

Generic Name: Dolutegravir sodium/Rilpivirine hydrochloride

Therapeutic Class or Brand Name: Juluca™

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 121099022803

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/23/2018

Date Last Reviewed / Revised: 5/22/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of HIV-1 infection.
- II. Patient has been treated with a stable antiretroviral medication regimen for at least the past 6 months and criteria A through C are met:
 - A. Patient is virologically suppressed, with HIV-1 RNA < 50 copies/mL
 - B. No history of treatment failure on current regimen.
 - C. Patient has no previous history of resistance to any of the individual components of Juluca™ (dolutegravir and rilpivirine).
- III. Juluca™ will be used to replace the current maintenance antiretroviral medication regimen (current regimen will be discontinued once treatment with Juluca is initiated).

EXCLUSION CRITERIA

- Juluca™ should not be administered with any other antiretroviral products.
- Juluca™ should not be administered to patients who are newly diagnosed with HIV-1 infection and who have never been previously treated with antiretrovirals.
- Coadministration of Juluca™ is contraindicated with the following drugs:

Drug Class	Drugs within class
Antiarrhythmics	Dofetilide
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital, oxcarbazepine
Antimycobacterials	Rifampin, rifapentine
Herbal Supplements	St. John's wort (<i>Hypericum perforatum</i>)
Glucocorticoid (systemic)	Dexamethason (more than a single-dose treatment)
Proton-Pump Inhibitors	Esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

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 the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Juluca/pdf/JULUCA-PI-PIL.PDF .
2. <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0> .
3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/22/2019	1. Policy reviewed – no changes.
5/23/2018	1. Medication Policy created.

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 judgement in providing the most appropriate care for their patients.