

# LEARN ABOUT THE HIV LIFE CYCLE

AND HOW BIKTARVY® WORKS

Have your clients ask their healthcare provider if BIKTARVY is right for them.

BIKTARVY is a complete, 1-pill, once-a-day prescription medicine used to treat HIV-1 in adults and children who weigh at least 31 pounds. It can either be used in people who have never taken HIV-1 medicines before, or people who are replacing their current HIV-1 medicines and whose healthcare provider determines they meet certain requirements.

BIKTARVY does not cure HIV-1 or AIDS. HIV-1 is the virus that causes AIDS.

### **IMPORTANT SAFETY INFORMATION**

What is the most important information I should know about BIKTARVY?

#### **BIKTARVY may cause serious side effects:**

▶ Worsening of hepatitis B (HBV) infection. Your healthcare provider will test you for HBV. If you have both HIV-1 and HBV and stop taking BIKTARVY, your HBV may suddenly get worse. Do not stop taking BIKTARVY without first talking to your healthcare provider, as they will need to monitor your health, and may give you HBV medicine.

### Who should not take BIKTARVY?

#### Do not take BIKTARVY if you take:

▶ dofetilide ▶ rifampin ▶ any other medicines to treat HIV-1

# HELP YOUR CLIENTS UNDERSTAND HOW HIV TREATMENT WORKS



### **UNDERSTANDING TREATMENT CLASSES**

Treatments that fight HIV in similar ways are grouped together in something called a treatment class. Most HIV treatment classes fight the virus at a single step in the HIV life cycle. According to the US Department of Health and Human Services (DHHS), to effectively fight HIV, a complete treatment regimen generally includes 3 medicines from 2 or more treatment classes.



### TREATMENT CLASSES & RESISTANCE

Sometimes, HIV can develop resistance to 1 or more medicines your clients are taking, which means that the medicine and others in that drug class may no longer work. Using different classes of HIV treatments as part of a complete regimen and taking treatment as prescribed to stay undetectable may help keep HIV from developing resistance to your clients' treatment regimen. Resistance is permanent, irreversible, and can significantly limit a person's treatment options.



### HIGH BARRIER TO RESISTANCE

A medicine's barrier to resistance refers to how well it works, even when the virus has mutated or changed. That's why it's important for your clients to take their HIV treatment as prescribed and have a treatment with a high barrier to resistance, which means the treatment may still work even if HIV has changed.

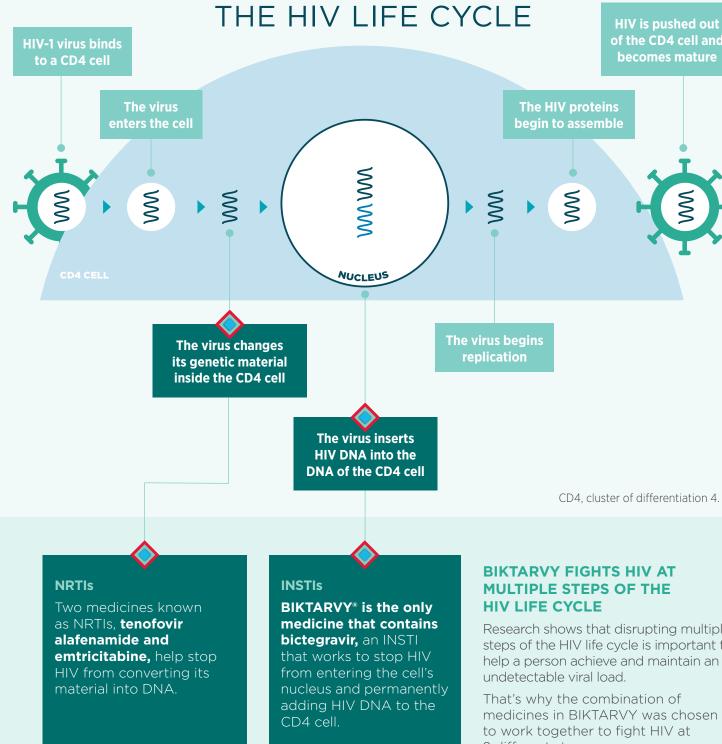
### TREATMENT CLASSES IN BIKTARVY®

- **♦ NRTI = nucleoside reverse transcriptase** inhibitors. A class of drugs used to treat HIV. The two NRTIs in BIKTARVY are called tenofovir alafenamide and emtricitabine.
- **◆ INSTI = integrase strand inhibitors.** A class of drugs used to treat HIV. The INSTI in BIKTARVY is called bictegravir.

### **IMPORTANT SAFETY INFORMATION** (cont'd) What are the other possible side effects of BIKTARVY?

### Serious side effects of BIKTARVY may also include:

- ▶ Changes in your immune system. Your immune system may get stronger and begin to fight infections that may have been hidden in your body. Tell your healthcare provider if you have any new symptoms after you start taking BIKTARVY.
- ▶ Kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys. If you develop new or worse kidney problems, they may tell you to stop taking BIKTARVY.
- Too much lactic acid in your blood (lactic acidosis), which is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.



