MEDICATION POLICY

Generic Name: Darunavir-Cobisistat/Emtricitabine/Tenofovir Alafenamide

Therapeutic Class or Brand Name: Symtuza®

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

Date of Origin: 7/30/2018 **Date Last Reviewed/Revised:** N/A

GPI Code: 1210990420

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

I. Adult patient with documented diagnosis of HIV- 1 infection

II. Patient fulfills ONE of the following criteria A or B:

A. Patient has no history of prior antiretroviral treatment

B. Patient has been on a stable antiretroviral regimen for at least six months with virological suppression (HIV-1 RNA less than 50 copies/mL AND has no known drug substitutions associated with resistance to darunavir or tenofovir

Exclusion Criteria:

- Coadministration of Symtuza with the following drugs are contraindicated:

Drug Class	Drug(s) Within Class
Alpha 1-adrenoreceptor antagonist	Alfuzosin
Antianginal	Ranolazine
Antiarrhythmic	Dronedarone
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin
Anti-gout	Colchicine (in patients with renal/hepatic impairment)
Antimycobacterial	Rifampin
Antipsychotics	Lurasidone, pimozide
Ergot derivatives	dihydroergotamine, ergotamine, methylergonovine
GI motility agent	Cisapride
Herbal product	St. John's Wort
Hepatitis C direct acting antiviral	Elbasvir/grazoprevir
HMG-CoA reductase inhibitors	Lovastatin, simavastatin
PDE-5 inhibitor	Sildenafil (for treatment of pulmonary artery hypertension
Sedatives/hypnotics	Midazolam (oral), triazolam

MEDICATION POLICY

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 progess notes showing current medical necessity criteria are met and the medication is effective.

Appendix:

N/A

References:

1. http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SYMTUZA-pi.pdf