



Prior Authorization Criteria

STRIBILD® [elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate (DF)] PA CRITERIA

Stribild is a four-drug combination of elvitegravir, an HIV integrase strand transfer inhibitor, cobicistat, a CYP3A4 inhibitor, and emtricitabine and tenofovir DF, both HIV nucleoside analog reverse transcriptase inhibitors (HIV NRTI).

Indication: a complete regimen for the treatment of HIV-1 infection in adults and pediatric patient 12 years of age and older, who weighing at least 35 kg 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/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 Stribild.

Select the diagnosis:

HIV-1 infection ICD-10 code(s): _____

Initial requests for Stribild may be approved if ALL of the following criteria are met:
(Yes should be checked for each statement):

Yes No Age \geq 12 years

AND

Yes No Weight \geq 35 kg

AND

Yes No CrCl \geq 70 mL/minute

AND

Yes No Antiretroviral treatment-naïve **OR** virologically-suppressed (HIV-1 RNA $<$ 50 copies/mL) on a stable antiretroviral regimen for \geq 6 months.

AND

Yes No Resistance testing within the past 3 months demonstrating virologic susceptibility to all of the following components of Stribild: elvitegravir, emtricitabine and tenofovir DF.

AND

Yes No Patient tested positive for the HLA-B*5701 allele.

OR

Patient has pre-existing cardiovascular disease or significant risk factors for development of cardiovascular disease.

OR

Patient has severe hyperlipidemia

OR

Patient exhibits resistance, or experienced intolerance to an adequate trial (at least 1 month) of alternative therapies.

AND



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- Yes No Will not be co-administered with alfuzosin, carbamazepine, cisapride, ergot derivatives (eg, dihydroergotamine, ergotamine, methylergonovine), lovastatin, lurasidone, midazolam (oral), phenobarbital, phenytoin, pimozide, rifampin, sildenafil (for the treatment of pulmonary arterial hypertension), simvastatin, St John's wort, or triazolam

Provide the reason(s) why a preferred agent cannot be used:

Authorization is for 12 months.

Please list medications tried or failed, and/or any other information the physician feels is important to this review:

Reauthorization:

Yes No A documented viral load assay and CD4 count indicating that the patient is stable on Stribild (stable or increase in CD4 counts AND viral load <50 copies/ml)

Yes No CrCl >50 mL/minute

Additional information to consider: Stribild should not be considered for use if:

- Co-infection with HIV-1 and Hepatitis B Virus
- The patient has osteoporosis
- Severe hepatic impairment (Child-Pugh Class C)