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HIV TREATMENT, PREVENTION, AND SUPPORT FROM **TPAN**
MARCH + APRIL 2018

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POSITIVELY AWARE 2018 22ND ANNUAL HIV DRUG GUIDE

YOUR RESOURCE

An A-to-Z handbook to the most commonly prescribed medications for treating HIV—with insight from an HIV specialist and an activist

THE PHARMACIST
Eric K. Farmer, PharmD

DR. FARMER IS an HIV clinical pharmacist at the Indiana University Health LifeCare Clinic at Methodist Hospital in Indianapolis. He was instrumental in starting formal clinical pharmacy services in 2009 at LifeCare, one of the largest providers of HIV medical services in the state of Indiana. At LifeCare, Dr. Farmer provides pharmacy services that include medication adherence counseling and patient education, drug information services, medication procurement, medication therapy management, and medical care coordination services. He currently serves as a clinical preceptor for APPE students, PGY1 residents, and PGY2 residents at IU Health and is on the clinical faculty of the Midwest AIDS Training and Education Center. He is involved in the PGY2 ID Residency Advisory Committee as well as the Indiana HIV/STD Advisory Council with the Indiana State Department of Health. Dr. Farmer graduated from Butler University with his Doctor of Pharmacy in 2007. He then completed an ASHP-accredited PGY1 pharmacy residency at Eskenazi Health (formerly Wishard Health Services) in Indianapolis, and subsequently an ASHP-accredited PGY2 HIV specialty pharmacy residency at the Center for HIV/AIDS Care and Research at Boston Medical Center.

THE ASSOCIATE EDITOR
Enid Vázquez

POSITIVELY AWARE Associate Editor Enid Vázquez earned her B.A. in journalism from the University of Wisconsin-Madison. She became interested in health reporting because of the importance it has on people's lives. Enid considers herself privileged to be working on behalf of people living with HIV/AIDS, which she sees as a condition fueled as much by societal discrimination as by a virus. As such, it makes her reporting socio-political as well as medical. She enjoys medical updates that help extend not just life, but improve quality of life, for readers. Enid has a special interest in sexual violence and sexual freedom, and in serving the sex trade worker and transgender communities. She thanks pharmacist Eric Farmer, coworkers, and others for their patience as she took time out to help her family in Puerto Rico in the aftermath of Hurricane Maria.

THE DOCTOR
W. David Hardy, MD

DR. HARDY SERVES as Senior Director of Evidence-based Practices (Research), ACTG clinical research site (CRS) leader, MACS site Principle Investigator, DC Cohort site co-principal investigator, and HIV/primary care provider at Whitman-Walker Health in Washington, D.C. He holds academic appointments as Clinical Professor of Medicine at George Washington University School of Medicine and Health Sciences and Adjunct Professor of Medicine at Johns Hopkins University School of Medicine. From 2002 to 2013 he served as Director, Division of Infectious Diseases at Cedars-Sinai Medical Center and Professor of Medicine at the David Geffen School of Medicine at UCLA. Dr. Hardy served as chief medical officer for Calimmune (2013-2015), a small, California-based and funded (CIRM), translational science company investigating gene-modified CD4+ T cells and hematopoietic stem cells as a potential cure for HIV infection. He has cared for people living with HIV since 1982, conducted research on HIV and related diseases since 1984, serves as Chair-Elect of the Board of Directors of the HIV Medicine Association (HIVMA) and Chair of the Education Committee of the American Academy of HIV Medicine (AAHIVM).

THE ACTIVIST
Moisés Agosto-Rosario

Moisés is a longtime treatment advocate and educator for people living with HIV/AIDS. A frequent public speaker and writer in both English and Spanish, Moisés has played a crucial role in ensuring that communities of color have equal access to care, treatment, and lifesaving information and has won numerous awards for his work with the HIV community. He is currently the Director of Treatment for the National Minority AIDS Council (NMAC). Before joining NMAC, Moisés served as the editor of *SIDA Ahora*, the Spanish publication of the People with AIDS Coalition of New York, and was an active member of ACT UP. He also worked as project manager for the International Treatment Preparedness Coalition (ITPC) with the HIV Collaborative Fund for HIV Treatment Preparedness, a project of the Tides Center. In this role, he was responsible for programs around the world. He has also served as the Vice President and Managing Director for Community Access, a Nelson Communications Company and member of the Publicis Healthcare Group. Moisés graduated from the University of Puerto Rico in Rio Piedras with a B.A. in Literature and Education.

AGOSTO-ROSARIO BY JONATHAN TIMMES · VÁZQUEZ BY JOHN GRESS

I am a latino, a student, and an HIV educator.
And I am living with HIV.

Let's stop HIV together.™
-Justin

Justin has lived with HIV since 2006.

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A WORLD POSITIVELY AWARE
OF HIV AND RELATED CONDITIONS.

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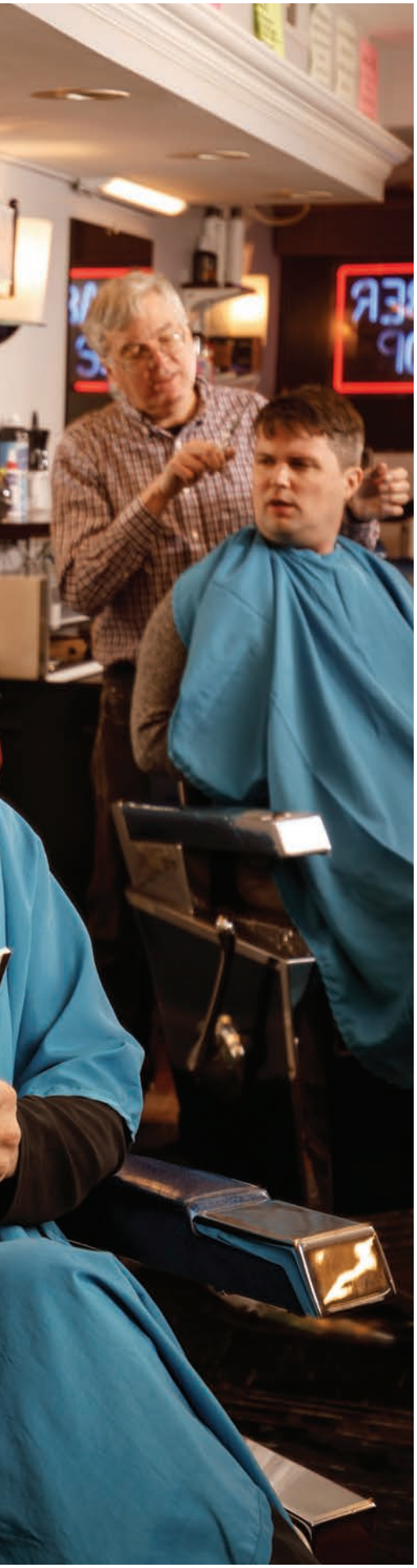
TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals gathered in a living room to share information and support in response to the HIV/AIDS epidemic. POSITIVELY AWARE is the expression of TPAN's mission to share accurate, reliable, and timely treatment information with anyone affected by HIV.

FROM LEFT: ANNETTE FIELDS, CARLOS PEREZ, TERRY LEWIS, AND SAM HOEHNLE PHOTOGRAPHED BY JOHN GRESS AT SLADE'S BARBERSHOP IN CHICAGO



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EVERY ISSUE

POSITIVELY AWARE 2018 22ND ANNUAL HIV DRUG GUIDE

ON THE COVER

Keith Marek, Shayvonna Albrecht, LeSherri James, D'Eva Longoria, Bruno Mondello, Michael McNamara, Jimmy Simpson, Angelique Munro, Chad Hendry, Terry Lewis, Sam Hoehnle, Annette Fields, and Carlos Perez, photographed by John Gress at Slade's Barbershop in Chicago. Read what they have to say; go to PAGE 81.

Gay parenthood

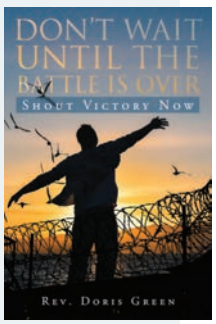
After our report on gay and HIV-positive parents in the January + February issue, Associate Editor Enid Vázquez came across *Gay Parent* magazine, "a leader in LGBTQ parenting resources since 1998." The issue listed camps specific to LGBT families, fertility options, and personal stories. Even the cover photos looked similar. Synchronicity.

Poz Cruise Retreat sets sail November 2018

The 14th annual Poz Cruise takes place November 11–18, 2018, sailing roundtrip from New Orleans to Cozumel, Hondoras, and Costa Maya. Founder and travel agent Paul Stalbaum said that more than 250 people from all over the U.S. and Canada attend the retreat, including spouses and other family members. In addition to fun, there are presentations providing valuable information to those living with HIV. Stalbaum said that more $60,000 in donations and scholarships have been raised to date. The cruise creates incredible bonding experiences each year. Rates begin at $649. Details at pozcruise.com.

New book from prison minister

Long-time HIV activist Rev. Doris Green, a prison minister featured in the July + August 2010 issue of Positively Aware, has published a new book, *Don't Wait Until The Battle Is Over: Shout Victory Now!* Rev. Green began ministering to incarcerated folks more than 30 years ago, when prison ministries were scarce. She writes, "When I first entered prison, I judged the people I met. I had been taught to. Ministries were for innocent victims like babies and orphans, not for people who had committed crimes. Or so I thought. But as the prisoners I met shared their life experiences with me, I began to understand how much we had in common. I had lived some of the very same experiences that the people in prison had lived. I, Evangelist Doris Green, could've been incarcerated!" According to her publisher, the book "is the story of how a liberatory prison ministry was built, and a record of the painstaking process through which incarcerated people make amends." Rev. Green is the founder of Men & Women in Prison Ministries/Universal House of Refuge Center. She served as the director of Correctional Health and Community Affairs at the AIDS Foundation of Chicago for 13 years. She helped launch the Faith Responds to AIDS (FRA) interfaith coalition in Chicago in 2006. *Don't Wait Until The Battle Is Over* is available wherever books are sold.



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EDITOR'S NOTE

JEFF BERRY

@PAeditor

BACK TO THE FUTURE

One pill, once a day. That's kind of been the HIV drug mantra ever since the first single-tablet regimen (STR) Atripla launched over 10 years ago. But it's something that has continuously been out of reach for me—until recently.

When I started antiretroviral therapy not long after being diagnosed in 1989, I was on one medication, but it was AZT—taken several times a day. That's all there was back then, and we now know that AZT by itself is suboptimal therapy, meaning it isn't effective at suppressing the virus, and leads to resistance when taken on its own.

I kept trying different suboptimal regimens but it wasn't until seven years later that I finally got on effective therapy, and it was difficult to take—one of the medications in my regimen came in the form of two pills three times a day, on an empty stomach, eight hours apart, while drinking 64 ounces of water daily. I ended up in the hospital with kidney stones one summer after attending a street fair and not staying hydrated. The drugs in the regimens that followed either caused massive diarrhea, rash, or nightmares—not to mention the body changes caused by lipodystrophy from some of the older drugs.

Most of that is gone in the regimens available today for those newly diagnosed, many of which are one pill, once a day, with few side effects. But that one pill, once a day "holy grail" remains elusive for many of us who have been living with HIV for a number of years, and have been through a lot of different HIV medications—the term used for us is treatment-experienced (it's nice to be experienced at something, I guess).

For the last three or four years I had finally settled into a regimen that consisted of two pills taken once a day, which was a huge improvement over some of those earlier regimens. When they recently combined those two pills into one, it was a big moment for me. Here I was, almost 30 years later, and finally I was on a one pill, once-a-day regimen (Juluca). Woo-hoo! Of course, I still had to take other pills (for high blood pressure, cholesterol, my vitamins), but suddenly there was a shift in how I perceived my HIV treatment. It was just so easy.

Some treatment-experienced individuals who are multi-drug resistant must still take handfuls of pills, sometimes multiple times a day, in order to manage their HIV. New drugs under investigation will help to address this by targeting HIV at different points in the lifecycle. Other drugs nearing approval later this year should be effective in some people who have developed resistance to existing drugs. The first single-tablet regimen (STR) with a protease inhibitor taken once daily may help improve adherence for those who struggle with it currently.

Many of us are anxiously awaiting the long-acting injectables that are now in development, and expected to be approved next year. Simplifying treatment by using only two drugs instead of three is already happening, and more two-drug combinations are on the way. Whether there will be significant cost savings using generic versions of existing drugs remains to be seen, but more and more drugs are being approved as generic (as this issue went to press, a generic STR similar to Atripla was approved).

In this year's drug guide we've added information about cost-sharing and patient assistance programs for PrEP and PEP, as well as for those for HIV medications (see page 71). But changes may be on the way for consumers, as some big health insurers no longer allow the amount of the co-pay cards to be applied towards their deductible or out-of-pocket maximum, or steer them towards other cost-containing measures such as step therapy or individual generics that break up an STR. Stay tuned.

Dr. David Hardy joins us for the first time as the doctor for the 2018 HIV Drug Guide (is there a doctor in the house?), and talks about what lies ahead in "The Future of HIV Therapy" on page 12; renowned treatment advocate Moisés Agosto-Rosario provides the activist commentary; pharmacist Eric Farmer worked with Associate Editor Enid Vázquez on updating the HIV Drug Guide; and our beautiful cover and superb design of this issue come from creative director Rick Guasco and photographer John Gress.

The medications used to treat HIV have changed (thankfully), but the goal of therapy remains the same—to suppress the virus and get to undetectable. The benefits include not only improved health, but also the fact that you can't transmit HIV to others when you are on suppressive therapy and undetectable (U=U). That in turn helps break down the stigma often associated with HIV.

And that's a future we can all look forward to..

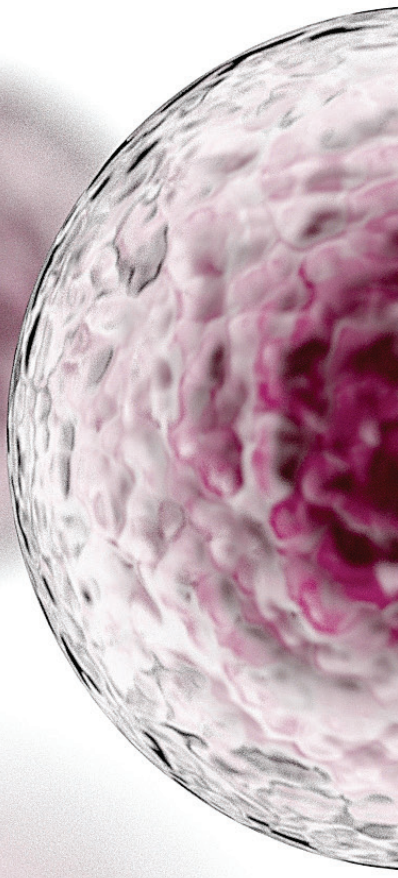
Take care of yourself and each other.

That one pill, once a day "holy grail" remains elusive for many of us who have been living with HIV for a number of years, and have been through a lot of different HIV medications—the term used for us is treatment-experienced.

