MetroPlus Health

Policy and Procedure

Title: Trogarzo (ibalizumab-uiyk)	**Division: Medical Management** **Department: Pharmacy, Utilization Management**
Approval Date: 1/28/2022	**LOB: Medicaid, HIV SNP, HARP, CHP, Medicare, UltraCare, MetroPlus Gold, Goldcare I&II, Essential Plan, QHP**
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Retired Date:	**Page 1 of 5**

1. POLICY DESCRIPTION

Human Immunodeficiency Virus (HIV) Type-1 Infection- Antiretrovirals, CD4-directed post-attachment HIV-1 inhibitor, Trogarzo

2. RESPONSIBLE PARTIES

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS

Trogarzo (ibalizumab-uiyk), 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. Trogarzo is a post-attachment inhibitor that blocks HIV-1 from infecting CD4 T cells by binding to domain 2 of CD4 cell receptors. This blocks interaction of gp120 and HIV co-receptors.

4. POLICY:

A. MULTIDRUG RESISTANT HIV-1 INFECTION

Trogarzo will be considered medically necessary when the following conditions of coverage have been met:

Initial Approval

1. The patient is 18 years of age or older **AND**
2. The patient has a diagnosis of multi-drug resistant HIV-1 infection defined by:
    i. Patient has been treated with an antiretroviral regimen for at least 6 months and has recently failed therapy in the last 8 weeks. (Documentation required: Chart notes and pharmacy claims if available) * **AND**
    ii. Patient has documented resistance to at least one medication from each of the three classes of antiretroviral medications[#] (NRTI, NNRTI and PI). Documented resistance testing must be submitted for all 3 classes of medication. **AND**
3. The patient's baseline viral load is greater than 1,000 copies/mL (Documentation required: lab results) * **AND**

4. The patient's dose is within FDA labeling:
    i. 2,000mg loading dose followed by a maintenance dose of 800mg every 2 weeks. **AND**
5. Trogarzo is used in combination with an optimized background antiretroviral regimen.

*** Written documentation must be submitted for approval**
 # See Appendix

Approve x 6 months (loading dose + maintenance dose)

Renewal Request:
1. Decrease in viral load from the baseline indicating clinically significant disease response and improvement to achieve < 200 copies/mL **AND**
2. Patient will continue to take an optimized background regimen on antiretroviral therapy in combination with Trogarzo **AND**
3. Dose is within FDA approved labeling:
    a. Maintenance dose of 800mg every 2 weeks.

***Written documentation must be submitted for approval**

Approve x 6 months (maintenance dose only)

5. LIMITATIONS/EXCLUSIONS:
1. Non-FDA approved indications

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J1746	Injection, ibalizumab-uiyk, 10 mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description

B20	Human immunodeficiency virus [HIV] disease
Z16.33	Resistance to antiviral drug(s)
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

8. APPENDIX

Drug Class	Examples
NRTI	Abacavir {ABC} (Ziagen), Didanosine {ddI} (Videx), Emtricitabine {FTC} (Emtriva), Lamivudine {3TC} (Epivir), Stavudine {d4T} (Zerit), Tenofovir AF {TAF} (Vemlidy), Tenofovir DF {TDF} (Viread), Zidovudine {ZDV} (Retrovir)
NNRTI	Doravirine {DOR} (Pifeltro), Efavirenz {EFV} (Sustiva), Etravirine {ETV} (Intelence), Nevirapine {NVP} (Viramune), Rilpivirine {RPV} (Edurant)
PI	Atazanavir {ATZ} (Reyataz), Cobicistat {Cobi} (Tybost), Darunavir {DRV} (Prezista), Fosamprenavir {FPV} (Lexiva), Indinavir {IDV} (Crixivan), Lopinavir {LPV}, Ritonavir {RTV} (Norvir), Saquinavir {SQV} (Invirase), Tipranavir {TPV} (Aptivus)
2 NRTIs	Combivir {3TC/ZDV}, Descovy {FTC/TAF}, Epzicom {ABC/3TC}, Temixys/Cimduo {3TC/TDF}, Truvada {FTC/TDF}
2 NRTIs + NNRTI	Atripla {FTC/TDF/EFV}, Complera {FTC/TDF/RPV}, Delstrigo {3TC/TDF/DOR}, Odefsey {FTC/TAF/RPV}, Symfi/Symfi Lo {3TC/TDF/EFV}
2 NRTIs + INSTI	Biktarvy {FTC/TAF/Bictegravir}, Triumeq {ABC/3TC/DTG}, Trizivir {ABC/ZDV/DTG}
2 NRTIs + INSTI+ Booster PI	Genovya {FTC/TAF/Elvitegravir/Cobi}, Stribild {FTC/TDF/Elvitegravir/Cobi}
2 NRTIs + Boosted PI	Symtuza {FTC/TAF/DRV/Cobi}

NRTI + INSTI	Dovato {3TC/DTG}
NNRTI + INSTI	Juluca {RPV/DTG}, Cabenuva {RPV/CAB}
Boosted PI	Evotaz {ATZ/Cobi}, Kaletra {LPV/RTV}, Prezcobix {DRV/Cobi}

9. REFERENCES

1. Trogarzo [package insert]. Montreal, Quebec, Canada: Theratechnologies, Inc. April 2021.
2. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. January 2017.
3. "Trogarzo (Ibalizumab/TMB-355): Multi-Drug Resistant HIV." IPD Analytics, February 15, 2018.
4. Emu B, Fessel J, Schrader S, Kumar P, Richmond G, Win S, Weinheimer S, Marsolais C, Lewis S. Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1. N Engl J Med. 2018 Aug 16;379(7):645-654.
5. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf. Accessed January 11th, 2022.

REVISION LOG:

REVISIONS	DATE
Creation date	1/11/2022
Annual Review	1/31/2023

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Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.02.02 11:10:50 -05'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.02.03 12:05:32 -05'00' **Date:**
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, MetroPlus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

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All coding and website links are accurate at time of publication.
MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization