UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Genvoya

Program	Step Therapy
Medications	Genvoya® (elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide)
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	4/2017
Effective Date	6/2017

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Triumeq® (abacavir, dolutegravir, and lamivudine) before providing coverage for Genvoya® (elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide).

Genvoya is a four-drug combination of elvitegravir, an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat, a CYP3A inhibitor, and emtricitabine and tenofovir alafenamide (TAF), both HIV- 1 nucleoside analog reverse transcriptase inhibitors (NRTIs) and is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya. Genvoya is not recommended in patients with estimated creatinine clearance below 30 mL per minute.[1]

Triumeq, a combination of dolutegravir (integrase strand transfer inhibitor, abacavir, and lamivudine (both nucleoside analogue reverse transcriptase inhibitors), is indicated for the treatment of HIV-1 infection.[2]

Both Genvoya and Triumeq are equally recommended as initial combination treatment regimens for antiretroviral-naïve patients with HIV-1 infection in the most recent Department of Health and Human Services Adult and Adolescents Treatment Guidelines.[3]

Members currently on Genvoya therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. **Genvoya** will be approved on the following criterion:

1. Diagnosis of HIV

-AND-

2. <u>One</u> of the following:

a. Patient has tested positive for the HLA-B*5701 allele

-OR-

b. Patient has pre-existing cardiovascular disease

-OR-

c. Patient has significant risk factors for the development of cardiovascular disease

-OR-

d. Patient has a creatinine clearance that falls within the range of 30 to 50 mL per minute

-OR-

e. Patient has experienced intolerance to Triumeq therapy

-OR-

f. Patient is currently on Genvoya therapy

Authorization will be issued for 12 months.

B. **Genvoya for Post Exposure Prophylaxis**

1. Patient has a diagnosis of post-exposure prophylaxis

Authorization will be issued for 4 weeks.

NOTE: Genvoya will pay at the point-of-sale if the patient has a diagnosis of post-exposure prophylaxis.

3. References:

1. Genvoya [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2015.

2. Triumeq [package insert]. Research Triangle Park, NC: ViiV Healthcare; September 2015.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf. Section accessed January 8, 2016

Program	Step Therapy –Genvoya (elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide)
Change Control	
7/2016	New Program. Aligning with Employer & Individual on clinical criteria but changed authorization duration from 24 to 12 months.
2/2017	Updated policy template. Added note about paying at point-of-sale with post-exposure prophylaxis diagnosis.
4/2017	Added HIV diagnosis requirement and review criteria for post-exposure prophylaxis