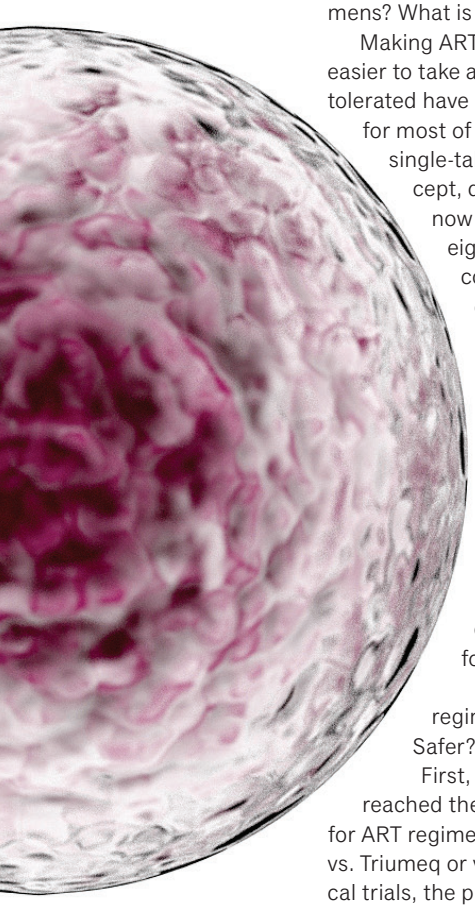
PHOTO: JOHN GRESS

THE FUTURE OF HIV THERAPY

New strategies are here—and more are on the way, says **W. David Hardy, MD**



The progress made over the past 20 years to improve antiretroviral (ART) regimens making them more potent, safer and better tolerated, simpler and easier to take, and less susceptible to viral resistance has been nothing short of spectacular. While some people may think that this progress is completed and that further improvements in ART regimens are unnecessary or a waste of resources, many others, including many people living with HIV (PLWH), think otherwise.



So what more can we expect as further refinements or enhancements to ART regimens? What is the future of ART?

Making ART regimens simpler and easier to take as well as safer and better-tolerated have been major driving forces for most of our newer regimens. The single-tablet regimen or STR concept, debuted with Atripla and now with six and soon-to-be eight more STRs, has made combination ART (cART), once almost impossible for many PLWH to take, a simple one-pill, once-a-day reality. More than almost any other advance, this "pharmaceutical magic" of squeezing three or four medications into one pill has revolutionized cART by conquering the once daunting, but essential, daily adherence challenge for most PLWH.

How then can ART regimens be further improved? Safer? Simpler? Or more potent?

First, we have most likely reached the peak in terms of potency for ART regimens. In the recent Biktarvy vs. Triumeq or vs. Tivicay + Descovy clinical trials, the proportion of (PLWHIV) who had undetectable viral loads after one year of treatment was over 90% in three of the four study arms in these trials (the fourth was 89%). Expecting a greater proportion of PLWH in large clinical trials to achieve undetectable viral loads is not realistic due to the small number of PLWH who will always have some side effects to any ART regimen as well as the usual "life events" which inevitably cause trial dropouts.

Can we make ART regimens simpler than one-pill once a day? The next quantum leap in this direction will be to decrease the frequency of taking (or administering) the ART regimen. More on this below.

So, we are left with improving the safety or tolerability of ART regimens. Since the beginning of modern (post–1996) ART development, we have progressively discarded older, more toxic anti-HIV agents in favor of newer, less toxic ones. (Aren't we all happy to have discarded AZT, ddI [Videx], d4T [Zerit], indinavir [Crixivan], nelfinavir [Viracept], and Kaletra?) The quest for safer, better-tolerated anti-HIV agents was significantly advanced with the development of TAF, the new and improved version of Viread (TDF). TAF, through more "pharmacologic magic," maintains the potency of Viread but markedly decreases the kidney and bone mineral toxicities of Viread. PLWH can now feel more confident that their ART regimen will not cause kidney failure or bone weakening and fractures as they suppress their HIV over many years to come.

But, can the safety of TAF be improved?

TWO-DRUG ART REGIMENS

A new ART strategy that PLWH will soon become familiar with, if they have not already, is treating HIV with two rather than three anti-HIV drugs. *What*?—many of you veterans are crying. Haven't we already and repeatedly tried to challenge the proven magic "ART number of three" and always been disappointed with the results never being as potent? So why try this failed strategy again?

All great points and questions.

One large and several small clinical trials have recently demonstrated the two-drug combination of a boosted protease inhibitor (e.g., Kaletra, Reyataz/Norvir, or Prezista/Norvir) plus just Epivir (3TC) can effectively suppress HIV as well as the same boosted protease inhibitor with two other drugs (e.g., Truvada). The advantage of such a two-drug regimen is the elimination of Viread (TDF) and decreased kidney and bone mineral toxicity. But the gastrointestinal and cholesterol-elevating side effects are still there with the boosted protease inhibitor. >>

Enter Tivicay (dolutegravir), the only integrase inhibitor whose potency and resistance to HIV resistance appears to be equal to that of a boosted protease inhibitor—without the gastrointestinal and cholesterol-elevating side effects.

In November 2017, the FDA approved the first two-drug STR regimen, Juluca, based on results from two large Phase 3 randomized clinical trials. In these studies, PLWH with undetectable viral loads receiving their first- or second-line ART regimen (NNRTI, boosted PI, or INSTI) without prior virologic failure, were assigned to switch to Juluca or stay on their current ART regimen. After a year, 95% of PLWH in both groups continued to have undetectable viral loads. It's important to point out that this was switch therapy, not first-line therapy. What's notable about Juluca is that it is the only STR that does not contain any NRTIs (our oldest class of anti-HIV drugs) but *does* contain what many believe is the most potent integrase inhibitor, Tivicay, and a "next-generation" NNRTI, Edurant (rilpivirine). Juluca is the smallest STR to date and is well-tolerated with few significant side effects.

But still, why two drugs instead of the time- and experience-tested three drugs in a combination ART regimen? One frequent explanation is that by eliminating one of the three drugs, potential toxicity will be decreased as well, hence, "less is more." Whether this is true has yet to be seen, but it does make intuitive sense. However, the "holy grail" principles of the three-drug ART regimen have always been potency, resistance to HIV resistance, and durability of nondetectability. Is Tivicay truly as potent as a boosted protease inhibitor with a high enough barrier to HIV resistance to maintain long-term undetectable viral load? Only time and great experience with Tivicay (dolutegravir)-containing regimens will answer this.

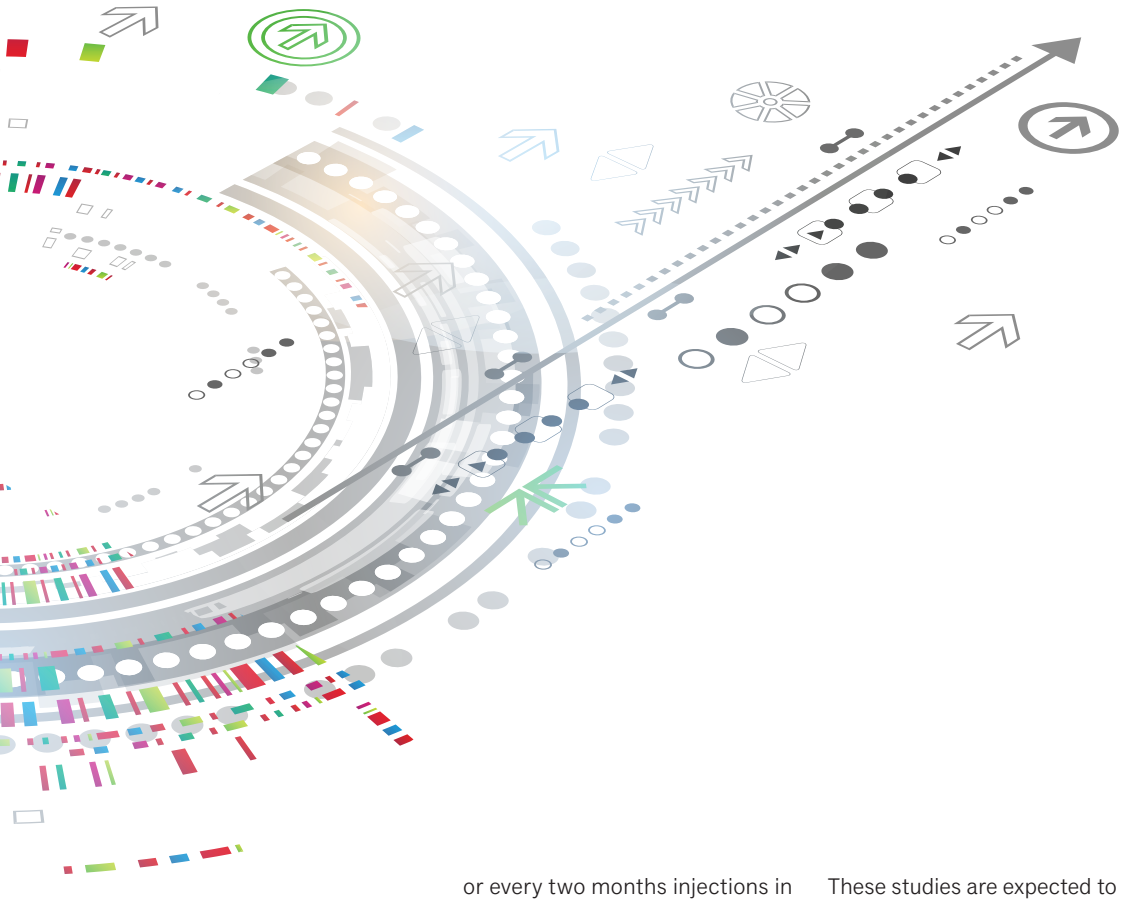
What can we expect in the not-too-distant future for further two-drug ART regimens?

Currently there are ongoing Phase 3 clinical trials of Tivicay plus Epivir (3TC), two for PLWH who are starting ART for the first time (GEMINI 1 & 2) and a single study for PLWH with undetectable viral loads receiving a TAF-containing ART regimen who will be assigned to switch to Tivicay plus Epivir or maintain their TAF-containing ART regimen (TANGO). The first-line trial is fully enrolled and will report out results later this year; the TANGO study is slated to begin enrollment in the first three months of 2018. Earlier Phase 2 studies of Tivicay and Epivir (first-line–ACTG 5353; switch–ASPIRE) have shown promising results with this two-drug ART regimen.

If this two-drug regimen is successful, one immediate casualty of the Tivicay plus Epivir ART regimen will be the loss of the need for Ziagen (abacavir). Given its controversial side effects (see HIV Drug Guide), losing it will not result in many tears.

LONG-ACTING INJECTABLE ART

As mentioned above, one strategy for making ART simpler and more convenient would be to change the frequency with which anti-HIV medications need to be taken or administered. Two investigational anti-HIV medications have been developed into long-acting injectable (into muscle)



ISTOCKPHOTO

forms and have completed testing in a successful Phase 2 study (LATTE-2) and are now in Phase 3 clinical trials.

Cabotegravir is an investigational integrase inhibitor similar to Tivicay. Edurant is already approved by the FDA as an oral anti-HIV (NNRTI) medication (see the HIV Drug Guide). Both have been developed into injectable forms which maintain high enough drug levels in the blood to suppress HIV and allow for monthly or every two months dosing.

This combination of co-administered (one injection of each drug in each butt muscle) monthly or once every two months is being studied for HIV treatment in the FLAIR (first-line ART) and ATLAS and ATLAS-2M (switch ART in PLWH with undetectable viral loads) studies. Results from the FLAIR and ATLAS studies may be released in late 2018. ATLAS-2M is slated to start enrollment in the first three months of 2018. The Phase 2 study (LATTE 2) showed very good HIV suppression and few generalized side effects, but almost 100% of the PLWH receiving the monthly or every two months injections in their butt muscles reported mild, short-term (2–5 days) "injection site reactions," consisting of pain, redness, and swelling where they received the injections.

Interestingly, the majority of PLWH in the study preferred the injections over their previous daily tablet ART regimens. This was reported to be due to greater convenience of monthly or every two months dosing, lack of being reminded daily of their HIV-positive status, and not having to remember and manage tablet prescriptions.

More will be revealed regarding this new way of receiving ART as results from the studies above become available.

It is important to note that injectable cabotegravir given every two months by itself is also being compared to Truvada for pre-exposure prophylaxis (PrEP) in two large studies being conducted by the HIV Prevention Trials Network (HPTN). HPTN 083 (for HIV-uninfected men and transgender women who have sex with men) and HPTN 084 (HIV-uninfected women in sub-Saharan Africa) are currently enrolling study participants. These studies are expected to enroll HIV-uninfected persons for several more months due to their large size (083 = 4500; 084 = 3200).

CONCLUSION

The quest to improve our currently available armamentarium of anti-HIV medications remains active and ongoing. While the number of entirely new anti-HIV drugs is limited (bictegravir and cabotegravir), the strategies for how we create new regimens and how we administer them is where the action is for the future. Although effective combination ART for HIV treatment is now over 20 years old, it is still evolving, growing, and improving. We look forward to the results of some of these new ART regimen strategies later this year and in years to come.

The future of ART remains bright. PA

W. DAVID HARDY, MD, is Senior Director of Evidence-based Practices at Whitman-Walker Health in Washington, D.C. and Adjunct Professor of Medicine at John Hopkins University School of Medicine.

Understanding drug interactions

Medicines help us feel better and stay healthy, but we need to be aware of potential drug interactions

A drug interaction is a reaction between two (or more) drugs (called a drug-drug interaction) or between a drug and a food or beverage (called a drug-food interaction). An existing medical condition can make certain drugs potentially harmful (called a drug-condition interaction). For example, taking a nasal decongestant if you have high blood pressure may cause an unwanted reaction.

Medicines help us feel better and stay healthy. But drug interactions can cause problems by reducing or increasing the action of a medicine or causing adverse (unwanted) side effects.

Are drug interactions a problem for people with HIV?

TREATMENT WITH HIV medicines (called antiretroviral therapy or ART) helps people with HIV live longer, healthier lives. But drug interactions, especially drug-drug interactions, can complicate HIV treatment.

Drug-drug interactions between HIV medicines are common, and may reduce or increase the concentration of an HIV medicine in the blood. This can make the affected HIV medicine less effective, or so strong that it causes dangerous side effects.

Drug-drug interactions between HIV medicines and other medicines may make hormonal birth control less effective. Women using hormonal contraceptives may need to use an additional or different method of birth control to prevent pregnancy.

Can drug-food interactions and drug-condition interactions affect people with HIV?

YES, THE USE of HIV medicines can lead to both drug-food interactions and drug-condition interactions.

Food or beverages can affect the absorption of some HIV medicines and increase or reduce the concentration of the medicine in the blood. Depending on the HIV medicine, the change in concentration may be helpful or harmful. Instructions for HIV medicines affected by food specify whether to take the medicine with or without food. (HIV medicines not affected by food can be taken with or without food.)

Pregnancy is a condition that can affect how the body processes HIV medicines.

Because of these pregnancy-related changes, dosing of an HIV medicine may change during different

CONTINUED ON PAGE 18 >>

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In adults with HIV on ART who have diarrhea not caused by an infection

Tired of planning your life around diarrhea?

Enough is Enough

Get relief. Pure and simple. Ask your doctor about Mytesi.

Mytesi (crofelemer):

- Is the **only** medicine FDA-approved to relieve diarrhea in people with HIV
- **Treats diarrhea differently** by normalizing the flow of water in the GI tract
- Has the same or fewer side effects as placebo in clinical studies
- Comes from a tree sustainably harvested in the Amazon Rainforest

What is Mytesi?

Mytesi is a prescription medicine that helps relieve symptoms of diarrhea not caused by an infection (noninfectious) in adults living with HIV/AIDS on antiretroviral therapy (ART).

