

Clinical Pharmacy Program Guidelines for Complera

Program	Prior Authorization
Medication	Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
Issue Date	11/2016
Pharmacy and Therapeutics Approval Date	4/2017
Effective Date	6/2017

1. Background:

Complera, a combination of two nucleoside analog HIV-1 reverse transcriptase inhibitors (emtricitabine and tenofovir disoproxil fumarate) and one non-nucleoside reverse transcriptase inhibitor (rilpivirine), is indicated for use as a complete regimen for the treatment of HIV-1 infection in (1) patients 12 years of age and older with no antiretroviral treatment history and with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy, and (2) in certain virologically-suppressed (HIV-1 RNA <50 copies/mL) patients on a stable antiretroviral regimen at start of therapy in order to replace their current antiretroviral treatment regimen.²

2. Coverage Criteria:

<p>A. Complera will be approved on the following criteria:</p> <p style="margin-left: 40px;">1. Diagnosis of HIV</p> <p style="text-align: center; margin-left: 100px;">-AND-</p> <p style="margin-left: 40px;">2. One of the following:</p> <p style="margin-left: 80px;">a. Patient has tested positive for the HLA-B*5701 allele</p> <p style="text-align: center; margin-left: 100px;">-OR-</p> <p style="margin-left: 80px;">b. Patient has pre-existing cardiovascular disease</p> <p style="text-align: center; margin-left: 100px;">-OR-</p> <p style="margin-left: 80px;">c. Patient has significant risk factors for the development of cardiovascular disease</p> <p style="text-align: center; margin-left: 100px;">-OR-</p>
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d. Patient has experienced intolerance to Triumeq therapy

-OR-

e. Patient has hepatitis B coinfection

Authorization will be issued for 12 months.

B. Complera for Post Exposure Prophylaxis

1. Patient has a diagnosis of post-exposure prophylaxis

Authorization will be issued for 4 weeks.

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

3. References:

1. 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 October 21, 2016
2. Complera [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2016.

Program	Prior Authorization –Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
Change Control	
Date	Change
11/2016	New guideline
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