Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Trogarzo™

Policy Number: HS-334

Original Effective Date: 4/5/2018

Revised Date(s): 08/27/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Trogarzo™ (ibalizumab) is a humanized monoclonal antibody developed for the treatment of multidrug resistant HIV-1 infection. Trogarzo™ is different from other antiretroviral agents as it binds primarily to the second extracellular domain of the CD4+ T cell receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents HIV from infecting CD4+ immune T cells while preserving normal immunological function.[1]

Trogarzo™ 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. It received US approval in 2018. The drug is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks. There are currently no contraindications to the drug, however, Reconstitution Inflammatory Syndrome (IRIS) has been reported in patients treated with combination antiretroviral therapies. The most commonly reported adverse reactions were diarrhea, dizziness, nausea, and rash.[2]

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – All Markets
- ☑ Medicare – All Markets

Coverage

Trogarzo is **considered medically necessary** for members with HIV-1 infection when all of the following are met:

Initial Authorization

1. Member is greater than 18 years of age; **AND,**
2. Member has had an inadequate response to 6 months of treatment with anti-retroviral therapy (ART) **and** have failed therapy within the last 8 weeks; **AND,**
3. Member has documentation of viral load (VL) greater than 1,000 copies/mL; **AND,**
4. Member has multidrug resistant HIV-1 infection with documentation of resistance to **ONE** medication from **EACH** of the following classes of antiretroviral medications as measured by resistance testing:
   a. Protease inhibitor (PI)
   b. Nucleoside reverse transcriptase inhibitors (NRTI)
   c. Non-nucleoside reverse transcriptase inhibitors (NNRTI)

AND

5. Trogarzo will be used in combination with an optimized background regimen (OBR); **AND,**
6. Prescriber has provided verification to the patient's willingness and ability to travel every two weeks for healthcare professional infusion.

Continuation of Care

1. Member shows a decrease in viral load from baseline, **AND;**
2. Member continues to take anti-retroviral therapy (ART) throughout Trogarzo therapy.

CODING

Covered CPT Codes – None.

Covered HCPCS Code
33590 Unclassified Biologics

Covered ICD-10 Codes
B20 Human immunodeficiency virus [HIV] disease
Z21 Asymptomatic human immunodeficiency virus [HIV] infection status

NOTE: ICD-10 B20 cannot be billed with Z21.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Theratechnologies announces decision by FDA to extend the ibalizumab review period to April 3, 2018. Market Wired Web site http://www.marketwired.com/press-release/-2240525.htm. Published November 13, 2017. Accessed February 28, 2018.
2. Trogarzo™ highlights of prescribing information Published March 2018. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761065lbl.pdf. Accessed April 23, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
8/27/2018	• Approved by MPC. Updated coding.
4/5/2018	• Approved by MPC. New.