Important Safety Information

Mytesi is not approved to treat infectious diarrhea (diarrhea caused by bacteria, a virus, or a parasite). Before starting you on Mytesi, your healthcare provider will first be sure that you do not have infectious diarrhea. Otherwise, there is a risk you would not receive the right medicine and your infection could get worse. In clinical studies, the most common side effects that occurred more often than with placebo were upper respiratory tract (sinus, nose, and throat) infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

For Copay Savings Card and Patient Assistance, see Mytesi.com

Mytesi® (crofelemer) 125 mg delayed-release tablets

RELIEF, PURE AND SIMPLE

Please see complete Prescribing Information at Mytesi.com.

NP-390-7

IMPORTANT PATIENT INFORMATION

This is only a summary. See complete Prescribing Information at Mytesi.com or by calling 1-844-722-8256. This does not take the place of talking with your doctor about your medical condition or treatment.

What Is Mytesi?

Mytesi is a prescription medicine used to improve symptoms of noninfectious diarrhea (diarrhea not caused by a bacterial, viral, or parasitic infection) in adults living with HIV/AIDS on ART.

Do Not Take Mytesi if you have diarrhea caused by an infection. Before you start Mytesi, your doctor and you should make sure your diarrhea is not caused by an infection (such as bacteria, virus, or parasite).

Possible Side Effects of Mytesi Include:

- Upper respiratory tract infection (sinus, nose, and throat infection)
- Bronchitis (swelling in the tubes that carry air to and from your lungs)
- Cough
- Flatulence (gas)
- Increased bilirubin (a waste product when red blood cells break down)

For a full list of side effects, please talk to your doctor. Tell your doctor if you have any side effect that bothers you or does not go away.

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.

Should I Take Mytesi If I Am:

Pregnant or Planning to Become Pregnant?

- Studies in animals show that Mytesi could harm an unborn baby or affect the ability to become pregnant
- There are no studies in pregnant women taking Mytesi
- This drug should only be used during pregnancy if clearly needed

A Nursing Mother?

- It is not known whether Mytesi is passed through human breast milk
- If you are nursing, you should tell your doctor before starting Mytesi
- Your doctor will help you to decide whether to stop nursing or to stop taking Mytesi

Under 18 or Over 65 Years of Age?

- Mytesi has not been studied in children under 18 years of age
- Mytesi studies did not include many people over the age of 65. So it is not clear if this age group will respond differently. Talk to your doctor to find out if Mytesi is right for you

What Should I Know About Taking Mytesi With Other Medicines?

If you are taking any prescription or over-the-counter medicine, herbal supplements, or vitamins, tell your doctor before starting Mytesi.

What If I Have More Questions About Mytesi?

For more information, please see the full Prescribing Information at Mytesi.com or speak to your doctor or pharmacist.

To report side effects or make a product complaint or for additional information, call 1-844-722-8256.

napo pharmaceuticals
a subsidiary of jaguar health

Rx Only

Manufactured by Patheon, Inc.
for Napo Pharmaceuticals, Inc. San Francisco, CA 94105

Mytesi comes from the *Croton lechleri* tree harvested in South America.

>> stages of pregnancy. But pregnant women should always consult with their health care providers before making any changes to their HIV regimens.

How can I avoid drug interactions?

TELL YOUR health care provider about all prescription and nonprescription medicines you are taking or plan to take. Also tell your health care provider about any vitamins, nutritional supplements, and herbal products you take.

Before taking a medicine, ask your health care provider or pharmacist these questions:

- **How should I take the medicine?**
- **While taking the medicine, should I avoid any other medicines or certain foods or beverages?**
- **Can I take this medicine safely with the other medicines that I am taking? Are there any possible drug interactions I should know about? What are the signs of those drug interactions?**
- **In the case of a drug interaction, what should I do?**

TAKE MEDICINES according to your health care provider's instructions. Drug labels and package inserts include important information about possible drug interactions. Tell your health care provider if you have any side effect that bothers you or that does not go away.

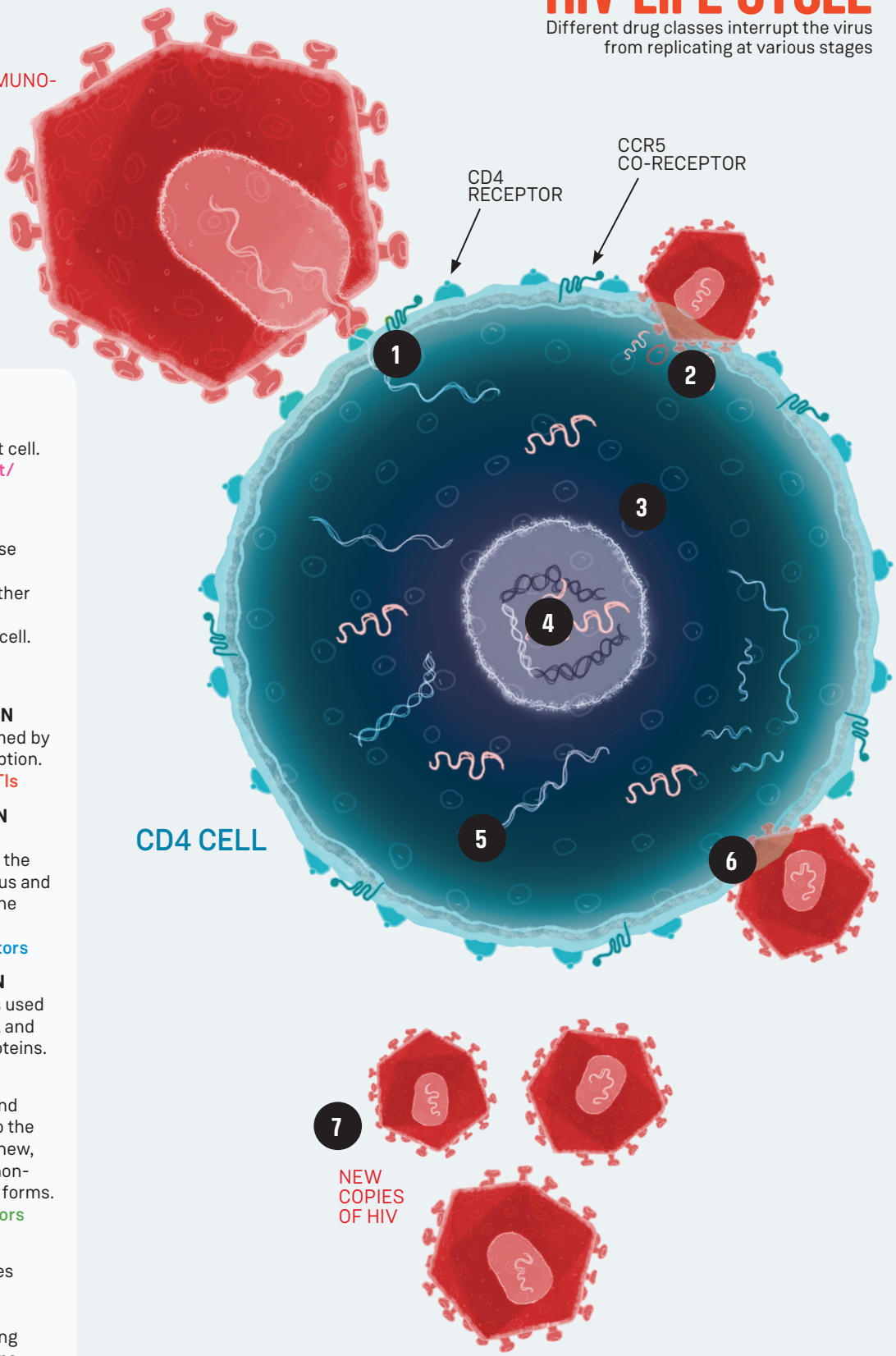
LEARN MORE about drug interactions at aidsinfo.nih.gov/drugs and fda.gov.

The HIV Drug Interaction Checker by the University of Liverpool is an online resource that allows you to check drug-drug interactions between an HIV drug and any other prescription or over-the-counter medication. There is also a mobile app, the HIV iChart (for the app you'll need to use the generic, or scientific name, not the brand name). Go to hiv-druginteractions.org.

ISTOCKPHOTO

HIV LIFE CYCLE

Different drug classes interrupt the virus from replicating at various stages



1: BINDING
HIV binds to the surface of a host cell.
CCR5 antagonist/ Entry inhibitor

2: FUSION
HIV's RNA reverse transcriptase, integrase, and other viral proteins fuse to the host cell.
Fusion inhibitor

3: REVERSE TRANSCRIPTION
Viral DNA is formed by reverse transcription.
NRTIs and NNRTIs

4: INTEGRATION
Viral DNA is transported into the host cell's nucleus and integrates into the host's DNA.
Integrase inhibitors

5: REPLICATION
New viral RNA is used as genomic RNA and to make viral proteins.

6: ASSEMBLY
New viral RNA and proteins move to the cell's surface; a new, immature (and non-infectious) virus forms.
Protease inhibitors

7: BUDDING
The virus matures (and becomes infectious) by protease releasing individual proteins.

ILLUSTRATION FOR POSITIVELY AWARE BY ABBEY DENLINGER

Standard practice

DHHS **treatment guidelines** for first-time HIV therapy

A regimen should be individualized on the basis of virologic efficacy (suppression of viral load to less than 50 copies per mL), toxicity, pill burden, dosing frequency, drug-drug interaction potential, resistance testing results, comorbid conditions (such as kidney disease, hepatitis B or C, etc.), and cost. More details including recommendations for treatment-experienced individuals and those for pregnant women are in the documents from the U.S. Department of Health and Human Services (DHHS) online. AIDSinfo has mobile applications that allow access to federally approved HIV/AIDS treatment and research information and are offered free of charge, including a Guidelines app, at aidsinfo.nih.gov/apps.

NOTE: At press time, the newest single-tablet regimen (STR), Biktarvy (bictegravir/TAF/FTC), had yet to be added to the guidelines.

Recommended initial regimens for most people with HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use.

INSTI + 2 NRTIs:

Triumeq
(DTG/ABC/3TC[a])
if HLA-B*5701 negative: AI

Tivicay with Descovy or Truvada
(DTG + tenofovir[b]/FTC[a])
TAF/FTC and TDF/FTC: AI

Genvoya or Stribild
(EVG/c/tenofovir[b]/FTC)
TAF/FTC and TDF/FTC: AI

Isentress HD or Isentress with Descovy or Truvada
(RAL + tenofovir[b]/FTC[a])
TDF/FTC: AI
TAF/FTC: AII

Recommended initial regimens in certain clinical situations

These regimens are effective and tolerable, but have some disadvantages when compared with the regimens listed above, or have less supporting data from randomized clinical trials. However, in certain clinical situations, one of these regimens may be preferred (see Table 7 for examples).

Boosted PI + 2 NRTIs:

(In general, boosted DRV is preferred over boosted ATV.)

Prezcobix or Prezista + Norvir with Descovy or Truvada
(DRV/c or DRV/r) + tenofovir[b]/FTC[a]
DRV/r: AI
DRV/c: AII

Evotaz or Reyataz + Norvir with Descovy or Truvada
(ATV/c or ATV/r) + tenofovir[b]/FTC[a]
BI

Prezcobix or Prezista + Norvir with Epzicom
(DRV/c or DRV/r) + ABC/3TC[a]
If HLA-B*5701–negative: BII

Evotaz or Reyataz + Norvir with Epzicom
(ATV/c or ATV/r) + ABC/3TC[a]
If HLA-B*5701–negative and HIV RNA <100,000 copies/mL,
ATV/r: CI
ATV/c: CIII

KEY TO ACRONYMS

3TC: lamivudine
ABC: abacavir
ATV: atazanavir
ATV/c: atazanavir/cobicistat
ATV/r: atazanavir/ritonavir
BID: twice daily
DRV: darunavir
DRV/c: darunavir/cobicistat
DRV/r: darunavir/ritonavir
DTG: dolutegravir
EFV: efavirenz
EVG: elvitegravir
EVG/c: elvitegravir/cobicistat
FTC: emtricitabine
INSTI: integrase strand transfer inhibitor
LPV/r: lopinavir/ritonavir
NNRTI: non-nucleoside reverse transcriptase inhibitor
NRTI: nucleoside reverse transcriptase inhibitor
PI: protease inhibitor
RAL: raltegravir
RPV: rilpivirine
TAF: tenofovir alafenamide
TDF: tenofovir disoproxil fumarate

RATING OF RECOMMENDATIONS

A: Strong
B: Moderate
C: Optional

RATING OF EVIDENCE

I: Data from randomized controlled trials
II: Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes
III: Expert opinion

Recommended initial regimens in certain clinical situations

NNRTI + 2 NRTIs:

Atripla;
or Sustiva + Descovy
(EFV + tenofovir[b]/FTC[a])
EFV/TDF/FTC: BI
EFV + TAF/FTC: BII

Odefsey or Complera
(RPV/tenofovir[b]/FTC[a])
If HIV RNA <100,000 copies/mL;
CD4 >200 cells/mm^3: BI

INSTI + 2 NRTIs:

Isentress HD or Isentress
with Epzicom
(RAL[c] + ABC/3TC[a])
If HLA-B*5701–negative and
HIV RNA < 100,000 copies/mL: CII

Regimens to consider when ABC, TAF, and TDF cannot be used[d]

Prezista + Norvir with
Isentress HD or Isentress
(DRV/r + RAL) (BID)
If HIV RNA <100,000 copies/mL and
CD4 >200 cells/mm^3: CIII

Kaletra + Epivir (lamivudine)
(LPV/r + 3TC[a]) (BID)[e]
CI

* Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human services. Available at aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/11/what-to-start. Accessed January 26, 2018, Table 6.

FOOTNOTES

a. 3TC may be substituted for FTC, or vice versa, if a non–fixed-dose NRTI combination is desired.
b. TAF and TDF are two forms of tenofovir approved by the FDA. TAF has fewer bone and kidney toxicities than TDF, while TDF is associated with lower lipid levels. Safety, cost, and access are among the factors to consider when choosing between these drugs.
c. RAL can be given as 400 mg BID or 1200 mg (two 600 mg tablets) once daily.
d. Several other NRTI-limiting treatment strategies are under investigation. See the section titled Selected Strategies That Are Under Evaluation and Not Yet Recommended for discussion regarding these regimens.
e. LPV/r plus 3TC is the only boosted PI plus 3TC regimen with published 48-week data in a randomized controlled trial in ART-naïve patients. Limitations of LPV/r plus 3TC include twice-daily dosing, high pill burden, and greater rates of gastrointestinal side effects than other PIs.

THESE COMBINATIONS ARE AVAILABLE AS **CO-FORMULATED DRUGS** (NOT A COMPLETE LIST)

ABC/3TC
Epzicom

ATV/c
Evotaz

DRV/c
Prezcobix

DTG/ABC/3TC
Triumeq

EFV/TDF/FTC
Atripla

EVG/c/TAF/FTC
Genvoya

EVG/c/TDF/FTC
Stribild

LPV/r
Kaletra

RPV/TAF/FTC
Odefsey

RPV/TDF/FTC
Complera

TAF/FTC
Descovy

TDF/FTC
Truvada

NOT YET INCLUDED IN THE GUIDELINES AT PRESS TIME:
bictegravir/TAF/FTC
Biktarvy

Getting the most out of your drug guide

Below are tips to help give you the knowledge you need to work with your providers to make empowered, informed choices about your treatment. Medications included in the 2018 HIV Drug Guide are those most commonly used, or expected to be approved in the coming year.

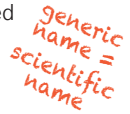
With so many choices out there, we order the drug pages by those that are the best options and list them first, followed by commonly prescribed drugs in each category. To quickly find your drug, go to page 26. Older drugs that are no longer used or rarely prescribed are only pictured on the HIV drug pullout chart.

