimen.”