Mass General Brigham
Health Plan

Antiretroviral Agents

Apretude® (cabotegravirinjection), Cimduo® (lamivudine/tenofovir disoproxil fumarate), Rukobia® (fostemsavir), Selzentry® (maraviroc), Symfi® (efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg), Symfi Lo® (efavirenz 400 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg), Temixys® (lamivudine/tenofovir disoproxil fumarate), Tivicay® (dolutegravir tablet), Trogarzo® (ibalizumab-uiyk), Viramune XR® (nevirapine extended-release)
Effective 01/02/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Trogarzo and Sunlenca are available through both pharmacy and medical benefits. All other agents are available through pharmacy benefit only.		

Overview

No PA	Drugs that require PA†
Apretude®(cabotegravir injection) PD	Cimduo® (lamivudine/tenofovir disoproxil fumarate)
Aptivus®(tipranavir)	nevirapine extended-release
Atripla®# (efavirenz/emtricitabine/tenofovir)	Rukobia®(fostemsavir) PD
	Selzentry® (maraviroc solution)
Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) PD	Selzentry® (maraviroc tablet) * BP
Cabenuva® (cabotegravir/rilpivirine) PD	Sunlenca® (lenacapavir) DUAL
Combivir®# (lamivudine/zidovudine)	Symfi® (efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg)*
Complera®(emtricitabine/rilpivirine/tenofovir disoproxil fumarate)	Symfi Lo® (efavirenz 400 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg) *
Descovy® (emtricitabine/tenofovir alafenamide) PD	Temixys® (lamivudine/tenofovir disoproxil fumarate)
Delstrigo® (doravirine/lamivudine/tenofovir disoproxil fumarate) PD	Tivicay® (dolutegravir tablet) >1 unit/day
didanosine	Trogarzo® (ibalizumab-uiyk) DUAL
Dovato® (dolutegravir/lamivudine) PD	

Edurant®(rilpivirine)	
Emtriva® # (emtricitabine)	
Epivir®# (lamivudine 10 mg/mL solution)	
Epivir®# (lamivudine 150 mg, 300 mg tablet)	
Epzicom®# (abacavir/lamivudine)	
Evotaz® (atazanavir/cobicistat)	
Fuzeon®(enfuvirtide)	
Genvoya® (elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide) [PD]	
Invirase®(saquinavir)	
Intelence®# (etravirine)	
Isentress®(raltegravir)	
Juluca® (dolutegravir/rilpivirine) [PD]	
Kaletra®# (lopinavir/ritonavir)	
Lexiva®# (fosamprenavir)	
nevirapine	
Norvir® (ritonavir packet, solution)	
Norvir ® # (ritonavir tablet) [PD]	
Odefsey® (emtricitabine/rilpivirine/tenofoviralafenamide) [PD]	
Pifeltro® (doravirine) [PD]	
Prezcobix® (darunavir/cobicistat) [PD]	
Prezista® # (darunavir)	
Retrovir® #(zidovudine)	
Reyataz®# (atazanavir)	
stavudine	
Stribild®(elvitegravir/cobicistat/emtricitabine/tenofovir disoproxilfumarate)	
Sustiva®# (efavirenz)	
Symtuza® (darunavir/cobicistat/emtricitabine/ tenofovir alafenamide) [PD]	
Tivicay PD®(dolutegravir tablet for oral suspension)	
Triumeq® (abacavir/dolutegravir/lamivudine) [PD]	
Triumeq PD® (abacavir/dolutegravir/lamivudine) [PD]	
Truvada® # (emtricitabine/tenofovir disoproxil fumarate)	
Tybost® (cobicistat)	
Viracept®(nelfinavir)	
Vocabria®(cabotegravir tablet)	
Ziagen®# (abacavir)	

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

[PD] Preferred Drug. Requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for antiretroviral agents, a trial with a preferred agent is not required prior to approval of a non-preferred agent.

