BILLING AND CODING GUIDE

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)

PATIENT COVERAGE

1) Complete a **TROGARZO® Enrollment Form** and FAX the patient's enrollment package to THERA patient support™ at 1-855-836-3069.

2) A Patient Care Coordinator will then assess and advise on the patient's private or government insurance coverage, including AIDS Drug Assistance Programs (ADAPs). The Patient Care Coordinator will also assist in applying any eligible co-pay assistance.

3) TROGARZO® may then be ordered and given at your office.

HOW TO ORDER

TROGARZO® Authorized Distributor: **CuraScript SD Acute: 800.211.1455**

TELEPHONE	1-877-599-7748 (Mon-Fri 8:30AM-7PM ET)
FAX	1-800-862-6208
WEBSITE	www.curascriptsd.com

For information on payment, shipping or return policies, please contact Curascript SD directly.

THERA patient support®

Questions?
Contact us at 1-833-23-THERA (1-833-238-4372), Mon-Fri 8:30AM-8PM ET

See back page for full Important Safety Information.

Note: Individual payer organizations should be contacted for coverage and reimbursement policies and processes, including prior authorization, if necessary.

PRODUCT INFORMATION

TROGARZO® is available in a carton containing two single-dose vials.

Each vial contains
200 mg ibalizumab-uiyk

TROGARZO® DOSE	VIALS REQUIRED	CARTONS REQUIRED
Loading Dose (2,000 mg ibalizumab-uiyk)	10	5
Maintenance Doses (800 mg ibalizumab-uiyk)	4	2

NDC	DESCRIPTION
62064-122-02	Pack of 2 vials, each containing 200 mg of ibalizumab-uiyk for intravenous use

ICD-10 CODE	DESCRIPTION
B20	Human immunodeficiency virus (HIV) disease
Z16.33	Resistance to antiviral drug(s)

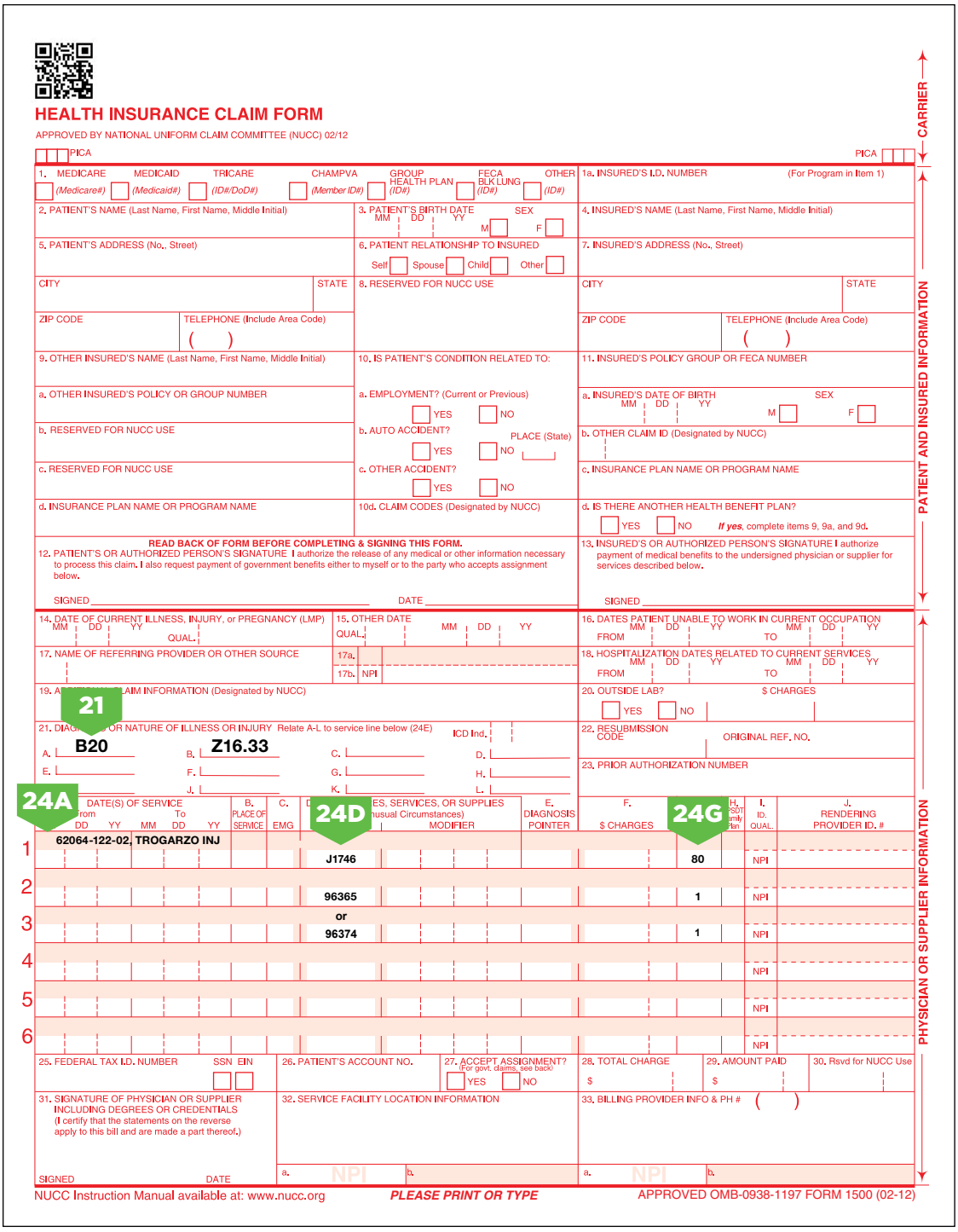
CPT CODE	DESCRIPTION
96365	IV infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
96374	IV push, single or initial substance/drug lasting 15 minutes or less

HCPCS CODE	DESCRIPTION
J1746	Injection, ibalizumab-uiyk, 10 mg

See back page for full Important Safety Information.

Please check with payor to verify coding or special billing requirements. Correct coding is the responsibility of the provider submitting a claim for the item or service.

SAMPLE CMS-1500 CLAIM FORM



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B20 B. Z16.33 C. D. E. F. G. H. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24A DATE(S) OF SERVICE From DD YY MM DD YY To	B. PLACE OF SERVICE	C. EMG	24D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	24G DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 62064-122-02, TROGARZO INJ			J1746			80		NPI	
2			96365			1		NPI	
3			or 96374			1		NPI	
4								NPI	
5								NPI	
6								NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

21

Enter applicable ICD-10 Diagnosis Codes:

- B20
- Z16.33

24A

Enter product information (NDC) with qualifier:

- 62064-122-02

24D

Enter Drug Code (HCPCS) and Procedure Code (CPT):

- J1746
- 96365 or 96374

24G

For TROGARZO®, enter billing units according to the correct dose:

- For a **Loading Dose** (2,000 mg ibalizumab-uiyk): Enter 200
- For **Maintenance Doses** (800 mg ibalizumab-uiyk): Enter 80

Sample provided for reference only. Theratechnologies Inc. makes no guarantee of coverage by payors. Please check with payor to verify coding or special billing requirements. Correct coding is the responsibility of the provider submitting a claim for the item or service.

IMPORTANT SAFETY INFORMATION

Indication

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.

Contraindications

TROGARZO® is contraindicated in patients with a prior hypersensitivity reaction to TROGARZO® or any components of the product.

Warnings and Precautions

Hypersensitivity Including Infusion-Related and Anaphylactic Reactions

- Hypersensitivity reactions including infusion-related reactions and anaphylactic reactions have been reported following infusion of TROGARZO® during post-approval use. Symptoms may include dyspnea, angioedema, wheezing, chest pain, chest tightness, cough, hot flush, nausea, and vomiting. If signs and symptoms of an anaphylactic or other clinically significant hypersensitivity reaction occur, immediately discontinue administration of TROGARZO® and initiate appropriate treatment. The use of TROGARZO® is contraindicated in patients with known hypersensitivity with TROGARZO®.

Immune Reconstitution Inflammatory Syndrome

- Immune Reconstitution Inflammatory Syndrome (IRIS) has been reported in one patient treated with TROGARZO® in combination with other antiretrovirals. 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.

Embryo-Fetal Toxicity

- Based on animal data, TROGARZO® may cause reversible immunosuppression (CD4+ T cell and B cell lymphocytopenia) in infants born to mothers exposed to TROGARZO® during pregnancy. Immune phenotyping of the peripheral blood and expert consultation are recommended to provide guidance regarding monitoring and management of exposed infants based on the degree of immunosuppression observed. The safety of administering live or live-attenuated vaccines in exposed infants is unknown.

Adverse Reactions

The most common adverse reactions (all Grades) seen in clinical trial experience, reported in at least 5% of subjects receiving TROGARZO® were diarrhea (8%), dizziness (8%), nausea (5%) and rash (5%). Most (90%) of the adverse reactions reported were mild or moderate in severity. Two subjects experienced severe adverse reactions: one subject had a severe rash and one subject developed IRIS manifested as an exacerbation of progressive multifocal leukoencephalopathy.

Use in Specific Populations

- **Pregnancy:** No adequate human data are available to establish whether or not TROGARZO® poses a risk to pregnancy outcomes. Monoclonal antibodies, such as ibalizumab-uiyk, are transported across the placenta as pregnancy progresses; therefore, ibalizumab-uiyk has the potential to be transmitted from the mother to the developing fetus.
- **Lactation:** No data are available regarding the presence of TROGARZO® in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for HIV-1 transmission, instruct mothers not to breastfeed if they are receiving TROGARZO®.

Please see enclosed full Prescribing Information for TROGARZO®.

To report suspected adverse reactions,
contact THERA patient support®
(1-833-238-4372)
or the FDA at 1-800-FDA-1088
or www.fda.gov/medwatch.

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)

THERA technologies