Mass General Brigham
Health Plan

Anti-Retroviral Agents
Sunlenca (lenacapavir)
Trogarzo (ibalizumab-uiyk)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Notes	These medications are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Sunlenca, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations.

Trogarzo, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Sunlenca (lenacapavir)
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. Combination antiretroviral therapy with at least one other antiretroviral

7. Appropriate dosing

*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.

Trogarzo (ibalizumab-uiyk)

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 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. Combination antiretroviral therapy with at least one other antiretroviral
6. Appropriate dosing
7. Inadequate response or adverse reaction to ONE or contraindication to BOTH of the following:
    a. Rukobia® (fostemsavir)
    b. Sunlenca® (lenacapavir)

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be for 12 months.

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, 2024 [guideline on the Internet]. 2024February 27 [cited 2024 Apr 29]. 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. Trogarzo [package insert on the Internet]. Montreal (Canada): Theratechnologies Inc.; 2024 Dec.
4. Sunlenca [package insert]. Forster City (CA): Gilead Sciences, Inc.; 2024 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
05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Removed Rx drugs from medical criteria, Rx is available on MHDL. Sunlenca and Trogarzo remains. Effective 6/1/25
10/8/25 – Reviewed and updated for P&T. Added Yeztugo to MB policy. Drug will be available on pharmacy and medical benefits. Effective 11/17/25
3/11/26 – Reviewed and updated for P&T. Yeztugo was given preferred drug designation and PA will be removed. Effective 4/1/26
11/4/26 – Reviewed and updated for P&T. Added step-through with Rukobia and Sunleca to Trogarzo criteria. Updated formatting and references. Effective 1/4/27