MEDICATION POLICY

Generic Name: Elvitegravir/Cobicistat/Emtricitabine/Tenofovir disoproxil

Therapeutic Class or Brand Name: Stribild®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 7/14/14 **Date Last Reviewed/Revised:** 10/13/16

GPI Code: 1210990430

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of HIV-1 infection.

II. Documentation of one of the following A or B:

A. Resistance test (obtained within the past 3 months) demonstrating virologic susceptibility to all of the following components of Stribild®: elvitegravir, emtricitabine, and tenofovir.

B. Plasma viral load < 200 copies/mL if patient is already stable on Stribild®.

III. Minimum age requirement: 18 years old.

Exclusion Criteria:

- Stribild® should not be coadministered with other anti-retroviral products such as Atripla®, Complera®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Truvada®, Tybost®, Viread®, Vitekta®, lamivudine-containing products (Combivir®, Epivir®, Epivir-HBV®, Epzicom®, Triumeq®, Trizivir®), ritonavir-containing products (Norvir®, Kaletra®), or Hepsera®.
- Coadministration of Stribild® is contraindicated with drugs that are highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life threatening events. These drugs and other contraindicated drugs (which may lead to reduced efficacy of Stribild® are listed in the table below:

Drug Class	Drugs within class that are contraindicated with Stribild®
Alpha 1-Adrenoreceptor Antagonist	Alfuzosin
Anticonvulsants	Carbamazepine, Phenobarbital, Phenytoin
Antimycobacterial	Rifampin
Antipsychotic	Lurasidone, pimozide
Ergot Derivatives	Dihydroergotamine, Ergotamine, Methylergonovine
GI Motility Agent	Cisapride

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.

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Drug Class	Drugs within class that are contraindicated with Stribild®
Herbal Products	St. John's wort (*Hypericum perforatum*)
HMG-CoA Reductase Inhibitors	Lovastatin, Simvastatin
Phosphodiesterase-5 (PDE-5) Inhibitor	Sildenafil when dosed as Revatio® for the treatment of pulmonary arterial hypertension
Sedative/hypnotics	Triazolam, Orally administered midazolam

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 30 tablets per 30 days.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.
2. http://www.aetna.com/products/rxnonmedicare/data/2014/ID/antiviral-hiv.html.
3. https://masshealthdruglist.ehs.state.ma.us/MHDL/pubtheradetail.do?id=108&drugId=2648.
4. Medi-Span.
5. http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/stribild/stribild_pi.ashx.

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Historical Tracking Of Changes Made To Policy	
10/13/2016	1. **Changed** "II. B. Plasma viral load < 500 copies/mL" **to** "Plasma viral load < 200 copies/mL if patient is already stable on Stribild®" **under Prior Authorization Criteria**. 2. **Removed** "III. Documentation of one of the following A or B: A. Failure (after a minimum of a one month trial), intolerance, or contraindication to Atripla®; B. Resistance test (obtained within the past 3 months) demonstrating virologic resistance to efavirenz" **from Prior Authorization Criteria**. 3. **Changed** "Stribild® should not be coadministered with other anti-retroviral products such as Atripla®, Complera®, Emtriva®, Truvada®, Tybost®, Viread®, Vitekta®, lamivudine-containing products, ritonavir-containing products, or Hepsera®" **to** "Stribild® should not be coadministered with other anti-retroviral products such as Atripla®, Complera®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Truvada®, Tybost®, Viread®, Vitekta®, lamivudine-containing products (Combivir®, Epivir®, Epivir-HBV®, Epzicom®, Triumeq®, Trizivir®), ritonavir-containing products (Norvir®, Kaletra®), or Hepsera®" **under Exclusion Criteria**. 4. **Changed** "Coadministered of Stribild® is contraindicated with any of drugs listed in the table below" **to** "Coadministration of Stribild® is contraindicated with drugs that are highly dependent on CYP3A4for clearance and for which elevated plasma concentrations are associated with serious and/or life threatening events. These drugs and other contraindicated drugs (which may lead to reduced efficacy of Stribild® are listed in the table below" **under Exclusion Criteria**. 5. **Added** "Antipsychotic: Lurasidone, pimozide" **to table under Exclusion Criteria**. 6. **Removed** "Neuroleptic: Pimozide" **from table under Exclusion Criteria**. 7. **Changed** "PDE5" **to** "PDE-5" **on table under Exclusion Criteria**. 8. **Removed** "http://www.bmchp.org/app_assets/antiretroviral-agents_20130930t000342_en_web_8088eaa2d4d241468758ec853fc27724.pdf" **from References** (link no longer valid).
8/22/2015	1. **Changed** "II. Documented resistance test (obtained within the past 3 months) demonstrating virologic susceptibility to all of the following components of Stribild®: elvitegravir, emtricitabine, and tenofovir" **to** "II. Documentation of one of the following A or B: A. Resistance test (obtained within the past 3 months) demonstrating virologic susceptibility to all of the following components of Stribild®: elvitegravir, emtricitabine, and tenofovir; B. Plasma viral load < 500 copies/mL" **under Prior Authorization Criteria**. 2. **Added** "Tybost®" and "Vitekta®" **to list following** "Stribild® should not be coadministered with other anti-retroviral products such as" **under Exclusion Criteria**. 3. **Added** "Anticonvulsants: Carbamazepine, Phenobarbital, Phenytoin" **to table under Exclusion Criteria**.

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