Goal of therapy

UNDERSTANDING HIV TREATMENT is the key to success. The goal of therapy is to suppress the virus to an undetectable level (meaning the virus in your blood is so low, it cannot be detected by normal tests). This will keep you healthy, and the sooner you start therapy, the less damage to your immune system so you'll stay healthier, longer. When you are undetectable (less than 400 copies), it also means you can't transmit HIV to your partner. Getting to and staying undetectable means you need to take your medication as prescribed, and not miss doses.

Drug names

WHEN A DRUG IS IN DEVELOPMENT it's first given a "generic" or "scientific" name (such as dolutegravir). Once it's approved, it's given its brand name (Tivicay is the brand name of dolutegravir), which most people know it by. At medical conferences and in scientific publications you will often see three-character abbreviations used (DTG in the case of dolutegravir).



Recommendations for use

THE DEPARTMENT OF Health and Human Services (DHHS) and the International AIDS Society-USA (IAS-USA) both publish recommendations for the use of HIV antiretroviral drugs. We include information on some of these recommendations on page 20, and at the top of each drug page, as well as the pullout drug chart. DHHS and IAS-USA guidelines are very similar, but for consistency we reference only the DHHS guidelines. For the entire list go to aidsinfo.nih.gov or ias-usa.org/guidelines.

Drug pricing and access

THE AVERAGE WHOLESALE PRICE (AWP) is listed on each drug page and is one way to compare costs of drugs. It is not necessarily what you would pay if you had to pay the full retail price.

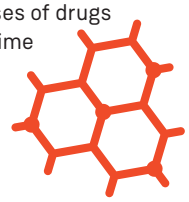
There are programs that can help cover all or part of the costs of these medications. In the drug co-pay and patient assistance program charts (beginning on page 72) we include information on how to access these programs.

Drug classes and co-formulations

A FIXED-DOSE COMBINATION (FDC) combines two or more drugs in one tablet, such as Prezcobix (darunavir/cobicistat). A single-tablet regimen (STR) contains drugs from different classes and is a complete regimen in one pill, such as Triumeq (dolutegravir/lamivudine/abacavir).

When a drug is a co-formulation (combination) of different drugs, the generic names will be separated by slashes—for example, Genvoya is the co-formulation of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide.

Anti-HIV drugs should always be taken in combination using two or more drug classes (for example, an integrase inhibitor plus two nukes). Single-tablet regimens (STRs) are in their own category, and combine multiple classes of drugs into one tablet. STRs are widely used for first-time treatment and for their convenience, but they are not for everybody, including some people who are treatment-experienced or have multi-drug resistance.



More information online

OPERATED BY THE National Institutes of Health, AIDSinfo maintains factsheets on each HIV medicaton at aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines. Download iPhone and Android apps that provide drug info, treatment guidelines, and a glossary: aidsinfo.nih.gov/apps. You can also find the online version of your medication's drug page from our HIV Drug Guide by adding your drug's name after typing positivelyaware.com/ into your browser (for example, positivelyaware.com/triumeq).

For pagination purposes, this page has been intentionally left blank.

Start here

In this guide, HIV drugs are grouped into seven categories— plus, one additional category for select non-HIV drugs. More information is available at positivelyaware.com

- **STR** — SINGLE-TABLET REGIMEN (MULTIPLE DRUG CLASSES)
- **INSTI** — INTEGRASE STRAND TRANSFER INHIBITOR (INTEGRASE INHIBITOR)
- **PI** — PROTEASE INHIBITOR
- **PKE** — PHARMACOKINETIC ENHANCER (BOOSTER)
- **NRTI** — NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NUKE)
- **NNRTI** — NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NON-NUKE)
- **EI** — ENTRY INHIBITOR
- **NON-HIV** — NON-HIV DRUG (NOT AN ANTIRETROVIRAL)

Triumeq ★ RECOMMENDED INITIAL REGIMEN FOR MOST PEOPLE

dolutegravir/abacavir/lamivudine **(DTG/ABC/3TC)**

STANDARD DOSE

One tablet once daily, without regard to food, for people with no evidence of INSTI resistance. An additional 50 mg dose of dolutegravir (brand name Tivicay) separated by 12 hours from Triumeq is required for people who have INSTI drug resistance or are taking certain other medications. Tablet contains 50 mg of the INSTI dolutegravir plus 600 mg abacavir and 300 mg lamivudine.

For adults and children weighing at least 88 pounds (40 kg). Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Dose cannot be adjusted for people with kidney or liver problems. Triumeq should not be used in people with CrCl less than 50 ml/min or liver impairment.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
triumeq.com
(877) 844-8872

AWP

$3,366.24/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Triumeq: Tivicay, Ziagen, and Epivir. Triumeq is generally well tolerated. The most common side effects that occurred in 2–3% of study subjects are insomnia, headache, and fatigue. Dolutegravir can cause a small, reversible increase in serum creatinine within the first few weeks of treatment without affecting actual kidney function. INSTIs have been associated with adverse neuropsychiatric effects (such as suicidal ideation) in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring patients with pre-existing psychiatric conditions on an INSTI. Conflicting data suggest a small risk for heart problems when using abacavir-containing regimens in people with high risk for cardiovascular disease. Monitor for signs of hypersensitivity reaction (HSR) to abacavir. Prior to starting Triumeq, all individuals should be given a blood test for HLA-B*5701 (a genetic marker) to identify patients at risk for this reaction. This test is covered by most insurance and also by LabCorp/ViiV (see company contact on co-pay chart). Read more about HSR online. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the lamivudine component. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See the individual drugs contained in Triumeq: Tivicay, Ziagen, and Epivir. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other interactions not listed here. Do not take with the anti-arrhythmic dofetilide. Do not take with the following medications, since they are already in this medication or have medication from similar drugs: Atripla, Biktarvy, Combivir, Descovy, Odefsey, Emtriva, Epivir-HBV, Epzicom, Genvoya, Stribild, Tivicay (unless required), Trizivir, Truvada, or Ziagen. Triumeq should be taken two hours before or six hours after taking antacids or laxatives, the ulcer medication Carafate, iron or calcium supplements, or buffered medications. Triumeq can be taken together with iron- or calcium-containing supplements if taken with food. Other acid reducers/heartburn medications (e.g., Prilosec, Pepcid, Zantac, Prevacid) are okay to use. Avoid co-administration with oxcarbazepine, phenobarbital, phenytoin, or St. John's wort. Start metformin at lowest dose and titrate based on glycemic control. Monitor for metformin adverse effects.

MORE INFORMATION

Triumeq is currently listed as a Recommended Initial Regimen for Most People in the DHHS guidelines and is the only single-tablet regimen (STR) that contains Epzicom as the NRTI backbone. Compared to other INSTIs, dolutegravir has a higher genetic barrier against the development of drug resistance, similar to the protease inhibitors (such as Prezista). Triumeq has relatively few drug interactions and is well tolerated. Triumeq does not cover HBV as well as other STRs and therefore requires another anti-HBV medication in addition to its lamivudine component. A new STR containing dolutegravir was approved late last year; see Juluca page. Triumeq is the largest of the STR pills, which can potentially be an issue for individuals who have difficulty swallowing.

Dr. David Hardy says:
Triumeq was the fourth STR, approved in 2014, the second STR containing an integrase inhibitor (this time without a booster), and the first STR with Ziagen/Epivir instead of Viread/Emtriva. In three of four studies in people starting their first HIV regimen (including one study for women only), Triumeq was shown to be superior to (better than) Atripla, Prezista + Norvir, and Reyataz + Norvir, and similar to the other INSTI-containing regimen (Isentress). These results were strengthened by the finding that in these four studies, no HIV resistance (viral mutation) was found when a person's viral load did not (or stopped) responding to Triumeq and their viral load became detectable. This was a new and unique finding for Triumeq compared to other INSTI-containing regimens (Stribild and Isentress). In clinical trials, side effects have been uncommon and rarely a reason to stop treatment. The absence of HIV resistance with Triumeq seen in clinical practice has continued since its approval. One still controversial factor that has concerned some HIV-treating medical care providers and people living with HIV (PLWH) has been previous reports of an increased risk of heart attacks with Ziagen, one of the medications in Triumeq. Although no heart attacks were seen in the four large clinical trials of Triumeq (see above), this finding seen in previous studies limits its use. Also because of Ziagen, people living with HIV must have a blood test to assure that they will not have a serious allergic reaction. This is a simple, one-time test to detect a gene which occurs in 5% to 7% of Caucasians, 2% of African Americans, and 1% of Asians. Due to the favorable findings mentioned above, Triumeq has been a recommended first-line ART regimen since its approval. Side effects were initially very mild, transient, and uncommon. Recently, a small number of reports, primarily from Europe, have reported increased cases of insomnia, mental stimulation, and worsening of mental health problems.

Activist Moisés Agosto-Rosario says:
This STR is recommended as initial therapy. Treatment-experienced individuals may not benefit from Triumeq because of drug resistance to any of its components. Dolutegravir can cause a reversible increase in kidney function. INSTIs have been associated with adverse neuropsychiatric effects. It is recommended to monitor patients with pre-existing psychiatric conditions. Triumeq is more tolerable than and as effective as Atripla. A hypersensitivity reaction due to the drug abacavir may develop. A blood test that can predict predisposition to the hypersensitivity reaction is required. There is a risk for cardiovascular disease because of abacavir. Patients at risk for, or who have a family history of, heart disease must discuss this with their doctor and monitor their heart condition. The third drug, lamivudine, has shown a safe profile.

Biktarvy

● DHHS RECOMMENDATION NOT YET ESTABLISHED

bictegravir/emtricitabine/tenofovir alafenamide **(BIC/FTC/TAF)**

STANDARD DOSE

One tablet once daily without regard to food. Tablet contains 50 mg of the INSTI bictegravir plus 200 mg emtricitabine and 25 mg tenofovir alafenamide (TAF).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Biktarvy is not recommended for people with CrCl less than 30 mL/min or people with severe liver impairment.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
biktarvy.com
(800) GILEAD-5
(445–3235)

AWP

$3,534.78/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See also Descovy, contained in this drug (bictegravir is not marketed separately). See package insert for the most complete list. Most common side effects observed in study participants include nausea (5%), headache (5%), and diarrhea (6%). Five individuals in Study 1490 and none in Study 1489 stopped Biktarvy due to side effects, none due to kidney problems. Serum creatinine, estimated creatinine clearance, urine glucose, and urine protein should be obtained before initiating Biktarvy and should be monitored during therapy. INSTIs have been associated with adverse neuropsychiatric effects (such as suicidal ideation) in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring patients with pre-existing psychiatric conditions on an INSTI. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See package insert when available for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other interactions not listed here. Do not take with rifampin, the antiarrhythmic dofetilide, or St. John's wort. Not recommended to be taken with rifabutin or rifapentine. Do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Atripla, Combivir, Complera, Descovy, Emtriva, Epivir, Epzicom, Genvoya, Isentress, Juluca, Kaletra, Norvir, Odefsey, Stribild, Tivicay, Triumeq, Trizivir, Truvada, Tybost, or Viread; also Epivir-HBV, Hepsera, and Vemlidy, all three for hepatitis B. Biktarvy should be taken two hours before taking laxatives or antacids, the ulcer medication sucralfate, oral iron or calcium supplements (but these two can be used with Biktarvy if taken together with food), or buffered medications. Start metformin at lowest dose and titrate based on glycemic control. Monitor for metformin adverse effects. When starting or stopping Biktarvy in people on metformin, dose adjustment of metformin may be necessary to maintain optimal glycemic control. Can be used with ethinyl estradiol and norgestimate, as well as midazolam and sertraline. Can be taken with the hepatitis C medications Epclusa, Harvoni, Sovaldi, and Vosevi.

MORE INFORMATION

Received FDA approval as this issue went to press in February 2018. Biktarvy is the first unboosted INSTI-containing STR with TAF, and the second unboosted INSTI STR overall (the other is Triumeq). ("Unboosted" means that drug levels of the primary antiretroviral drug, in this case bictegravir, do not require another medication such as Norvir or cobicistat to increase its drug levels in the body.) Biktarvy was approved for both people switching from another HIV regimen, on which they have undetectable viral load (less than 50 copies/mL) for at least three months with no history of treatment failure or resistance to components of Biktarvy, as well as people taking HIV therapy for the first time. It is also the smallest triple-therapy INSTI-based STR tablet on the market, which may help some individuals with difficulty swallowing pills. Can be given to people with impaired kidney function. Pediatric study is ongoing. The INSTI medications are currently DHHS recommended for first-time HIV therapy for most people. The data show that the drug resistance barrier is comparable to that of dolutegravir. In Studies 1489 (Biktarvy vs. Triumeq) and 1490 (Biktarvy vs. Tivicay + Descovy), both in treatment-naïve individuals (those taking HIV medicines for the first time), Biktarvy was shown to be non-inferior to the comparator drugs in getting patients to undetectable levels (viral load less than 50 copies/ml). In Studies 1878 (switching from a boosted protease inhibitor regimen to Biktarvy) and 1844 (switching from Triumeq to Biktarvy), where participants were already undetectable, Biktarvy maintained undetectable viral loads after the switch (92% and 94% of participants taking it in Study 1878 and Study 1844, respectively).

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Probably more than any other new HIV medication available, this newly approved STR will have the most impact on changing HIV treatment in 2018. Many consider this three-drug, unboosted, integrase inhibitor-and-TAF-containing STR to be a crowning achievement. But is it any better than currently available ART regimens? Data from a clinical trial currently under review demonstrated very high and very close (92% vs. 93%) rates of undetectable viral loads among people receiving their first anti-HIV regimen with Biktarvy or Triumeq. Although there was more mild nausea reported by people receiving Triumeq versus those receiving the bictegravir regimen, only one out of 315 PLWH stopped Triumeq due to nausea. In another clinical trial comparing Biktarvy and Tivicay (dolutegravir) given with Descovy (FTC/TAF) (currently one of the most popular first-time regimens prescribed by HIV-treating healthcare providers), again bictegravir and dolutegravir both resulted in very high and similar rates of undetectable viral loads (89% for bictegravir; 93% for Tivicay). Based on the clinical trial data [here and online], it is difficult to see significant differences between this new STR and Triumeq or Tivicay + Descovy, or any clear advantage of switching from a suppressive and well-tolerated, boosted protease inhibitor regimen to the this new STR…other than reducing the number of pills in an ART regimen.

Activist Moisés Agosto-Rosario says: BIC, FTC, and TAF are drugs contained in this new STR. FTC and TAF are approved drugs used in other STRs such as Genvoya. Bictegravir, an INSTI, is the new drug in this STR. INSTI drugs are recommended by the U.S. Department of Health and Human Services (DHHS) for any person starting HIV therapy for the first time. This new STR includes TAF instead of TDF

TAF has been shown to not have the same level of kidney or bone mineral density effects as TDF. Bictegravir might cause moderate-to-severe elevation of liver enzymes. Your doctor must monitor liver enzymes regularly. Other side effects are diarrhea, muscle aches, headache, and fatigue. See the package insert for more information.

Genvoya ★ RECOMMENDED INITIAL REGIMEN FOR MOST PEOPLE

elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/COBI/FTC/TAF)

STANDARD DOSE

One tablet once daily with food. Tablet contains 150 mg of the INSTI elvitegravir boosted by 150 mg cobicistat plus 200 mg emtricitabine and 10 mg tenofovir alafenamide (TAF).

