Tybost (cobicistat)
Policy Number: C7081-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2015	11/6/2019	11/6/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q1 2020 20200122C7021-A

PRODUCTS AFFECTED:
Tybost (cobicistat)

DRUG CLASS:
Antiviral/Anti-Infective Agent/Pharmacokinetic Enhancer

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Tybost 150 mg Tablet

FDA-APPROVED USES:
Indicated to increase systemic exposure of once daily darunavir or atazanavir in combination with other antiretroviral agents in the treatment of HIV-1 infection.

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: HIV-1 infection

REQUIRED MEDICAL INFORMATION:
A. HIV TREATMENT:

1. Documentation of HIV diagnosis with baseline CD4 count and viral load
   AND
2. Documented use with Reyataz (atazanavir) 300 mg daily or Prezista (darunavir) 800mg daily
   AND
3. Documentation of a trial/failure, contraindication, or intolerance to Norvir (ritonavir) as the pharmacologic booster.
   AND
4. If combined with tenofovir DF or combination products containing Viraead (tenofovir DF): Baseline creatinine clearance ≥ 70 mL/min (Coadministration not recommended if CrCl < 70 ml/min)

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

QUANTITY:
1 tablet daily, 30 day supply

PRESCRIBER REQUIREMENTS:
Prescribed by or in consult with an HIV specialist or infectious disease specialist

AGE RESTRICTIONS:
18 years of age or older

CONTINUATION OF THERAPY:
A. HIV TREATMENT:

1. Documentation of continued use of atazanavir 300 mg daily or darunavir 800mg daily
   AND
2. Continued or persistent viral load reduction or undetectable viral load, with a minimum 0.5 log decrease in the viral load from baseline and a minimum 25% increase in CD4 count.
   AND
3. If combined with tenofovir DF or combination products containing tenofovir DF: Baseline creatinine clearance ≥ 70 mL/min (Coadministration not recommended if CrCl < 70 ml/min).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Tybost are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindicated if the patient is also receiving any of the following: Any fixed-dose combination tablets that contain cobicistat (Stribild or Genvoya), Atazanavir in combination with efavirenz in treatment-experienced patients, Atazanavir in combination with etravirine, Concomitant use with any drug that are contraindicated due to the potential for serious and/or life-threatening events or loss of therapeutic effect: Darunavir 600 mg twice daily, Darunavir in combination with efavirenz, nevirapine, or etravirine, Lopinavir/ritonavir or regimens containing ritonavir. More than one antiretroviral that requires pharmacokinetic enhancement (i.e., two protease inhibitors or a protease inhibitor in combination with elvitegravir). Other HIV-1 protease inhibitors including fosamprenavir, saquinavir, or tipranavir

OTHER SPECIAL CONSIDERATIONS:
Pregnancy: Cobicistat-containing regimens are not recommended for use in pregnant women as inadequate cobicistat concentrations, as well as viral breakthroughs, have been reported during the 2nd and 3rd trimesters.

BACKGROUND:
Tybost (cobicistat) is a mechanism-based inhibitor of cytochrome P450 3A (CYP3A). It is indicated to be used as protease inhibitor enhancer with only atazanavir and the once daily formulation of darunavir. False elevations in serum creatinine have been reported in patients taking Tybost. It is hypothesized that Tybost inhibits tubular secretion of creatinine without affecting actual renal glomerular function. Additional monitoring may be required if Tybost is used in a patients ART regimen that contains tenofovir DF. Tenofovir is principally eliminated by the kidney and renal impairment, including cases of acute renal failure and Fanconi syndrome, have been reported with the use of tenofovir DF. In addition, Tybost coadministered with tenofovir DF is not recommended in

patients who have an estimated creatinine clearance below 70 mL/min because dose adjustment of tenofovir DF is required below 50 mL/min and such dose adjustments have not been established for coadministration with Tybost.

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. TYBOST® (cobicistat) tablets, for oral use [Package insert]. Foster City, CA: Gilead Sciences, Inc; 2017.
2. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf
3. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Transmission in the United States. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/ PerinatalGL.pdf. Accessed (July, 12th 2018).