OPTIMA HEALTH PLAN

MEDICAL/PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

DRUG REQUESTED: Trogarzo® (ibalizumab-uiyk) **IV (J1746) (Medical)**

MEDICATION WILL BE PROVIDED BY THE PHYSICIAN'S OFFICE

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization – 6 months.

❑ Member is 18 years old or older

AND

❑ Diagnosis of HIV-1 infection

AND

❑ Medication is being prescribed or in consultation with an Infectious Disease Specialist **OR** Specialist in HIV treatment

AND

❑ Member has been treated with antiviral therapy for at **least 6 months**

AND

❑ Member has been identified to have multidrug resistant HIV-1 infection with documented resistance to at least **ONE** antiretroviral medication from at least **three (3)** of the following antiretroviral drug classes **(genotype/phenotype resistance testing results included)**:

- ❑ Nucleoside Reverse Transcriptase Inhibitors
- ❑ Non-Nucleoside Reverse Transcriptase Inhibitors

(Continued on next page)

- ❑ Protease Inhibitors
- ❑ Entry Inhibitors
- ❑ Integrase Inhibitors

❑ Member has a viral load greater than 1,000 copies/mL

Current Viral Load: _____ copies/mL (**recent lab work indicating viral load prior to initiating therapy must be included)**

AND

❑ Provider confirms ibalizumab will be used in conjunction with an optimized background regiment for antiretroviral therapy.

Reauthorization Approval - 12 months. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

❑ Submission of documentation and/or lab work indicating patient has had a decrease in viral load since initiation of ibalizumab.

Viral Load: _____ copies/mL **after 6 months of treatment**

AND

❑ Prescriber confirms member has continued an optimized background regimen during ibalizumab therapy.

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 1/17/2019
REVISED/UPDATED: ~~3/23/2019;~~ **(Reformatted)** ~~7/12/2019;~~ **9/25/2019**