For adults and children weighing at least 55 pounds (25 kg) and having a creatinine clearance of at least 30 mL/min (measurement of kidney function).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Dose cannot be adjusted for people with kidney or liver problems. Genvoya is not recommended for people with CrCl less than 30 mL/min or severe liver problems.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
genvoya.com
(800) GILEAD-5
(445-3235)

AWP

$3,534.78/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Genvoya: Emtriva and Tybost (elvitegravir is not marketed separately, and neither is TAF for use in HIV, but see Descovy). Common side effects reported in at least 5% of study participants include nausea, diarrhea, headache, and fatigue. Before taking Genvoya, kidney function testing should be conducted, including serum creatinine, serum phosphorus, urine glucose, and urine protein. These measurements should continue to be monitored while taking Genvoya. Cobicistat can cause a small, reversible increase in serum creatinine within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). While cobicistat does not affect actual kidney function, its effect on SCr can make monitoring of impaired kidney function more difficult or less accurate. INSTIs have been associated with adverse neuropsychiatric effects (such as sleep disturbances, depression, anxiety, suicidal ideation) in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring patients with pre-existing psychiatric conditions on an INSTI. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See package insert and DHHS guidelines for a more complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are many other drug interactions not listed here. Do not take with the following medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Complera, Emtriva, Epivir, Epzicom, Isentress, Juluca, Kaletra, Norvir, Odefsey, Stribild, Tivicay, Triumeq, Trizivir, Truvada, Descovy, Tybost, or Viread; also Epivir-HBV, Hepsera, or Vemlidy (TAF). Separate by at least 2 hours from antacids containing aluminum, magnesium hydroxide, or calcium carbonate. Safe to take with other medications used for heartburn and GERD such as Nexium, Pepcid, Prevacid, Prilosec, Tagamet, and Zantac. Cobicistat has many drug interactions similar to those seen with Norvir. Do not take with cholesterol-lowering drugs containing lovastatin or simvastatin (Advicor, Altoprev, Mevacor, Simcor, Vytorin, Zocor), alfuzosin, carbamazepine, phenobarbital, phenytoin, ergotamine, dihydroergotamine, methylergonovine, oral midazolam, lurasidone, pimozide, Revatio, rifampin, rifabutin, rifapentine, Serevent, triazolam, or St. John's wort. Dose of clarithromycin may need to be reduced based on kidney function. An alternative corticosteroid to systemic dexamethasone should be considered. Risks versus benefits of using with voriconazole should be assessed with expert consultation. Cholesterol-lowering drugs such as atorvastatin should be used with caution and started at the lowest dose possible. Monitor closely for increased side effects from these medications, such as muscle pain. Concentrations of antidepressants such as fluoxetine, paroxetine, bupropion, or amitriptyline may be increased, and their doses may need to be reduced. Genvoya increases levels of nasal and inhaled fluticasone, which may lead to symptoms of Cushing's syndrome. An alternative corticosteroid is recommended. Cialis, Levitra, and Viagra levels are increased; doses should not exceed 10 mg Cialis or 2.5 mg Levitra per 72 hours, or 25 mg Viagra per 48 hours. Monitor for increased side effects of these medications. Effectiveness of oral contraceptives may be decreased; consider using alternative or additional contraception methods. Reduce Daklinza dose to 30 mg. Can be taken with Harvoni. Taking with Olysio, Viekira Pak, or Zepatier is not recommended. Monitor kidney function more closely with Epclusa.

MORE INFORMATION

Genvoya is one of two single-tablet regimens that can be given to people with impaired kidney function. Genvoya is not recommended for use in pregnancy. Switching regimen or close monitoring should be considered for pregnant women already taking this regimen.

Dr. David Hardy says:
Genvoya is commonly called the "new and improved" version of Stribild because it contains three of the four medications which Stribild contains. What makes Genvoya different is that the Viread component of Stribild has been "updated" with a new medication called TAF (tenofovir alafenamide fumarate). TAF is known as a "prodrug" which means that it's kind of like a "prequel"—it comes before the older, already known version. In this case the already known version is Viread. TAF (as the name shows) contains tenofovir, but through pharmaceutical magic, the amount of tenofovir needed to effectively suppress HIV has been reduced from 300 mg in Stribild to only 10 mg in Genvoya. This 97% reduction in tenofovir theoretically means that there is much less tenofovir in the blood and therefore much less chance of kidney or bone mineral density (solidness of bone) harming side effects. Clinical trials have shown that Genvoya is similar to (just as good as) Stribild for treating HIV, but that Genvoya has much fewer negative side effects on both kidneys and bones. Further, additional small studies proved that Genvoya can be safely used in people with pre-existing mild to moderate kidney disease. Like Stribild, however, Genvoya, contains a "booster" (Tybost) which can possibly cause drug interactions with other medications. Overall, Genvoya has been commonly prescribed with excellent HIV suppression and tolerability.

Activist Moisés Agosto-Rosario says: Genvoya is the first STR to use TAF instead of TDF. Genvoya has a lot of drug interactions. Individuals taking Genvoya should not take certain medicines that lower cholesterol like some statins. This STR increases blood levels of some antidepressants, oral contraceptives, and nasal inhaling corticosteroids. Blood levels of treatment for erectile dysfunction are raised, therefore lower doses are recommended. It's important to monitor kidney function. Cobicistat can cause increases in kidney functions such as serum creatine production. Discuss with your doctor all prescribed and over-the-counter medications that you take.

Odefsey ✔ RECOMMENDED INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

rilpivirine/emtricitabine/tenofovir alafenamide (RPV/FTC/TAF)

STANDARD DOSE

One tablet once daily, with a standard meal (more than 390 calories). See below. Tablet contains 25 mg of the NNRTI rilpivirine plus 200 mg emtricitabine and 25 mg tenofovir alafenamide (TAF).

Nutritional drinks, even high-calorie protein shakes or products like Ensure, should not be used in place of a meal where you chew the food. Taken with a protein shake, rilpivirine levels were still half of what they are with a meal.

HIV RNA (viral load) must be less than 100,000 copies/mL and CD4 T-cell count must be above 200 cells/mm^3 before starting Odefsey due to higher rates of virological failure in these patients.

For adults and children 12 years of age and older weighing at least 77 pounds (35 kg) and having a CrCl of at least 30 mL/min.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

MANUFACTURERS

Gilead Sciences, Inc.
gilead.com
odefsey.com
(800) GILEAD-5
(445-3235)

Janssen Therapeutics
janssentherapeutics.com
(800) JANSSEN
(526-7736)

AWP

$3,216.92/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Odefsey: Edurant and Emtriva (TAF is not marketed separately for HIV). Moderate to severe side effects are uncommon: insomnia, headache, and depressive disorders (depression, negative thoughts, suicidal thoughts or actions) were each seen in 2% of study participants on rilpivirine-containing regimens. Cases of rash and increased liver enzymes have also been reported with regimens containing rilpivirine. Cobicistat can cause a small, reversible decrease in kidney function test (eGFR or estimated CrCl, resulting from increased serum creatinine, or SCr) within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). The most common (greater than 10%) side effect seen in clinical trials with Descovy (the fixed-dose combination of Emtriva and TAF) is nausea. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Do not take Odefsey with any other antiretroviral medication unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Complera, Edurant, Emtriva, Epivir, Epivir-HBV, Epzicom, Descovy, Genvoya, Hepsera, Intelence, Stribild, Sustiva, Triumeq, Trizivir, Truvada, or Viread. Proton pump inhibitors (PPIs, heartburn or stomach acid drugs like Nexium, Prevacid, Prilosec, etc.) can't be taken with Odefsey. Antacids containing aluminum, magnesium hydroxide, or calcium carbonate can be taken two hours before or four hours after Odefsey. Stomach acid reducing drugs like Pepcid, Tagamet, and Zantac can be taken 12 hours before or four hours after a dose of Odefsey. Do not take with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, or the herb St. John's wort. Taking Odefsey with rifabutin is not recommended. Do not take with more than one dose of the injectable steroid dexamethasone (sometimes given in the ER or hospital). Use caution if used with fluconazole, itraconazole, ketoconazole, posaconazole, and voriconazole. Use azithromycin when possible instead of the antibiotics clarithromycin, erythromycin, or telithromycin, because these drugs increase rilpivirine levels, which can increase the risk for side effects. Reduced methadone levels can be seen and while dose adjustments are not necessary, it is recommended to monitor for withdrawal symptoms. Odefsey should also not be taken with other medications that prolong QTc interval or medications with a known risk of torsades de pointes May be taken with Daklinza, Harvoni, Olysio, Sovaldi, Zepatier, or Epclusa. Cannot be taken with Viekira Pak.

MORE INFORMATION

Odefsey is one of two single-tablet regimens that can be given to people with impaired kidney function. Rilpivirine-containing regimens can be difficult to take because of their food requirement and drug interactions. In addition, strict adherence is critical due to the relatively low barrier to the development of resistance. A rilpivirine-based regimen may, however, be advantageous in people with high risk for heart disease due to its relatively low impact on lipid profile. The Odefsey tablet is smaller in size than any other STR (except the dual-drug Juluca), which may be advantageous to individuals who have difficulty swallowing.

See package insert for more information on potential side effects and interactions.

Dr. David Hardy says:
Odefsey is commonly considered the "new and improved" version of Complera. Clinical trials have shown that switching people who are receiving Atripla or Complera to Odefsey results in similar (as good) results in terms of suppressing HIV as keeping them on their initial ART regimen. Those who switched from Atripla to Odefsey also had decreased side effects (grogginess, vivid dreams). Odefsey continues to have the same potency problems that Complera has, that is, it is not as effective in suppressing high viral loads (more than 100,000 copies/ml). Similar to Complera, Odefsey is well tolerated with minimal to rare side effects. Therefore, Odefsey has not been recommended for initial treatment of all folks, but rather only those with low viral loads (less than 100,000 copies/ml). Odefsey's use as an ART regimen for switching people with undetectable viral loads off of their protease inhibitor-containing regimen to reduce side effects or for simplifying their ART regimen has not been specifically tested, but would probably work as it did with Complera.

Activist Moisés Agosto-Rosario says: See also Complera. Whenever a new medication is prescribed, it is important to tell your doctor what other prescribed and over-the-counter medicines you are taking. This includes alternative remedies and herbs. Drug interactions can increase the risk of side effects or decrease the therapeutic level of a drug. Do not take Odefsey with other anti-retrovirals unless instructed by a doctor. Interactions exist with some antacids, antifungals, and antibiotics. If while taking Odefsey you suffer from depression or insomnia, tell the doctor immediately. Watch closely your liver enzymes and kidney function.

Juluca

● DHHS RECOMMENDATION NOT YET ESTABLISHED

dolutegravir/rilpivirine **(DTG/RPV)**

STANDARD DOSE

One tablet once daily, with a meal (see Edurant), for adults who are virologically suppressed (have undetectable viral load) on a current ART regimen for at least 6 months and who have no history of treatment failure or resistance mutations associated with rilpivirine or dolutegravir. Tablet contains 50 mg of the INSTI dolutegravir plus 25 mg of the NNRTI rilpivirine.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. For proper absorption, rilpivirine must be taken with a meal that you chew—not just nutritional drinks or protein shakes.

No dose adjustment is necessary for patients with mild or moderate renal (kidney) impairment (CrCl greater than 30mL/min), or mild to moderate hepatic (liver) impairment; however increased monitoring for adverse effects is recommended for patients with severe renal impairment or end-stage kidney disease.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
(877) 844-8872
juluca.com

AWP

$3,094.80/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in this medication: Tivicay and Edurant. Both drugs are generally well tolerated. Side effects observed in greater than 2% of study participants were diarrhea and headache. Dolutegravir and rilpivirine can each cause a small, reversible increase in kidney function test (serum creatinine) within the first few weeks of treatment without affecting actual kidney function. INSTIs have been associated with adverse neuropsychiatric effects (such as suicidal ideation) in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring patients with pre-existing psychiatric conditions on an INSTI. Liver enzymes should be monitored in people with hepatitis B or C and taking dolutegravir. Stop taking if you experience signs of liver problems (yellowing of the skin or whites of the eyes; dark or tea-colored urine; pale-colored bowel movements; nausea or vomiting; loss of appetite; and pain, aching, or tenderness on the right side below the ribs).

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list. See the individual drugs contained in this medication: Tivicay and Edurant. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions not listed here. Do not take with the anti-arrhythmic dofetilide. If taking rifabutin, add an Edurant tablet to Juluca dose. Do not take Juluca with any other antiretroviral medication unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Biktarvy, Complera, Edurant, Genvoya, Isentress HD, Isentress, Odefsey, Stribild, Tivicay, and Triumeq. Should be taken four hours before or six hours after taking laxatives or antacids (like Maalox), the ulcer medication sucralfate, oral iron or calcium supplements (or take these together with Juluca and a meal), H-2 blocker acid reducers (Pepcid, Zantac) or buffered medications; but take Juluca dose four hours before or 12 hours after H-2 blocker acid reducers (Pepcid, Zantac). Cannot be taken with proton pump inhibitors (such as Prilosec, Prevacid, Protonix, Nexium). Avoid taking with some seizure medicines (carbamazepine, oxcarbazepine, phenobarbital, and phenytoin) or St. John's wort. HIV treatment guidelines suggest that metformin be started at the lowest dose and titrated based on glycemic control. Monitor for metformin adverse effects. When starting or stopping Tivicay in people on metformin, dose adjustment of metformin may be necessary to maintain optimal glycemic control.

MORE INFORMATION

Approved in November 2017, this is the first HIV drug developed and approved specifically for maintenance therapy. This means that after people achieve an undetectable HIV viral load with the use of initial 3-drug therapy, they can switch to this 2-drug regimen for maintenance (or continuation) of that success. This is a new HIV treatment strategy and potentially a game changer, especially with other dual-drug antiviral medications on the way. Those able to take their medications correctly and are able to achieve undetectable viral loads can take advantage of this drug-sparing strategy. Currently people taking HIV treatment must start out with a three-drug regimen (which may include the use of one of the single-tablet regimens, or STRs), then switch to Juluca after being undetectable for six months. Juluca still works against two life cycles of the virus, just as 3-drug regimens do. This is how the combination was used in clinical studies to date. This combination was listed in U.S. HIV guidelines as a "Strategy with good supporting evidence" around the time of its FDA approval. The guidelines also called Juluca "a reasonable option when using nucleoside drugs is not desirable" (for example, due to previous toxicity), with an A1 rating (strong recommendation based on randomized controlled trials). Juluca is the first nucleoside-free STR. It is the smallest STR, which may be advantageous to individuals who have difficulty swallowing.

See package insert for more information on potential side effects and interactions.

Dr. David Hardy says:
Juluca, approved by the FDA in late 2017, is a departure from the six previous STRs. This is because instead of being approved for initial treatment and/or for use as a "switch regimen," Juluca is specifically and only approved as a "switch regimen" in people with undetectable viral loads and no previous history of failed ART regimens. Juluca is also the first two-drug, instead of a three-drug, STR. What, may you ask, is the idea behind using only two drugs to keep HIV suppressed rather than the usual three drugs? One large and several small previous clinical trials have tested the effectiveness of switching people with undetectable virus to two instead of three antiretroviral medications. Most of these studies have been effective and almost all have contained boosted protease inhibitors. The use of Tivicay and Edurant as a two-drug "maintenance" ART regimen is unique and follows on the results of two large phase 3 studies including over 1,000 individuals with undetectable viral loads receiving an NNRTI-, boosted PI-, or INSTI-containing ART regimen and no previous failed ART regimens. Half of the individuals were switched to Juluca or remained on their previous ART regimen. Ninety-five percent of both groups maintained undetectable viral loads a year later. More people who received Juluca reported side effects and stopped it than those who stayed on their previous ART regimens, but no new or unexpected side effects were reported. It still remains to be seen how many HIV-treating healthcare providers and patients will elect to switch to Juluca in 2018.

