

Generic Name:
Bictegravir/Emtracitabine/Tenofovir Alfenamide

Therapeutic Class or Brand Name: Biktarvy®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 12109903240330

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2018

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of HIV-1 infection.
- II. Documentation of one of the following A or B AND must meet criteria listed under each treatment category:
 - A. Patient has no treatment history with antiretrovirals.
 - B. Patient is currently being treated with antiretrovirals for at least 3 months and documentation of criteria 1 through 3 are met:
 1. Virologically-suppressed with HIV-1 RNA < 50 copies/mL .
 2. No history of treatment failure.
 3. Resistance test (obtained within past 3 months) demonstrating virologic susceptibility to all of the following components of Biktarvy: bictegravir, emtracitabine and tenofovir.
- III. Minimum age requirement :18 years old

EXCLUSION CRITERIA

- Biktarvy® should not be administered with any other antiretroviral products.
- Coadministration of Biktarvy® is contraindicated with dofetilide and rifampin.

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. http://www.gilead.com/~media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.pdf .
2. <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/Of> .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/18/2018	1. 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.