Palmetto Infusion Services COMPLIANCE

MRN:_____

Phone: 1-800-809-1265 Fax: 1-866-872-8920 **DOB:** _____

STANDARD TROGARZO™ (ibalizumab-uiyk) PLAN OF TREATMENT

(Re) Certification Period From_____**to** _____

NOTE: *We may require a detailed Letter of Medical Necessity or clinical supporting documentation (depending on diagnosis), to be able to verify eligibility and payment for this treatment through Medicare and/or other insurance plans.*

1. Patient Name: _____Height (inches): _____Weight (lbs):_____

2. Allergies: _____

3. DIAGNOSIS: ☐ **B20 Human immunodeficiency virus [HIV] disease**

☐ **Secondary ICD-10 code:** _____**Diagnosis description:** _____

Orders: Obtain weight each visit as tolerated. Instruct patient/caregiver on medications and signs/symptoms of adverse reaction. Assess patient for response to therapy. Utilize existing central line for administration or initiate a peripheral IV with each infusion as needed. Sodium Chloride 0.9% flush 3-10 ml before and as needed during the infusion. Follow infusion with Heparin 100 units/ml 1 – 5 ml per line type or to peripheral IV as required for multiple day treatments. Pump, tubing, 0.22-micron filter, and supplies needed to complete prescribed therapy. Pharmacist to perform clinical drug monitoring. **Extended one (1) hour post infusion monitoring after first treatment. If the patient does not experience any adverse reaction, then the post-infusion observation time can be reduced to 15 minutes thereafter.** ***If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES***

4. Dose:

TROGARZO™ (ibalizumab-uiyk) administered IV over 30 minutes via pump (via cephalic vein if possible), follow each infusion with Sodium Chloride 0.9% 30 ml flush.

5. Frequency:

_____ Induction Dose: 2000 mg IV dose per 250 ml Sodium Chloride 0.9%

_____ Maintenance Dose: 800 mg IV per 250 ml Sodium Chloride 0.9% every 14 days*

*If dosing is delayed by 3 days or longer, the referring physician will be notified. Product information suggests that if maintenance dosing is delayed, that 2000mg loading dose should be administered as early as possible then resuming maintenance (800 mg) dosing every 14 days thereafter. Additional 2000 mg dose will require an additional order, insurance verification, and dependent on product availability.

Special orders: _____

6. Physician's Signature: _____/ _____Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____NPI: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms available at www.palmettoinfusion.com

Revised 5/14/18

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Guidelines for Prescribing TROGARZO™ (ibalizumab-uiyk)

(Required documentation with all initial referrals)

Patient Name: _____ **Referral Date:** _____

___ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-7)*
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

___ Include patient demographic information and insurance information. (Copy of insurance cards if available)

___ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy.**

- TROGARZO™, a CD4-directed post-attachment HIV-1 inhibitor, 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.

___ Other as requested: _____

_____

_____

_____

_____

** **Warnings/Precautions:** **Immune Reconstitution Inflammatory Syndrome (IRIS):** has been reported in patients treated with combination antiretroviral therapies. During the initial phase of combination antiretroviral therapies, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment. **Adverse Reactions:** The most common adverse reaction (incidence ≥ 5%) were diarrhea, dizziness, nausea, and rash. **Pregnant or Breastfeeding:** The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers in the United States not breastfeed their infants to avoid the risk of postnatal transmission of HIV-1 infection. Dose modifications of TROGARZO are not required when administered with any other antiretroviral or any other treatments. TROGARZO™ does not impact CD4 function. See full prescribing information

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 5/14/18