GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF)

Baseline Resistance Testing

This document is in response to your request for information regarding Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) and resistance testing at the time of treatment initiation. This document includes content from or references to clinical practice guidelines, and the inclusion of these guidelines should not be interpreted as a treatment recommendation or an endorsement of the guidelines by Gilead Sciences.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warning are available at: www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Product Labeling[1]

Indications and usage

BIC/FTC/TAF is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥14 kg:

- with no antiretroviral (ARV) treatment history, or
- with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, FTC, or tenofovir, or
- to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to BIC or tenofovir.

Testing when initiating and during treatment with BIC/FTC/TAF

Testing for drug resistance prior to or when initiating BIC/FTC/TAF is not currently discussed in the Biktarvy US Prescribing Information (Section 2.1 Testing When Initiating and During Treatment with BIKTARVY).

Clinical Practice Guidelines

Please refer to the US Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV for further recommendations on drug resistance testing in ARV-naïve and virologically suppressed, treatment-experienced patients: https://clinicalinfo.hiv.gov/en/guidelines.

Additionally, please refer to the International Antiviral Society-USA Guidelines for Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults:

2024 Recommendations for further recommendations on baseline resistance testing: https://pubmed.ncbi.nlm.nih.gov/39616604/

Reference

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning, please refer to the Biktarvy US Prescribing Information available at: www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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