VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guideline

COMPLERA: (Emtricitabine, rilpivirine and tenofovir)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Non-nucleoside, nucleoside, and nucleotide reverse transcriptase inhibitor combination; rilpivirine binds to reverse transcriptase and does not require intracellular phosphorylation for antiviral activity; emtricitabine is a cytidine analogue while tenofovir disoproxil fumarate (TDF) is an analog of adenosine 5'-monophosphate. Each drug interferes with HIV viral RNA dependent DNA polymerase activities resulting in inhibition of viral replication.

Pre-Authorization Criteria: For use as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naive adult patients with HIV-1 RNA ≤100,000 copies/mL at the start of therapy, and in certain virologically suppressed (HIV-1 RNA <50 copies/mL) adult patients on a stable antiretroviral regimen for ≥6 months with no treatment failure or substitutions due to resistance to emtricitabine, rilpivirine, or tenofovir disoproxil fumarate in order to replace their current antiretroviral treatment regimen.

Note:
VCHCP requires that Complera be prescribed by an Immunology Clinic physician with current American Academy of HIV medicine (AAHIVM) certification or a physician boarded in Infectious Disease.

Dosing: Adult:
HIV: Oral: One tablet once daily Emtricitabine 200 mg, rilpivirine 25 mg, and tenofovir disoproxil fumarate 300 mg) with food

NOTE: Do not use in patients with HIV RNA ≥100,000 copies/mL and/or CD4 count ≤200 cells/mm^3

Adverse Reactions:
>10%-Cholesterol increased, LDL increased, ALT increased, AST increased
Other Severe Less Common Reactions: lactic acidosis, hepatomegaly, nephrotoxicity, rhabdomyolysis, myopathy, osteomalacia, fractures, pancreatitis, neutropenia, immune reconstitution syndrome, autoimmune disorders, hypersensitivity reaction, depression, suicidality, fat redistribution. Lactic acidosis and severe hepatomegaly, sometimes fatal.
Contraindications:

Concurrent use of carbamazepine, dexamethasone (>1 dose), oxcarbazepine, phenobarbital, phenytoin, proton pump inhibitors (PPIs), rifabutin, rifampin, rifapentine or St. John's wort. Renal impairment Cl_{cr} <50 mL/minute, ESRD requiring dialysis.

U.S. Boxed Warning:
Severe acute exacerbations of hepatitis B in patients who are coinfected with HBV and HIV-1 (requires monitoring of co-infected patients for several months)

References:

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2. Cohen CJ, Andrade-Villanueva J, Clotet B, et al, "Rilpivirine Versus Efavirenz With Two Background Nucleoside or Nucleotide Reverse Transcriptase Inhibitors in Treatment-Naive Adults Infected with HIV-1 (THRIVE): A Phase 3, Randomized, Non-Inferiority Trial," *Lancet*, 2011, 378(9787):229-37. [PubMed 21763935]
3. DHHS 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," February 12, 2013;1-267. Available at http://www.aidsinfo.nih.gov
4. DHHS, "Supplemental Information Regarding the Role of Rilpivirine (RPV) as Initial Therapy – August 16, 2011." Available at: http://aidsinfo.nih.gov/contentfiles/NNRTI_One_Page_Info-RPV.pdf
5. MacArthur RD, "Clinical Trial Report: TMC278 (Rilpivirine) versus Efavirenz as Initial Therapy in Treatment-Naive, HIV-1-Infected Patients," *Curr Infect Dis Rep*, 2011, 13(1):1-3. [PubMed 21308448]
6. Molina JM, Cahn P, Grinsztejn B, et al, "Rilpivirine Versus Efavirenz With Tenofovir and Emtricitabine in Treatment-Naive Adults Infected With HIV-1 (ECHO): A Phase 3 Randomized Double-Blind Active-Controlled Trial," *Lancet*, 2011, 378(9787): 238-46. [PubMed 21763936]
7. Pozniak AL, Morales-Ramirez J, Katabira E, et al, "Efficacy and Safety of TMC278 in Antiretroviral-Naïve HIV-1 Patients: Week 96 Results of a Phase IIb Randomized Trial," *AIDS*, 2010, 24(1):55-65. [PubMed 19926964]
8. www.uptodate.com: Rilpivirine, emtricitabine and tenofovir: Drug information
9. www.epocrates.com: Complera (emtricitabine/rilpivirine/tenofovir disoproxil) Drug information
10. *Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2022 recommendations of the International Antiviral Society-USA Panel. JAMA. 2023;329(1):63-84.*
11.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
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