Policy Title:	Trogarzo (ibalizumab-uiyk)		
Policy Number:	*To be determined*	**Department:**	PHA
Effective Date:	12/01/2019		
Review Date:	09/06/2019		
Revision Date:			

Purpose: To support safe, effective and appropriate use of Trogarzo (ibalizumab-uiyk)

Scope: Medicaid, Exchange

Policy Statement:

Trogarzo (ibalizumab-uiyk) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Trogarzo (ibalizumab-uiyk) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Member is at least 18 years old AND
- Member has a diagnosis of multi-drug resistant HIV-1 infection AND
- Member is heavily treatment-experienced and currently failing their antiretroviral therapy AND
- Member is using Trogarzo (ibalizumab-uiyk) in combination with other antiretroviral(s), as indicated for HIV-1 AND
- Dosing for the member is in accordance with the US Food and Drug Administration prescribing information.

Continuation of Therapy Criteria:

- Member meets all initial criteria AND
- Member is tolerating and adherent to Trogarzo therapy in combination with other antiretroviral(s) AND
- Member has achieved a clinically significant viral response with Trogarzo.

Dosing Limits (1 billable unit = 10 mg):

- Recommended Dose: A loading dose of 2,000 mg (200 billable units) followed by a maintenance dose of 800 mg (80 billable units) every 2 weeks. If maintenance dose if missed by 3 days or more beyond scheduled dosing day, administer a loading dose of 2,000 mg as soon as possible. Resume maintenance dosing every 14 days thereafter.
- Initial Coverage = 1,160 units
- Continuation of Therapy = 1,040 units

Coverage duration:

- Initial & Continuation of Therapy Coverage = 6 months

Investigational use: Trogarzo (ibalizumab-uiyk) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1746	Injection, ibalizumab-uiyk, 10mg

References:

1. Trogarzo [package insert]. Montreal, Quebec Canada; Thera technologies; March 2018.