BP Brand Preferred over generic equivalents. Requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

*A-rated generic available. Both brand and A-rated generic require PA.
†For Viread (tenofovir disoproxil fumarate tablet) requests > 1unit/day and Viread (tenofovir disoproxil fumarate powder) requests for members ≥ 13 years of age, review using the Hepatitis Antiviral Agents guideline.
DUAL Drug is available through both pharmacy and medical benefits

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Cimduo® (lamivudine/tenofovir disoproxil fumarate)
Temixys® (lamivudine/tenofovir disoproxil fumarate)
ALL of the following:
1. Diagnosis of HIV-1 infection
2. **ONE** of the following:
    a. Member is ≥ 18 years of age
    b. Member is < 18 years of age and weight ≥ 35 kg
3. Clinical rationale for use of the combination product instead of the commercially available separate agents *(see Appendix A)*
4. Concurrent antiretroviral therapy with at least one other antiretroviral
5. Requested quantity is ≤ 1 unit/day

Selzentry® (maraviroc solution)
Selzentry® (maraviroc tablet) [BP]
ALL of the following:
1. Diagnosis of HIV-1 infection

Symfi® and **Symfi Lo®** (efavirenz/lamivudine/tenofovir disoproxil fumarate)
ALL of the following:
1. Diagnosis of HIV-1 infection
2. **ONE** of the following:
    a. Member is ≥ 18 years of age
    b. Member is < 18 years of age **AND ONE** of the following:
        i. Request is for efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg and weight ≥ 40 kg
        ii. Request is for efavirenz 400 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg and weight ≥ 35 kg
3. Clinical rationale for use of the combination product instead of the commercially available separate agents *(see Appendix A)*
4. Requested quantity is ≤ 1 unit/day
5. If the request for BRAND NAME Symfi® or Symfi Lo®, member must meet the above criteria and the prescriber must also provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic (as per the Brand Name and Non-Preferred Generic Drug guideline)

Tivicay® (dolutegravir) >1 unit/day

For members < 18 years of age:

ALL of the following:

1. Diagnosis of HIV-1 infection
2. Physician attestation of co-administration with efavirenz, fosamprenavir/Norvir® (ritonavir), Aptivus® (tipranavir)/Norvir® (ritonavir), rifampin, or carbamazepine
3. **ONE** of the following:
    a. For member weight that is ≥ 20 kg, requested quantity is ≤ 2 units/day
    b. For member weight that is ≥ 14 kg to < 20 kg, requested quantity is ≤ 8 units/day for 10 mg tablet

For members ≥ 18 years of age:

ALL of the following:

1. Diagnosis of HIV-1 infection
2. **ONE** of the following:
    a. Physician attestation of co-administration with efavirenz, fosamprenavir/Norvir® (ritonavir), Aptivus® (tipranavir)/Norvir® (ritonavir), rifampin, or carbamazepine
    b. Integrase strand transfer inhibitor (INSTI)-associated resistance substitutions or clinically suspected INSTI-resistance (e.g., resistance to Isentress® or elvitegravir in Stribild®)
3. **ONE** of the following:
    a. For member weight that is ≥ 20 kg, requested quantity is ≤ 2 units/day
    b. For member weight that is ≥ 14 kg to < 20 kg, requested quantity is ≤ 8 units/day for 10 mg tablet

Trogarzo® (ibalizumab-uiyk)

ALL of the following:

1. Diagnosis of HIV-1 infection
2. Member is ≥ 18 years of age
3. Ongoing detectable viremia (e.g., > 200 copies/mL)
4. Resistance to at least one antiretroviral medication from each of three classes of antiretroviral medications (including combination agents): *See Appendix B*
    a. NRTI (Combivir, Viread, Epivir, etc.)
    b. NNRTI (Edurant, Intelence, Sustiva, etc.)
    c. PI (Prezista, Evotaz, Aptivus, etc.)
5. Concurrent antiretroviral therapy with at least one other antiretroviral
6. Appropriate dosing
7. **If reviewing under Pharmacy Benefit:** inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Rukobia (fostemsavir)
    b. Sunlenca (lenacapavir)

Rukobia® (fostemsavir)
Sunlenca® (lenacapavir)

ALL of the following:

1. Member has a diagnosis of HIV-1 infection
2. Member is ≥ 18 years of age
3. Member has ongoing detectable viremia (e.g., >200 copies/mL)

4. Member is antiretroviral experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral*
5. Failing current antiretroviral regimen due to resistance, intolerance or safety considerations†
6. Concurrent antiretroviral therapy with at least one other antiretroviral
7. Appropriate dosing
8. For Rukobia (fostemsavir), requested quantity is ≤ 2 units/day

*Implies documented history of resistance, adverse reaction, or contraindication to an antiretroviral that is not part of the current regimen.
†Implies documented resistance, adverse reaction, or safety concern with current antiretroviral regimen.

nevirapine extended-release
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of HIV-1 infection
2. Medical records documenting an inadequate response or adverse reaction to nevirapine immediate-release formulation

