Washington State Health Care Authority

Antivirals – HIV Combinations

Medical policy no. 12.10.99-2 Effective Date: TBD

Related medical policies:

- 12.10.99.02 Antivirals – HIV : emtricitabine alafenamide-tenofovir (Descovy)

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. 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. 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.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

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
Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Lamivudine/tenofovir disoproxil (**Temixys**) Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**)	Fixed-dose combination ART therapy may be considered medically necessary for the following indications for 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 a MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
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 (JULUCA only); **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. Significant drug interaction; **OR** b. Allergy to inactive ingredients contained in commercially separate agents; **OR** c. Active psychosis that is poorly managed; **OR** d. Severe substance use disorder; **OR** e. Diagnosed swallowing disorder; **OR** f. Cognitive impairment requiring assistance with activities of daily living; **AND** 6. Dovato and Juluca will not be co-administered with other ART products. If **ALL** criteria are met, the request will be **approved for 12 months**
Lamivudine/tenofovir disoproxil (**Temixys**) *Preferred Alternatives:* Lamivudine +Tenofovir Disoproxil (Viread) OR Lamivudine/tenofovir disoproxil (Cimduo)	**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. Significant drug interaction; **OR** b. Allergy to inactive ingredients contained in commercially separate agents; **OR** c. Active psychosis that is poorly managed; **OR** d. Severe substance use disorder; **OR** e. Diagnosed swallowing disorder; **OR** f. Cognitive impairment requiring assistance with activities of daily living; **AND** If **ALL** criteria are met, the request will be **approved for 12 month**

Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) *Preferred Alternatives:* 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** 5. Patient has documentation of one of the following: a. Significant drug interaction; **OR** b. Allergy to inactive ingredients contained in commercially separate agents; **OR** c. Active psychosis that is poorly managed; **OR** d. Severe substance use disorder; **OR** e. Diagnosed swallowing disorder; **OR**

	f. Cognitive impairment requiring assistance with activities of daily living; **AND** 6. Biktarvy is not co-administered with other ART products. If **ALL** criteria are met, the request will be **approved for 12 months**
Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) *Preferred Alternatives:* Doravirine (Pifeltro) + Lamivudine/tenofovir disoproxil (Cimduo) OR Doravirine (Pifeltro) + Lamivudine + Tenofovir Disoproxil	**Delstrigo** 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 Delstrigo; **AND** 3. Creatinine clearance greater than or equal to 50 mL/min; **AND** 4. Patient has documentation of one of the following: a. Significant drug interaction; **OR** b. Allergy to inactive ingredients contained in commercially separate agents; **OR** c. Active psychosis that is poorly managed; **OR** d. Severe substance use disorder; **OR** e. Diagnosed swallowing disorder; **OR** f. Cognitive impairment requiring assistance with activities of daily living; **AND** 5. Doravirine/lamivudine/tenofovir disoproxil is not co-adminstered with either of the following: a. Carbamazepine b. Oxcarbazepine c. Phenobarbital d. Phenytoin e. Enzalutamide f. Rifampin g. Rifapentine h. Mitotane i. St. John's Wort j. Any strong CYP3A inducer k. Other ART products If **ALL** criteria are met, the request will be **approved for 12 months**
Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) *Preferred Alternatives:*	**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**

Lamivudine/tenofovir disoproxil (Cimduo) + Efavirenz OR Efavirenz + Lamivudine + Tenofovir disoproxil	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. Significant drug interaction; **OR** b. Allergy to inactive ingredients contained in commercially separate agents; **OR** c. Active psychosis that is poorly managed; **OR** d. Severe substance use disorder; **OR** e. Diagnosed swallowing disorder; **OR** f. Cognitive impairment requiring assistance with activities of daily living; **AND** 8. Efavirenz/lamivudine/tenofovir disoproxil is not co-administered with any other ART products. If **ALL** criteria are met, the request will be **approved for 12 months**
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza)** *Preferred Alternatives:* Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir/Cobicistat (Prezcobix) OR Emtricitabine/Tenofovir Disoproxil (Truvada) + Darunavir (Prezista) + Cobicistat (Tybost)	**Symtuza** may be authorized when **ALL** of the following are met: 1. Confirmed diagnosis of HIV-1; **AND** 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. Patients who have chronic kidney with proteinuria, low phosphate or is grade 3 or worse;
    iv. T-score ≤ -2.0 (DXA) at the femoral neck or spine;
    v. 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**

7. Patient has documentation of one of the following:
    a. Significant drug interaction; **OR**
    b. Allergy to inactive ingredients contained in commercially separate agents; **OR**
    c. Active psychosis that is poorly managed; **OR**
    d. Severe substance use disorder; **OR**
    e. Diagnosed swallowing disorder; **OR**
    f. Cognitive impairment requiring assistance with activities of daily living; **AND**
8. Symtuza is not co-administered with either of the following:
    a. Alfusozin
    b. Carbamazepine
    c. Cisapride
    d. Colchicine (if patient has renal or hepatic impairment)

	e. Dronedarone f. Elbasivir/grazoprevir g. Ergot Derivatives h. HMG-CoA Inhibitors: lovastatin, simvastatin Ivabradine i. Lomitapide j. Lurasidone k. Midazolam (orally administered) l. Naloxegol m. Phenobarbital n. Phenytoin o. Pimozide p. Ranolazine Rifampin q. Sildenafil r. St. John's Wort s. Triazolam If **ALL** criteria are met, the request will be **approved for 12 months**
Drug Name	**Criteria (Reauthorization)**
Dolutegravir/lamivudine (**Dovato**) Dolutegravir/rilpivirine **(Juluca**) Lamivudine/tenofovir disoproxil (**Temixys**) Bictegravir/emtricitabine/tenofovir alafenamide (**Biktarvy**) Doravirine/lamivudine/tenofovir disoproxil (**Delstrigo**) Efavirenz/lamivudine/tenofovir disoproxil (**Symfi, Symfi Lo**) Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (**Symtuza**)	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.

Dosage and quantity limits

Drug Name	Strength	Quantity Limit
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
Temixys	Lamivudine 300 mg/tenofovir disoproxil 300 mg	30 tablets per 30 day supply
Biktarvy	Bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg	30 tablets per 30 day supply
Delstrigo	Doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil 300 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

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History

Date	Action and Summary of Changes
12/03/2020	Updated clinical and reauthorization criteria
07/15/2020	Updated note section from "TWO preferred agents" to "ONE preferred regimen"
04/13/2020	New policy created

Washington State Health Care Authority

Antivirals – HIV Combinations

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number

Medication and strength	Directions for use	Qty/Days supply

1. Has patient used this medication within the last 6 months? ☐ Yes ☐ No
   If yes, contact patient's pharmacy. The pharmacy may submit the claim with Expedited Authorization (EA) 85000000007: Continuation of antiviral treatment.

2. What is the intended use?
   ☐ HIV-1 Treatment Other:
   ☐ PrEP. Provide date of last negative test for HIV-1:

3. Is patient treatment naïve? ☐ Yes ☐ No
   If no:
   - Is patient virologically suppressed with HIV-1 RNA < 50 copies/mL? ☐ Yes ☐ No
   - Has patient been adherent on an ART regimen for at least the past 6 months? ☐ Yes ☐ No
   - Does patient have a history of treatment failure? ☐ Yes ☐ No
   - Does patient have known substitutions associated with resistance to the individual components the requested product? ☐ Yes ☐ No

4. What is the patient's current weight? kg Date taken:

5. Does patient have hepatic impairment? ☐ Yes ☐ No
   If yes: ☐ Moderate (Child-Pugh Class B) ☐ Severe (Child-Pugh Class C)
   ☐ Other. Specify:

6. What is the patient's creatinine clearance? mL/min Date taken:

7. Will patient be using any of the following medications? (check all that apply)

☐ Alfusozin	☐ Any strong CYP3A inducer	☐ Carbamazepine	☐ Colchicine
☐ Cisapride	☐ Dexamethasone	☐ Dofetilide	☐ Dronedarone
☐ Enzalutamide	☐ Elbasivir/Grazoprevir	☐ Ergot Derivatives	☐ Ivabradine
☐ HMG-CoA Inhibitors (i.e. lovastatin, simvastatin)		☐ Lurasidone	☐ Lomitapide
☐ Midazolam	☐ Mitotane	☐ Naloxegol	☐ Other ART products
☐ Oxcarbazepine	☐ Phenobarbital	☐ Phenytoin	☐ Pimozide
☐ Ranolazine	☐ Rifabutin	☐ Rifampin	☐ Rifapentine
☐ Sildenafil	☐ St John's Wort	☐ Triazolam	☐ Voriconazole

☐ Proton pump inhibitors (i.e. esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)

8. Does patient documentation in medical records of any of the following? (check all that apply)
   - ☐ Significant drug interaction
   - ☐ Allergy to inactive ingredients contained in commercially separate agents
   - ☐ Active psychosis that is poorly managed
   - ☐ Sever substance use disorder
   - ☐ Diagnosed swallowing disorder
   - ☐ Cognitive impairment requiring assistance with activities of daily living

9. **Please list any additional circumstances to consider with this request?**

Complete only for:
Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza)
Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy)

10. Check all that apply for patient:
    - ☐ Requires renal hemodialysis
    - ☐ Hypertension
    - ☐ Diabetes
    - ☐ Hepatitis C
    - ☐ African American with family history of kidney disease
    - ☐ High risk for bone complications as determined by a history of:
      - ☐ Arm or hip fracture with minimal trauma
      - ☐ Vertebral compression fracture
      - ☐ Chronic kidney with proteinuria, low phosphate or is grade 3 or worse
      - ☐ T-score ≤ -2.0 (DXA) at the femoral neck or spine
      - ☐ Taking glucocorticosteroids for more than two (2) months
        - What is the diagnosis requiring a chronic glucocorticoid regimen?
        - What is patient's current glucocorticoid regimen?
        - What is the expected duration of therapy of glucocorticoid regimen?

CHART NOTES and LAB TESTS ARE REQUIRED FOR THIS REQUEST

Prescriber signature	Prescriber specialty	Date