Activist Moisés Agosto-Rosario says:
Generally, individuals switch their HIV regimen because they experience side effects or because they developed drug resistance to their present regimen. People who switch to Juluca do it not because they simply develop resistance or can't tolerate their previous treatment. To the contrary, in order to switch to Juluca an individual must have undetectable viral load for at least six months and have never experienced drug resistance to either dolutegravir or rilpivirine. Juluca is a two-drug maintenance regimen designed for those who achieved undetectability, are looking to have less exposure to HIV medications, and would like sustainability in their viral suppression. Individually and together, dolutegravir and rilpivirine are safe and well tolerated.

darunavir/cobicistat/emtricitabine/ tenofovir alafenamide (DRV/COBI/FTC/TAF)

● DHHS RECOMMENDATION NOT YET ESTABLISHED

NOT YET APPROVED AT PRESS TIME. PHOTO UNAVAILABLE.

DOSE USED IN STUDIES

One tablet once daily with food, in patients without darunavir-related drug resistance. Film-coated tablet contains 800 mg of the protease inhibitor darunavir boosted by 150 mg cobicistat plus 200 mg emtricitabine and 10 mg tenofovir alafenamide (TAF).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. It's anticipated that this drug should not be used if kidney function is less than 30 mL/min or a person is on dialysis.

MANUFACTURER

Janssen Therapeutics
(800) JANSSEN
(526-7736)

AWP

Not yet esablished

POTENTIAL SIDE EFFECTS AND TOXICITY

See package insert when available. See the individual drugs contained in this medication: Prezista and Tybost (see also Prezcobix), as well as Emtriva (TAF is not marketed separately for HIV, but see Descovy). Darunavir contains a sulfa component; use with caution in patients with sulfa allergies. Diarrhea, rash, and nausea were the most common side effects seen in clinical research (between 5.5 and 8.6% in the AMBER study). The most common adverse events seen in the EMERALD study were nasopharyngitis (nose and throat inflammation), upper respiratory tract infections, and diarrhea, all affecting less than 5% of people taking this darunavir combination. Severe rash with darunavir may be rare but potentially life-threatening. Seek medical attention immediately. There may be a small increase in serum creatinine (SCr) and decrease in estimated creatinine clearance (CrCl), but this does not affect actual kidney function. However, patients experiencing a confirmed increase in serum creatinine of greater than 0.4 mg/dL from baseline should be closely monitored for renal safety. Serum phosphorus in patients with or at risk for kidney impairment should also be monitored. Cobicistat can cause a small, reversible increase in serum creatinine (SCr, which in turn affects the eGFR or estimated CrCl lab values) within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See package insert when available for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are many drug interactions not listed here. Cobicistat interacts with many drugs, because as a booster, it inhibits liver enzymes involved in drug metabolism. Do not take with the following medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Complera, Descovy, Emtriva, Epivir, Epzicom, Evotaz, Kaletra, Norvir, Odefsey, Prezista, Prezcobix, Reyataz, Stribild, Tivicay, Triumeq, Trizivir, Truvada, Tybost, or Viread; also Epivir-HBV, Hepsera, and Vemlidy (TAF).

MORE INFORMATION

Expected to receive FDA approval in 2018. This medication would be the first STR containing a protease inhibitor drug. A benefit of the PIs is their high genetic barrier to drug resistance. While medical providers may hate to say it out loud, this means greater forgiveness of missed doses; missing a dose here and there is never advisable but does happen. As such, a PI-based regimen suits some people who may have trouble with the near-perfect drug adherence required of HIV treatment. It takes several mutations (changes) in a person's virus to develop resistance to PIs. On the other hand, drug resistance rarely breaks through for people taking a regimen using a medication from the INSTI drug class, which is recommended by the DHHS for most people taking HIV therapy for the first time.

See package insert when available for more complete information on potential side effects and interactions. Package insert already available in Europe, where it is approved under the brand name Symtuza; go to ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004391/WC500235524.pdf.

Dr. David Hardy says:
DRV/COBI/FTC/TAF was approved by the European FDA in September 2017 under the brand name Symtuza. It is anticipated to be approved by the U.S. FDA in 2018. What will make DRV/COBI/FTC/TAF unique among STRs is that it is the first to contain a boosted PI. It will essentially combine two currently available medications, Prezcobix and Descovy, into one tablet which promises to be smaller (more pharmaceutical magic) than the size of a Prezcobix tablet. For those who are taking a boosted PI and doing well with it, DRV/COBI/FTC/TAF will offer these folks the opportunity to experience the benefits of a one-tablet-once-a-day regimen for the first time. It is anticipated that many HIV-treating healthcare providers will offer this new STR to their patients on PI-containing regimens…and many people will be asking for it. For those whose continuous access or adherence to their ART regimens has been, or is predicted to be, difficult or unreliable, this new STR will offer them an option for a proven "HIV resistance-resistant" ART regimen in one pill. On the other hand, some HIV-treating healthcare providers and patients question whether or not a boosted PI regimen is better than one of the integrase inhibitor regimens, especially Triumeq, whose track record for also being "HIV resistance resistant" is excellent, but not as long as that of boosted PIs. Clinical trial data with DRV/COBI/FTC/TAF and clinical experience with Prezcobix and Descovy show that people tolerate this regimen fairly well, but not as well as they tolerate unboosted integrase inhibitors (Triumeq and Isentress). Nausea, queasiness, and diarrhea are the most common side effects seen with DRV/COBI/FTC/TAF or its two components.

Activist Moisés Agosto-Rosario says:
DRV/COBI/FTC/TAF is the first STR to have a PI (darunavir). Darunavir has a high barrier to drug resistance. TAF shows lower risk for bone and kidney toxicity. DRV/COBI/FTC/TAF is a favorable candidate for HIV initial therapy. There are drug-drug interactions due to the way darunavir and cobicistat are metabolized by the liver. Let your doctor know about prescribed and over-the-counter medicines that you take. DRV/COBI/FTC/TAF might increase sugar levels in the blood. Tell your doctor if you are allergic to sulfa drugs. DRV/COBI/FTC/TAF is to be taken with food. Most common side effects are headache, diarrhea, nausea, fatigue, and rash.

doravirine/tenofovir DF/lamivudine (DOR/TDF/3TC)

● DHHS RECOMMENDATION NOT YET ESTABLISHED

INVESTIGATIONAL DRUG AT PRESS TIME. PHOTO UNAVAILABLE.

DOSE USED IN STUDIES

One tablet once daily without regard to food. Tablet contains 100 mg of the NNRTI doravirine plus 300 mg lamivudine and 300 mg tenofovir DF (TDF).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Dose cannot be adjusted for people with kidney problems; DOR/TDF/3TC should not be used in people with moderate or severe kidney impairment or severe liver impairment.

MANUFACTURER

Merck and Co.
(800) 622-4477

AWP

Not yet established

POTENTIAL SIDE EFFECTS AND TOXICITY

See package insert when available. An analysis at 48 weeks showed that the most common drug-related side effects that occurred in more than 5% of participants taking either 100 mg of doravirine or 600 mg of efavirenz (brand name Sustiva) were diarrhea, nausea, dizziness, headache, abnormal dreams, insomnia, nightmares, and sleep disorder. All of the above side effects, except nausea and insomnia, occurred in a greater number of participants in the efavirenz group than in the doravirine group. Three participants taking doravirine and six participants taking efavirenz stopped treatment because of a side effect. In one study, side effects observed in 10% or more of 383 patients taking this doravirine regimen included nausea (11%), neuropsychiatric symptoms (such as depression, abnormal dreams, insomnia, and dizziness) (11%), diarrhea (14%), and headache (14%). In Phase 2b study, neuropsychiatric side effects with doravirine were significantly less than were seen with participants receiving efavirenz. In the Phase III study comparing doravirine to darunavir (brand name Prezista) plus ritonavir, an analysis at 48 weeks showed that participants in both groups experienced side effects related to the brain (including dizziness, depression, insomnia, and abnormal dreams), but no one dropped out of the study because of these side effects. Doravirine lowered cholesterol levels while darunavir + ritonavir increased them. Headache, diarrhea, and cold symptoms were the most frequently reported side effects in the group taking the fixed-dose tablet containing doravirine. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the lamivudine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See package insert when available for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not. Do not take with any other HIV antiretroviral medication unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Complera, Descovy, doravirine, Epivir, Emtriva, Epzicom, Genvoya, Juluca, Odefsey, Stribild, Triumeq, Trizivir, Truvada, or Viread; also Epivir-HBV, Hepsera, or Vemlidy (TAF), all three used for hepatitis B.

MORE INFORMATION

Expected to receive FDA approval this year. A stand-alone version of doravirine is also being developed; see doravirine page. Doravirine was found to be non-inferior to boosted darunavir (Prezista) at 48 weeks in the DRIVE-FORWARD study. Darunavir is one of two protease inhibitor medications recommended for first-time use in certain clinical situations by U.S. HIV treatment guidelines. This co-formulation of doravirine with the generic versions of Viread and Epivir will likely make the price less expensive. Doravirine has not yet been compared to an integrase inhibitor (INSTI), almost all of which are DHHS recommended for most people taking HIV medication for the first time (one INSTI STR was approved as this issue went to press, and has not yet received a recommendation). The doravirine STR is being studied in treatment-naïve individuals (first time on HIV therapy) who have virus that doesn't respond well to other NNRTIs (the DRIVE BEYOND study). It is also being studied in people with undetectable viral loads on their current treatment who are switched to the doravirine STR (the Phase 3 DRIVE-SHIFT study).

See package insert when available for more complete information.

Dr. David Hardy says:
Doravirine is considered a "second generation" NNRTI because of its enhanced resistance profile compared to Sustiva and other older "first generation" NNRTIs. In fact, lab studies predict that it may be effective after a first generation NNRTI has failed and left HIV resistance mutations. To date, data from two large clinical trials comparing doravirine to Sustiva and to Prezista/Norvir have shown that doravirine has similar anti-HIV potency as those two known potent medications and with fewer side effects. Doravirine is also being dveloped as an STR, and as a stand-alone pill. The FDA has set a target action date of Oct. 23, 2018, for both applications for doravirine and doravirine/Viread/Epivir under the Prescription Drug User Fee Act (PDUFA).

Activist Moisés Agosto-Rosario says: This new STR contains the investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) doravirine (DOR). This new drug is effective against NNRTI drug-resistant mutations. Individuals with resistance to other NNRTIs will benefit from regimens containing DOR. The potency of doravirine is comparable to efavirenz and boosted darunavir, when used in combination with two nucleoside reverse transcriptase inhibitors (NRTIs) in treatment-naïve individuals. Brain and central nervous system side effects are less common in individuals taking doravirine compared to those taking efavirenz. Doravirine has not yet been approved by the FDA. It will be available as a stand-alone NNRTI. This co-formulation with TDF and 3TC promises to be a safe and potent NNRTI-based STR.

Stribild ★ RECOMMENDED INITIAL REGIMEN FOR MOST PEOPLE

elvitegravir/cobicistat/emtricitabine/tenofovir DF **(EVG/COBI/FTC/TDF)**

STANDARD DOSE

One tablet once daily with food. Tablet contains 150 mg of the INSTI elvitegravir boosted by 150 mg cobicistat plus 200 mg emtricitabine and 300 mg tenofovir DF (TDF).

For adults and children 12 years of age and older weighing at least 77 pounds (35 kg).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Dose cannot be adjusted for people with kidney or liver problems. Stribild should not be started in individuals with estimated CrCl less than 70 mL/min and should be discontinued if CrCl decreases to less than 50 mL/min. Stribild is not recommended for patients with severe liver problems, or during pregnancy.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
stribild.com
(800) GILEAD-5
(445–3235)

AWP

$3,707.99/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Stribild: Emtriva, Viread, and Tybost (elvitegravir is not marketed separately). Common side effects reported in 10% or more of study participants include nausea and diarrhea. Other less common side effects include abnormal dreams and headache. Before taking Stribild, kidney function testing should be conducted including serum creatinine, serum phosphorus, urine glucose, and urine protein. These measurements should continue to be monitored while taking Stribild. Cobicistat can cause a small, reversible increase in serum creatinine within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). INSTIs have been associated with adverse neuropsychiatric effects (such as sleep disturbances, depression, anxiety, suicidal ideation) in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring patients with pre-existing psychiatric conditions on an INSTI. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are many other drug interactions not listed here. Do not take Stribild with any other antiretroviral medication unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Complera, Emtriva, Epivir, Epzicom, Isentress, Kaletra, Norvir, Odefsey, Stribild, Tivicay, Triumeq, Trizivir, Truvada, Descovy, Tybost, or Viread; also Epivir-HBV, Hepsera, or Vemlidy (TAF), all three used for hepatitis B. Separate by at least 2 hours from antacids containing aluminum, magnesium hydroxide, or calcium carbonate. Stribild is safe to take with other medications used for heartburn and GERD, such as Nexium, Pepcid, Prevacid, Prilosec, Tagamet, and Zantac. Do not take Stribild with alfuzosin, carbamazepine, phenobarbital, phenytoin, ergotamine, dihydroergotamine, methylergonovine, oral midazolam, pimozide, Revatio, rifampin, rifabutin, rifapentine, Serevent, triazolam, or St. John's wort. An alternative corticosteroid to systemic dexamethasone should be considered. No significant interactions with beclomethasone or prednisolone. Risks versus benefits of using Stribild and voriconazole together should be assessed with expert consultation. Do not use with lovastatin or simvastatin (Advicor, Altoprev, Mevacor, Simcor, Vytorin, and Zocor). Cholesterol-lowering drugs such as rosuvastatin and atorvastatin should be used with caution and started at the lowest dose possible. Monitor closely for increased side effects from these medications, such as muscle pain. Concentrations of antidepressants such as fluoxetine, paroxetine, bupropion, or amitriptyline may be increased by Stribild, and their doses may need to be reduced. Use with caution and therapeutic monitoring, if available, for antiarrhythmic drugs like digoxin. Stribild increases levels of nasal and inhaled fluticasone (e.g. Advair, Flonase, Breo Ellipta, Arnuity Ellipta, and Flovent) which may lead to symptoms of Cushing's syndrome (such as rounded face). An alternative corticosteroid is recommended. Use caution with beta blockers and calcium channel blockers. Cialis, Levitra, and Viagra levels are increased; doses should not exceed 10 mg Cialis or 2.5 mg Levitra per 72 hours, or 25 mg Viagra per 48 hours. Monitor for increased side effects of these medications, such as visual disturbances. Effectiveness of oral contraceptives may be decreased; consider using alternative or additional contraception methods. Coadminister bosentan and immunosuppressants like Prograf, Gengraf, Neoral, and Sandimmune with caution. Reduce Daklinza dose to 30 mg. Taking with Harvoni, Olysio, Viekira Pak, or Zepatier is not recommended. Monitor kidney function more closely with Epclusa.

MORE INFORMATION

The newer version of this drug, Genvoya, can be used by people with CrCl as low as 30 mL/minute. See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Stribild was the first STR to contain an INSTI medication (elvitegravir, formerly Vitekta) as well as the first to contain the "booster" Tybost. In order for elvitegravir to be given once a day and effectively suppress HIV, it must be given with a "booster", like Tybost or Norvir. Due to favorable comparisons against Atripla or Reyataz + Norvir, Stribild has been recommended as a first-line ART regimen almost since it was approved and remains in the DHHS guidelines as a first-line ART regimen recommended for all. Both clinical trials and clinical practice have demonstrated that Stribild has gastrointestinal side effects (nausea, queasiness, diarrhea) in some people (probably due to the Tybost), which may limit its use in these patients. Also, the Tybost "boosts" not only elvitegravir, but also many other medications, which may increase those medications' side effects. Because of the Viread, people who have pre-existing mild to moderate kidney disease, or who develop moderate kidney disease should not take Stribild. This limitation has been improved with the availability of newer STRs. Due to availability of newer STRs with less side effects and fewer drug interactions, Stribild's use has decreased.