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals and reauthorizations will be for 12 months.
2. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
3. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
4. The following quantity limits apply:

Cimduo	30 tablets per 30 days
Temixys	30 tablets per 30 days
Tivicay	30 tablets per 30 days
Rukobia	60 tablets per 30 days

Appendix
- **A. Rationale for combination therapy**
  - Documentation of significant psychiatric diagnosis (must include specific diagnosis) leading to documented difficulty with adherence
  - Homeless members who may have difficulty storing larger amounts of medications (documentation of homelessness on the PA form is sufficient)

- Documented difficulty with adherence leading to complications (low CD4 count leading to infections and/or hospitalizations)
- Child/adolescent member or a member with documented developmental issues without adequate supports to properly manage their own HIV regimen

B. HIV Antiretrovirals by Class

Integrase inhibitor	NRTI	NNRTI	PI	Fusion inhibitor	CCR5 antagonist	Post-attachment inhibitor
Bictegravir	Abacavir	Delavirdine	Atazanavir	Enfuvirtide	Maraviroc	Ibalizumab-uiyk
Cabotegravir	Didanosine	Efavirenz	Darunavir			
Dolutegravir	Emtricitabine	Etravirine	Fosamprenavir			
Raltegravir	Lamivudine	Nevirapine	Indinavir			
	Stavudine	Rilpivirine	Lopinavir			
	Tenofovir		Nelfinavir			
	Zidovudine		Ritonavir			
			Saquinavir			
			Tipranavir			
Attachment Inhibitor	**Capsid inhibitor**					
Fostemsavir	Lenacapavir					

References

1. Department of Health and Human Services (DHHS). Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents Living with HIV, 2021 [guideline on the Internet]. 2021 June 3 [cited 2021 Aug 7]. Available from: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf.
2. Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2021 update. Center for Disease Control and Prevention. 2021. Available from: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.
3. Apretude® [package insert on the Internet]. Research Triangle Park (NC): ViiV Healthcare; 2021 Dec.
4. Cimduo® [package insert on the Internet]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2018 Feb.
5. Temixys® [package insert on the Internet]. Republic of Korea: Celltrion Pharm, Inc.; 2019 Oct.
6. Symfi® [package insert on the Internet]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2019 Oct.
7. Symfi Lo® [package insert on the Internet]. Morgantown (WV): Mylan Pharmaceuticals Inc.; 2019 Oct.
8. Selzentry® [package insert on the Internet]. Research Triangle Park (NC): ViiV Healthcare; 2020 Oct.
9. Rukobia® [package insert]. Research Triangle Park (NC): ViiV Healthcare; 2020 July.
10. Tivicay® [package insert]. Research Triangle Park (NC): Viiv Healthcare; 2021 July.
11. Trogarzo® [package insert on the Internet]. Montreal (Canada): Theratechnologies Inc.; 2021 Apr.
12. Viramune XR® [package insert on the Internet]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc; 2019 Oct.
13. Sunlenca® [package insert]. Forster City (CA): Gilead Sciences, Inc.; 2022 Dec.

Review History

05/19/2021 – Created and Reviewed to match MH UPPL for 7/1/2021
07/19/2021 – Removed Cabenuva from criteria to match with MH UPPL. Effective 02/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH by adding "Drug that require PA vs No PA" table. No clinical changes. Effective 2/1/23.
02/08/2023 - Reviewed and updated for Feb P&T. Matched MH criteria. Updated table in Overview by adding the following drugs requiring PA: Apretude, Cimduo, Selzentry, Symfi/Lo, Temixys, Tivicay, Trogarzo, Viramune XR. Added criteria for the following: Apretude, Cimduo, Selzentry, Symfi/Lo, Tivicay, Trogarzo, Viramune XR. Added appendix. Updated references. Added QLs for Cimduo, Temixys, Tivicay. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Removed brand names Viramune and Viramune XR from the guideline due to obsolete status. Apretude®(cabotegravir injection) to be available dual benefit. Effective 6/5/23.
06/14/23 – Reviewed and updated for P&T. Admin update: clarified that Apretude and Trogarzo are available through pharmacy and medical benefits (dual). Effective 6/30/23
07/12/23 – Reviewed and updated for P&T. New drug, Sunlenca (lenacapavir), was added to policy requiring PA through both benefits. Apretude will be available without PA with preferred drug status. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23
12/13/23 – Reviewed and updated for P&T. Formatting update to reflect the removal of preferred status from Prezista. No clinical changes. Effective 1/2/24