◆ **CD4 cells** are an important part of the immune system

that help the body fight infections.

### **BIKTARVY FIGHTS HIV AT MULTIPLE STEPS OF THE**

Research shows that disrupting multiple steps of the HIV life cycle is important to help a person achieve and maintain an undetectable viral load.

That's why the combination of medicines in BIKTARVY was chosen to work together to fight HIV at 2 different steps.

Taking treatment as prescribed and taking a treatment with a high barrier to resistance, like BIKTARVY, can help reduce the risk of drug resistance.

## BIKTARVY® WAS DESIGNED TO ATTACK THE VIRUS RIGHT AWAY



The unique combination of medicines in BIKTARVY was designed to attack the virus right away and work together to lower the amount of HIV in your clients' blood to undetectable levels.



According to the DHHS guidelines, many patients can get to undetectable in as quickly as 8 to 24 weeks when taking their treatment as prescribed. Some people are even able to start treatment the same day as diagnosis.

BIKTARVY is the only INSTI-based single-tablet treatment recommended by the DHHS guidelines for a same-day start for those who meet certain criteria. Your clients should work with their healthcare provider to see if BIKTARVY is right for them.

### **IMPORTANT SAFETY INFORMATION** (cont'd)

### What are the other possible side effects of BIKTARVY? (cont'd)

Serious side effects of BIKTARVY may also include: (cont'd)

▶ Severe liver problems, which in rare cases can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

The most common side effects of BIKTARVY in clinical studies were diarrhea (6%), nausea (6%), and headache (5%). Tell your healthcare provider if you have any side effects that bother you or don't go away.

### What should I tell my healthcare provider before taking BIKTARVY?

- All your health problems. Be sure to tell your healthcare provider if you have or have had any kidney or liver problems, including hepatitis virus infection.
- ▶ All the medicines you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements. BIKTARVY and other medicines may affect each other. Keep a list of all your medicines and show it to your healthcare provider and pharmacist, and ask if it is safe to take BIKTARVY with all of your other medicines.
- If you are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant while taking BIKTARVY.
- If you are breastfeeding (nursing) or plan to breastfeed. Talk to your healthcare provider about the risks of breastfeeding during treatment with BIKTARVY.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.





# TALK TO YOUR CLIENTS ABOUT HOW BIKTARVY® WORKS.



Scan or visit BIKTARVY.com to learn more.

Please see Important Facts about BIKTARVY, including important warnings, on page 4.





### (bik-TAR-vee)

### MOST IMPORTANT INFORMATION ABOUT BIKTARVY

#### **BIKTARVY** may cause serious side effects, including:

 Worsening of hepatitis B (HBV) infection. Your healthcare provider will test you for HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking BIKTARVY. Do not stop taking BIKTARVY without first talking to your healthcare provider, as they will need to check your health regularly for several months, and may give you HBV medicine.

#### **ABOUT BIKTARVY**

BIKTARVY is a complete, 1-pill, once-a-day prescription medicine used to treat HIV-1 in adults and children who weigh at least 31 pounds. It can either be used in people who have never taken HIV-1 medicines before, or people who are replacing their current HIV-1 medicines and whose healthcare provider determines they meet certain requirements.

**BIKTARVY does not cure HIV-1 or AIDS.** HIV-1 is the virus that causes AIDS.

### Do NOT take BIKTARVY if you also take a medicine that contains:

- · dofetilide
- rifampin
- · any other medicines to treat HIV-1

#### **BEFORE TAKING BIKTARVY**

### Tell your healthcare provider all your medical conditions, including if you:

- Have or have had any kidney or liver problems, including hepatitis infection.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed.
   Talk to your healthcare provider about the risks of breastfeeding during treatment with BIKTARVY.

# Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-thecounter medicines, antacids, laxatives, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that interact with BIKTARVY.

### **IMPORTANT FACTS**

This is only a brief summary of important information about BIKTARVY® and does not replace talking to your healthcare provider about your condition and your treatment.

### POSSIBLE SIDE EFFECTS OF BIKTARVY

### BIKTARVY can cause serious side effects, including:

- Those in the "Most Important Information About BIKTARVY" section.
- · Changes in your immune system.
- New or worse kidney problems, including kidney failure.
- Too much lactic acid in your blood (lactic acidosis), which is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- Severe liver problems, which in rare cases can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.
- The most common side effects of BIKTARVY in clinical studies were diarrhea (6%), nausea (6%), and headache (5%).

These are not all the possible side effects of BIKTARVY. Tell your healthcare provider right away if you have any new symptoms while taking BIKTARVY.

Your healthcare provider will need to do tests to monitor your health before and during treatment with BIKTARVY.

### **HOW TO TAKE BIKTARVY**

Take BIKTARVY 1 time each day with or without food.

### **GET MORE INFORMATION**

- This is only a brief summary of important information about BIKTARVY. Talk to your healthcare provider or pharmacist to learn more.
- Go to BIKTARVY.com or call 1-800-GILEAD-5.
- If you need help paying for your medicine, visit BIKTARVY.com for program information.