Activist Moisés Agosto-Rosario says: The difference between Stribild and Genvoya is that Genvoya contains the prodrug for the original version of tenofovir DF. Stribild should be taken with food in order to lessen stomach discomfort. COBI is also used to boost the concentration of elvitegravir, the INSTI that together with TDF provides potent antiretroviral effect. Individuals prescribed Stribild must talk to their doctors about all the medicines taken, whether prescribed or over the counter. As with Genvoya, Stribild has many drug interactions because of its booster COBI. COBI can cause an increase of kidney functions such as serum creatine production. Individuals taking Stribild could still experience kidney toxicity and bone loss density due to TDF, the old version of tenofovir; therefore kidney function and bone density must be monitored.

Complera ✔ RECOMMENDED INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

rilpivirine/emtricitabine/tenofovir disoproxil fumarate **(RPV/FTC/TDF)**

STANDARD DOSE

One tablet once daily, with a standard meal (more than 390 calories) for adults and children 12 years of age and older weighing at least 77 pounds (35 kg). Tablet contains 25 mg of the NNRTI rilpivirine plus 200 mg emtricitabine and 300 mg tenofovir DF (TDF).

Nutritional drinks, even high-calorie protein shakes or products like Ensure, should not be used in place of a meal where you chew the food. Taken with a protein shake, rilpivirine levels were still half of what they are with a meal.

HIV RNA (viral load) must be less than 100,000 copies/mL and CD4 T-cell count must be above 200 cells/mm^3 before starting Complera due to higher rates of virological failure in these patients.

Take missed dose as soon as possible, unless it's closer to the time of your next dose. Do not double up on your next dose. Complera should not be used in people with CrCL less than 50 mL/min or severe liver impairment.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
complera.com
(800) GILEAD-5
(445-3235)

Janssen Therapeutics
janssentherapeutics.com
(800) JANSSEN
(526-7736)

AWP

$3,216.92/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Complera: Edurant and Truvada (co-formulation of Emtriva and Viread). Moderate to severe side effects are uncommon. Insomnia, headache, and depressive disorders (depression, negative thoughts, suicidal thoughts or actions) were each seen in 2% of study participants. Cases of rash and increased liver enzymes have also been reported with regimens containing rilpivirine. There may be a small increase in serum creatinine (SCr) and decrease in estimated creatinine clearance (CrCl). However, this does not affect actual kidney function. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted.

POTENTIAL DRUG INTERACTIONS

See the individual drugs contained in Complera: Edurant, Emtriva, and Viread. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Do not take Complera with any other HIV drug unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drugs: Atripla, Biktarvy, Combivir, Descovy, Edurant, Emtriva, Epivir, Epzicom, Genvoya, Intelence, Odefsey, Rescriptor, Stribild, Sustiva, Triumeq, Trizivir, Truvada, Viramune, or Viread; also Epivir-HBV, Hepsera, and Vemlidy (TAF), all three used for hepatitis B. Proton pump inhibitors (PPIs, heartburn or stomach acid drugs like Nexium, Prevacid, Prilosec, etc.) can't be taken with Complera. Antacids containing aluminum, magnesium hydroxide, or calcium carbonate can be taken at least two hours before or at least four hours after a Complera dose. Stomach acid reducing drugs like Pepcid, Tagamet, and Zantac can be taken at least 12 hours before or at least four hours after a Complera dose. Do not take Complera with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, or the herb St. John's wort (other herbals have not been studied with Complera, but consult with a pharmacist before taking any herbals or OTC supplements). Rifabutin must be taken with an extra Edurant tablet in addition to Complera. Do not take with more than one dose of the injectable steroid dexamethasone (sometimes given in the ER or hospital). Use caution if used with fluconazole, itraconazole, ketoconazole, posaconazole, and voriconazole. Use azithromycin when possible instead of the antibiotics clarithromycin, erythromycin, or telithromycin, because these drugs increase rilpivirine levels, which can increase the risk for side effects. Reduced methadone levels can be seen and while dose adjustments are not necessary, it is recommended to monitor for withdrawal symptoms. Complera should also not be taken with other medications that prolong QTc interval (a heart problem) or medications with a known risk of torsades de pointes. Complera may be taken with Daklinza, Harvoni, Olysio, Sovaldi, and Zepatier. Monitor for tenofovir toxicities with Epclusa. Complera cannot be taken with Viekira Pak.

MORE INFORMATION

Complera can be difficult to take because of its food requirement and drug interactions. In addition, strict adherence is critical due to its relatively low barrier to the development of resistance. A rilpivirine-based regimen may, however, be advantageous in people with high risk for heart disease due to its relatively low impact on lipid profile.

See package insert for more information about side effects and drug interactions.

Dr. David Hardy says:
Complera was the first alternative STR to Atripla and offered a single, once-a-day pill which could (and was recommended) to be taken with food. It does not have the pesky grogginess and vivid dreams associated with Atripla. While Complera's side effects were better than Atripla's, its potency was always questionable in people with high viral loads (more than 100,000 copies/mL). On the other hand, Complera's side effects have been minimal and therefore well tolerated. Primarily due to its lack of potency, it has never been recommended as a starting regimen. Since the development of the "new and improved" version of Complera, Odefsey, Complera's use has decreased. Because it has fallen further out of the recommended ART guidelines due to the issues above, it is rarely prescribed today.

Activist Moisés Agosto-Rosario says: When it was approved, Complera became the alternative for patients taking Atripla and suffering from neurotoxicity caused by efavirenz, one of the drugs in Atripla. Complera is not as potent as Atripla, therefore it is not recommended for patients with viral loads more than 100,000 copies/mL. It is important to be undetectable when switching to Complera in order to avoid drug resistance to other NNRTIs. Monitoring renal functions and liver enzymes is strongly recommended.

Atripla ✔ RECOMMENDED INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF)

STANDARD DOSE

One tablet once daily on an empty stomach, preferably at bedtime (food increases the risk of central nervous system, or CNS, toxicities). Tablet contains 600 mg of the NNRTI efavirenz plus 200 mg emtricitabine and 300 mg tenofovir DF (TDF).

For adults and children 12 years of age and older weighing at least 88 pounds (40 kg).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Do not split or crush the tablet. Dose cannot be adjusted for people with kidney problems and Atripla should not be used in people with moderate or severe kidney or liver impairment.

A SIMILAR GENERIC IS AVAILABLE (SYMFI LO, EFV/3TC/TDF).

MANUFACTURER

Bristol-Myers Squibb
bms.com
atripla.com
(800) 321-1335

Gilead Sciences, Inc.
gilead.com
(800) GILEAD-5
(445–3235)

AWP

$3,268.88/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Atripla: Sustiva and Truvada (co-formulation of Emtriva and Viread). Use with caution in individuals with depression or other psychiatric issues who are not under a psychiatrist's care. A 2014 study reviewed four previously published AIDS Clinical Trials Group (ACTG) studies regarding efavirenz and suicidal ideation and re-emphasized the fact that efavirenz has an association with suicidality (reported suicidal ideation or attempted or completed suicide), and should be used with caution in patients with severe or uncontrolled depression and/or a history of suicidality. Common side effects may include dizziness, drowsiness, abnormal or vivid dreams, difficulty concentrating, rash, diarrhea, nausea, fatigue, headache, and insomnia. These side effects may go away after a few weeks. Kidney function should be assessed before initiating treatment and throughout therapy as determined by a provider. Prior to initiation, people should be tested for hepatitis B (HBV) infection. Severe exacerbations of hepatitis B have been reported in people who are co-infected with hepatitis B and have discontinued the emtricitabine and/or tenofovir components. Monitor liver enzymes closely in people co-infected with hepatitis B and, if appropriate, initiation of anti-hepatitis B therapy may be warranted. The efavirenz component of Atripla has been associated with central nervous system (CNS) birth defects in non-human primates, and cases of neural tube defects have been reported after first trimester exposure in humans. A link between efavirenz and birth defects in humans has not been supported in meta-analyses. The recommendation is that women in their first trimester continue taking efavirenz as long as their viral load remains undetectable; however, efavirenz should only be used if the potential benefit outweighs the potential risk (as when other treatment options are not available). Because of the association with suicidality and neuropsychiatric effects, it is also recommended to screen for antenatal and postpartum depression in women with HIV who are taking a regimen containing efavirenz. The efavirenz in Atripla can cause a false positive for marijuana on certain drug tests. A more specific confirmatory test can be done.

POTENTIAL DRUG INTERACTIONS

See the individual drugs contained in Atripla: Sustiva, Emtriva, and Viread. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Do not take Atripla with the following medications, since these are already in this drug or they have medication from similar drugs: Biktarvy Combivir, Complera, Odefsey, Edurant, Emtriva, Epivir, Epzicom, Intelence, Rescriptor, Stribild, Genvoya, Sustiva, Triumeq, Trizivir, Truvada, Descovy, Viramune, or Viread; also Epivir-HBV, Hepsera, and Vemlidy (TAF). Atripla should not be taken with voriconazole, ergot derivatives, midazolam, pimozide, triazolam, bepridil, or St. John's wort. Atripla should also not be taken with other medications that prolong QTc interval (a heart problem) or medications with a known risk of torsades de pointes. No dose adjustment of Atripla needed with Sovaldi. Use caution when administering Atripla with Harvoni and monitor renal function closely due to possible increased tenofovir levels. Increase dose of Daklinza to 90 mg when used with Atripla. Atripla should not be taken with Epclusa, Olysio, Viekira Pak, or Zepatier.

MORE INFORMATION

Atripla is listed as a Recommended Regimen in Certain Clinical Situations in the DHHS guidelines based on a high rate of central nervous system side effects and a possible association with suicidality. Be careful when stopping Atripla, so that you avoid the rapid development of HIV resistance to it—check with your provider or pharmacist first.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Atripla was the first STR to be approved, in 2006. It was a popular, heavily recommended regimen for many years, until better STRs were approved. Due to its side effects (grogginess, vivid dreams, worsening of mental health conditions, and elevated cholesterol) along with a requirement to be taken without food and at bedtime, this STR fell out of the recommended guidelines several years ago. Clinical trials showed that the integrase inhibitor ART regimens were superior to Atripla. Atripla is now rarely, if ever, used in the U.S.; however, it remains commonly used in other parts of the world (Africa, India, and South America).

Activist Moisés Agosto-Rosario says: For quite some time Atripla was the preferred regimen for initial therapy. It is a potent antiviral that is well tolerated by some. Atripla contains efavirenz, a potent NNRTI known for its potential neurotoxicity. The result can be insomnia, depression, fatigue, and vivid dreams. Avoid Atripla if you have neuropsychiatric issues. Monitor your kidney and liver functions. It is known that TDF may cause kidney damage and decreases bone density. Watch for drug interactions.

Tivicay

★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

dolutegravir **(DTG)**

STANDARD DOSE

One 50 mg tablet once daily without regard to food, for people on HIV therapy for the first time (treatment-naïve) or treatment-experienced people who have never taken an INSTI. One 50 mg tablet twice daily, without regard to food, for people who have or who are suspected to have certain INSTI drug resistance or who are taking certain other medications.

Tivicay is approved for adults and children weighing at least 66 pounds (30 kg). For patients weighing 66 pounds to 88 pounds, the dose is one 10 mg tablet and one 25 mg tablet (35 mg total dose) once daily without regard to food. For patients weighing at least 88 pounds, the dose is one 50 mg tablet once daily without regard to food.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Not recommended for people with severe liver impairment. Use with caution in people with severe kidney impairment who have INSTI drug resistance or suspected resistance, because Tivicay levels may be decreased.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
tivicay.com
(877) 844-8872

AWP

10 mg tablets:
$397.82/month
25 mg tablets:
$994.57/month
50 mg tablets:
$1,989.13/month

POTENTIAL SIDE EFFECTS AND TOXICITY

In general, Tivicay is well tolerated with infrequent side effects. The most common moderate to severe side effects in clinical studies were insomnia (3%), headache (2%), and fatigue (2%). Mild insomnia was seen in 7% of participants in one study. Additionally, increased CPK (creatine kinase, a lab value indicating muscle damage), rhabdomyolysis (breakdown of muscle), and myopathy or myositis (muscle pain) were reported. INSTIs have been associated with adverse neuropsychiatric effects in some retrospective cohort studies and case series. The DHHS guidelines recommend to closely monitoring patients on an INSTI who have pre-existing psychiatric conditions. Tivicay can cause a small, reversible increase in kidney function test (serum creatinine) within the first few weeks of treatment without affecting actual kidney function. Liver enzymes should be monitored in people with hepatitis B or C.

POTENTIAL DRUG INTERACTIONS

Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions not listed here. It is important to take Tivicay only with other HIV drugs recommended by your provider because Tivicay and similar drugs are contained in other HIV medications: Biktarvy, Genvoya, Isentress, Isentress HD, Stribild, and Triumeq. Do not take with the anti-arrhythmic dofetilide. Intelence decreases Tivicay levels by 88%, therefore, these two medications must be coadministered with Kaletra, boosted Prezista, or boosted Reyataz. Tivicay should be taken two hours before or six hours after taking laxatives or antacids, the ulcer medication sucralfate, oral iron or calcium supplements, or buffered medications. It can be taken with iron- or calcium-containing supplements if taken together with food. Acid reducers (Pepcid, Zantac) and proton pump inhibitors (for example, Prilosec, Prevacid, Protonix, and Nexium) are okay to use. Avoid taking with Viramune, oxcarbazepine, phenytoin, phenobarbital, and St. John's wort. Start metformin at lowest dose and titrate based on glycemic control. Monitor for metformin adverse effects. Use alternatives to rifampin, carbamazepine, efavirenz, Aptivus/Norvir, and Lexiva/Norvir when possible in people with confirmed or suspected INSTI drug resistance, but these medications can be taken with Tivicay 50 mg *twice* daily. Should be okay to take with Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier.

MORE INFORMATION

Tivicay is part of the recently approved Juluca as well as Triumeq, both single-tablet regimens. Tivicay is a second-generation INSTI—it may work in many individuals whose virus has developed resistance to other INSTIs, but it needs to be dosed twice daily in these people. Compared to other INSTIs, Tivicay has a higher genetic barrier against the development of resistance, similar to the protease inhibitors (such as Prezista). Pediatric HIV guidelines added Tivicay last year as part of a preferred regimen. As of 2017, dolutegravir was classified as an alternative medication for pregnant women taking HIV therapy for the first time. It is particularly useful when drug interactions are a concern with the HIV protease inhibitor (PI) drugs or during acute (new) HIV infection in pregnancy. Tivicay is the smallest HIV pill on the market, a plus for patients who have difficulty swallowing.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Tivicay was the third integrase inhibitor approved, initially as a single agent and a year later as a component of the single-tablet regimen Triumeq. What makes Tivicay/Triumeq stand out from other INSTIs or STRs containing them is its proven high level of resistance to HIV resistance. To date (more than four years since approval), there has yet to be reported a confirmed case of Tivicay/Triumeq resistance in anyone taking one of those medications. Clinical trial data show that Triumeq is superior to (better than) Atripla (the former #1 STR) and both Prezista/Norvir and Reyataz/Norvir regimens in terms of suppressing viral loads, as well as having fewer side effects. Since Tivicay became available in 2013, it quickly became most HIV-treating healthcare providers' favorite INSTI due to its once-daily, unboosted dose and other characteristics discussed above. Many HIV treaters are not always comfortable with prescribing Triumeq due to the Ziagen which it contains. For those treaters, the two-pill combination of Tivicay and Truvada, and now increasingly Descovy, has become their favorite "go-to" first-line ART regimen. What will happen now that the newest INSTI STR Biktarvy (bictegravir/TAF/Emtriva) has been approved is not clear yet. Some HIV treaters and the people for whom they prescribe antiretrovirals may opt to simplify to the new one-pill-once-daily regimen, or stick with what is already working well.

