



Manual Prior Criteria

TYBOST™ (cobicistat) PA CRITERIA:

[CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen)]

Select the diagnosis:

HIV-1 infection

ICD-10 code(s): _____

Requests for Tybost (cobicistat) may be approved if the following criteria are met: (*Yes should be checked for each statement*):

- Yes No Age \geq 18 years.
- Yes No Will be co-administered with atazanavir or once-daily darunavir.
- Yes No No concomitant use of cobicistat with atazanavir or darunavir with alfuzosin, carbamazepine, cisapride, colchicine (in patients with renal and/or hepatic impairment), dronedarone, ergot derivatives (eg, dihydroergotamine, ergotamine, methylergonovine), lovastatin, lurasidone, midazolam (oral), phenobarbital, phenytoin, pimozide, ranolazine, rifampin, sildenafil (when used for pulmonary arterial hypertension), simvastatin, St. John wort, triazolam; concomitant use of cobicistat and atazanavir with indinavir, irinotecan, or nevirapine.

Authorization is for 12 months. Quantity Limit: 30 tablets every 30 days.

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

Reauthorization: If this is a reauthorization request, answer the following question:

Yes No Is there documentation of positive clinical response to therapy [stable or increase in CD4 counts and virologically-suppressed (HIV-1 RNA <50 copies/mL)]

Additional information to consider:

Tybost (cobicistat) should not be considered for use if:

- Co-administered with tenofovir DF in patients with CrCl <70 mL/min
- Antiretrovirals that are Not Recommended in Combination with Tybost [5.4]
 - More than one antiretroviral that requires pharmacokinetic enhancement (i.e., two protease inhibitors or a protease inhibitor in combination with elvitegravir)
 - Darunavir in combination with efavirenz, nevirapine, or etravirine
 - Atazanavir in combination with etravirine
 - Atazanavir in combination with efavirenz in treatment-experienced patients
 - Darunavir 600 mg twice daily
 - Other HIV-1 protease inhibitors including fosamprenavir, saquinavir, or tipranavir
 - Combination drugs or regimens containing ritonavir