Activist Moisés Agosto-Rosario says: Tivicay (dolutegravir) is recommended as a component of initial therapy. Dolutegravir can cause a reversible increase in kidney function. INSTIs have been associated with adverse neuropsychiatric effects. It is recommended to monitor patients with pre-existing psychiatric conditions.

Isentress HD (and Isentress)

★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

raltegravir **(RAL)**

STANDARD DOSE

ISENTRESS HD: Two 600 mg film-coated tablets once daily for individuals new to HIV therapy (treatment-naïve) or who are virologically suppressed (have undetectable viral load) on an initial regimen of Isentress.

ISENTRESS: One 400 mg film-coated tablet twice daily for people with HIV treatment experience; this Isentress dose may also be taken by those new to HIV therapy.

Isentress HD is for adults and children weighing at least 88 pounds (40 kg). Isentress is for adults and children weighing at least 4 pounds (2 kg). Both Isentress HD and Isentress can be taken without regard to food.

Isentress (but not Isentress HD) pediatric formulations are available as an oral suspension and flavored chewable tablets. Isentress dosing is based on weight for children less than 55 pounds; see package insert for dosing. The chewable tablets may be chewed or swallowed whole. Do not substitute chewable tablets or oral suspension for film-coated tablets.

Take missed dose as soon as possible, unless it's closer to the time of your next dose. Do not double up on your next dose.

MANUFACTURER

Merck and Co.
isentresshd.com
isentress.com
(800) 622-4477

AWP

ISENTRESS HD:
$1,800/month
ISENTRESS 400 mg:
$1,800/month

POTENTIAL SIDE EFFECTS AND TOXICITY

In general, raltegravir is very well tolerated with infrequent side effects. Those reported in up to 3–4% of study subjects include insomnia, nausea, and headache. The side effect profile in children is comparable to adults. Isentress may cause elevated levels of creatine kinase (a muscle enzyme). Inform your provider or pharmacist if you have a history of rhabdomyolysis, myopathy, or increased creatine kinase, or if you also take medications that may contribute to these conditions such as statins, fenofibrate, or gemfibrozil. INSTIs have been associated with adverse neuropsychiatric effects in some retrospective cohort studies and case series. The DHHS guidelines recommend closely monitoring people with pre-existing psychiatric conditions on an INSTI. Chewable tablets contain phenylalanine, which can be harmful to patients with phenylketonuria.

POTENTIAL DRUG INTERACTIONS

Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions not listed here. It is important to take Isentress HD and Isentress only with other HIV drugs recommended by your provider because they and similar drugs are contained in other HIV medications: Biktarvy, Genvoya, Stribild, Tivicay, and Triumeq. Isentress HD cannot be used with rifampin, but Isentress can; increase Isentress to 800 mg twice daily when using rifampin. Remember to decrease the raltegravir back to its original dose when you finish taking rifampin. There are no data on dosing of the chewable tablets with rifampin. There is no need to increase the raltegravir dose with rifabutin. With both Isentress HD and Isentress, avoid Gaviscon and other antacids containing aluminum or magnesium. Calcium-containing antacids like Tums (calcium carbonate) can be used with Isentress, but not Isentress HD. Other acid reducers (such as Pepcid, Zantac, Prilosec, and Prevacid) are okay to use. Raltegravir is not recommended with carbamazepine or phenobarbital. Raltegravir can be used with Daklinza, Harvoni, Olysio, Sovaldi, Viekira Pak, Zepatier, or Epclusa. Unlike Isentress, Isentress HD cannot be used with Intelence or boosted Aptivus.

MORE INFORMATION

Isentress HD was approved in 2017. While the previous version, Isentress, was well tolerated and highly effective, its twice-daily dose was seen by some as a small hindrance. According to DHHS HIV treatment guidelines, all INSTIs on the market are recommended as components of initial ART regimens for most people; Isentress HD has been added to this list. Raltegravir-based regimens may be preferred for patients with high cardiovascular risk. Isentress is the preferred INSTI medication in HIV treatment guidelines for pregnancy, 400 mg twice a day in combination with 2 NRTIs. In pediatric HIV guidelines, Isentress was downgraded in 2017 from "preferred" to an "alternative" part of an initial regimen last year for children ages 6–12.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Isentess HD was approved by the FDA in May 2017. It was developed to offer the option for a once-daily Isentress regimen. It's hard to imagine what the advantage of taking two Isentress HD plus another pill, all once daily, would be over taking one of the single-tablet regimens. **Isentress** was the first integrase approved, in 2007. It is the only INSTI which must be taken twice daily. Early clinical trials demonstrated very rapid (and still the most rapid) drops in viral loads (compared to protease inhibitor and NNRTI regimens), suggesting that it was more potent than older classes of antiretrovirals. However, we soon learned that this rapid drop in viral load did not correlate with resistance to HIV resistance, as this occurs at a rate similar to that for Atripla. At the time when Isentress was approved, it provided a critical new medication for many individuals who had run out of treatment options and kept them alive. With the development of newer once-daily INSTIs (Tivicay) and STRs (Stribild, Genvoya), the usefulness of Isentress has waned in favor of simpler ART regimens.

Activist Moisés Agosto-Rosario says: Raltegravir is an INSTI used in combination with other HIV antivirals. It is for use in adults and children. For children, it is formulated as an oral suspension or as chewable tablets. The addition of raltegravir to the menu of HIV treatment options is welcome by those with drug resistance and not able to build a new regimen. There is a 600 mg film-coated tablet once a day and a 400 mg film-coated tablet twice a day. Raltegravir has demonstrated to be effective and well tolerated. Concerns about drug resistance exist, but its quick effect in suppressing HIV has made it a choice not only for those with multidrug resistance but for those starting treatment for the first time.

Prezcobix

✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

darunavir/cobicistat **(DRV/COBI)**

STANDARD DOSE

One tablet (800 mg of the PI darunavir boosted by 150 mg cobicistat) once daily with food, in people with no darunavir-associated drug resistance, including both treatment-experienced individuals and those who are treatment naïve (taking HIV therapy for the first time).

This co-formulation is only available for people taking darunavir once daily, not those who require darunavir twice daily. When Prezcobix is co-administered with tenofovir disoproxil fumarate (brand name Viread, found in Truvada), Tybost is not recommended in patients with creatinine clearance (CrCL) less than 30 mL/min (a measure of kidney function).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Cobicistat should be used in pregnancy only if the benefits justify the risks. There is only limited data available in pregnancy. Cobicistat has not been studied in individuals under 18 years of age, thus Prezcobix should not be used in pediatric patients. Do not use in people with severe liver impairment.

MANUFACTURER

Janssen Therapeutics
prezcobix.com
(800) JANSSEN (526-7736)

AWP

$2,167.96/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the pages for the individual drugs contained in this medication: Prezista and Tybost. As darunavir (contained in Prezcobix) contains a sulfa component, patients with a known sulfonamide allergy should be monitored for rash after starting it. The most common side effects reported in at least moderate intensity in 5% or more of study participants were diarrhea, nausea, rash, headache, abdominal pain, and vomiting. Cobicistat can cause a small, reversible increase in serum creatinine (SCr, which in turn affects the eGFR or estimated CrCl lab values) within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). While cobicistat does not affect actual kidney function, its effect on SCr can make monitoring of impaired kidney function more difficult or less accurate. However, patients experiencing a confirmed increase in serum creatinine of greater than 0.4 mg/dL from baseline should be closely monitored for renal safety. Serum phosphorus in patients with or at risk for kidney impairment should also be monitored. Kidney impairment, including cases of acute kidney failure and Fanconi syndrome, has been reported in patients taking both cobicistat and Viread (tenofovir DF or TDF, also found in Truvada). When used with TDF, a baseline CrCl, urine glucose, and urine protein is needed; CrCl, urine glucose, and urine protein should be monitored regularly while taking Tybost-containing regimens. While very rare, severe rash (in less than 0.4% of those taking it), accompanied in some cases by fever and/or elevations of AST/ALT (liver enzymes), can be life-threatening. Seek medical attention immediately. Observational cohort studies reported an association between some PIs (including darunavir) and an increased risk of cardiovascular (CV) events. With PIs, there can be increased bleeding in hemophiliacs.

POTENTIAL DRUG INTERACTIONS

See the pages for the individual drugs contained in this medication: Prezista and Tybost. Tell your provider or pharmacist about all medications, herbals, and supplements that you're taking or thinking of taking, prescribed or not. Cobicistat interacts with many drugs, because, as a booster, it inhibits liver enzymes involved in drug metabolism. It is important to take Prezcobix only with other HIV medications recommended by your provider because the medications in Prezcobix and similar drugs are contained in other HIV medications: Evotaz, Genvoya, Kaletra, Norvir, Prezista, Stribild, and Tybost. Use with other protease inhibitors or Intelence, Sustiva, or Viramune is not recommended. Do not take with carbamazepine, dronedarone, ergot derivatives, triazolam, oral midazolam, lurasidone, phenobarbital, phenytoin, pimozide, Revatio, simvastatin, lovastatin, St. John's wort, alfuzosin, ranolazine, or rifampin. Not recommended to be taken with apixaban, avanafil, dabigatran etexilate (in renal impairment), everolimus, rifampentine, salmeterol, ticagrelor, voriconazole. Beclomethasone and prednisone as alternative corticosteroids may be considered, particularly for long-term use. Atorvastatin and rosuvastatin dose should not exceed 20 mg daily. Clinical monitoring is recommended with drospirenone, due to potential for hyperkalemia. Do not take with colchicine if there is kidney or liver impairment. Can be used with Daklinza. Cannot be taken with Zepatier. Based on the mechanism, drug interactions with other hepatitis C medications are probably similar to the interactions with Prezista + Norvir, but we are not certain.

MORE INFORMATION

Since Prezista (darunavir) must be used with a PK enhancer such as cobicistat or ritonavir, this formulation makes for greater convenience, one less pill, and one less co-pay. The resulting co-formulation, however, is rather large in size, but the tablets are designed as an immediate-release formulation, so no potential problem with absorption is anticipated if the tablets are chewed, split, or crushed. A single-tablet, once-daily regimen containing Prezista is expected to be approved this year (see darunavir/c/FTC/TAF drug page).

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
This two-drug tablet consolidated Prezista and the booster Tybost into one tablet. It assures that Prezista will always be taken with its necessary booster. It has the "distinction" of being the largest antiretroviral tablet, which may be a problem for some to swallow. It was developed not only to ensure boosting and reduce pill number, but also as part of the run-up to the development of DRV/COBI/FTC/TAF (which was approved in Europe under the band name Symtuza). Its side effects are identical to Prezista and Tybost.

Activist Moisés Agosto-Rosario says: This co-formulation combines the protease inhibitor darunavir with the booster cobicistat. When compared with Kaletra (lopinavir/ritonavir), darunavir shows that it is superior in efficacy and tolerability. It is also lipid friendly and less likely to cause metabolic complications such as diabetes, lipodystrophy, and high cholesterol. Liver enzymes must be monitored as well as kidney functions if used with Truvada. Many drug interactions can occur when using darunavir boosted with either ritonavir or cobicistat. A conversation with the doctor about all drugs taken is necessary. A single-tablet PI-based regimen combined with cobicistat, TAF, and Emtriva is expected to be approved in 2018.

Prezista

✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

darunavir (DRV)

STANDARD DOSE

One 800 mg tablet with 100 mg Norvir or 150 mg Tybost once daily with food for first-time therapy and treatment-experienced adults without Prezista-related resistance. One 600 mg tablet with 100 mg Norvir twice daily with food for pregnant women and those who have at least one Prezista-related resistance mutation. Prezista should always be taken with Norvir or Tybost.

For adults and children 3 years of age and older weighing at least 22 pounds (10 kg).

Prezista for children is dosed based on weight. There are 75 mg and 150 mg tablets as well as an oral suspension (100 mg/mL) (strawberry cream flavor) available for children three and older and adults who can't swallow pills.

Suspension needs to be taken with Norvir or Tybost, with food.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

MANUFACTURER

Janssen Therapeutics
prezista.com
(800) JANSSEN (526-7736)

AWP

75 mg, 150 mg, 600 mg, and 800 mg: $1,896.77/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Prezista contains a sulfa component and should be used with caution in patients with severe sulfa allergies. Most common side effects may include diarrhea, nausea, headache, rash, vomiting, and abdominal pain. Measure liver function before starting and then monitor, with perhaps closer monitoring for those with underlying liver problems, especially during the first several months. No dose adjustment necessary with mild to moderate liver disease, but Prezista + Norvir is not recommended for those with severe liver impairment. While very rare, severe rash (in less than 0.4% of those taking it), accompanied in some cases by fever and/or elevations of AST/ALT (liver enzymes), can be life-threatening. Seek medical attention immediately. When used with Tybost a small increase in serum creatinine (SCr) may be seen which does not translate to a decrease in kidney function. Observational cohort studies reported an association between some PIs (including darunavir) and an increased risk of cardiovascular (CV) events. There can be increased bleeding in hemophiliacs.

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list of interactions. Drug interactions of Prezista + Norvir may be different than those for Prezista + Tybost. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are many other drug interactions not listed here. Do not take with alfuzosin, dronedarone, colchicine (in patients with kidney or liver impairment), lurasidone, ranolazine, pimozide, ergot derivatives, triazolam, oral midazolam, rifampin, Revatio, Xarelto, or St. John's wort. Tramadol dose decrease may be needed. Monitor therapeutic effects and adverse reactions with use of some analgesics, such as fentanyl and oxycodone. Monitoring of clonazepam is recommended. With Prezista + Norvir, ticagrelor is not recommended and a decreased dose of perphenazine may be needed. Not recommended to be taken with apixaban, dabigatran etexilate (in renal impairment), everolimus, or rifampentine. May decrease levels of phenytoin and phenobarbital, and increase levels of carbamazepine; levels should be monitored. Reduced dose of rifabutin is recommended. Do not use lovastatin or simvastatin, or co-formulations containing these drugs (Advicor and Vytorin). Cholesterol-lowering alternatives are rosuvastatin, atorvastatin (should not exceed 20 mg per day), pitavastatin, and pravastatin, but should be used with caution and started at the lowest dose possible. Monitor for increased side effects from these medications. Reduce clarithromycin dose by 50 to 70% in kidney impairment. The antifungal drugs itraconazole or ketoconazole should be used with caution (maximum dose is 200 mg per day for either). Voriconazole should not be used unless the benefits outweigh the risks. Cialis, Levitra, and Viagra levels are increased; doses should not exceed 10 mg Cialis or 2.5 mg Levitra per 72 hours, or 25 mg Viagra per 48 hours. Monitor for increased side effects of these medications, such as visual disturbances. Prezista may increase levels of calcium channel blockers (like amlodipine) and beta blockers; clinical monitoring is recommended. A lower dose of trazodone and desipramine may be recommended. Close monitoring of INR levels required when using warfarin. Prezista increases levels of nasal and inhaled fluticasone (found in Advair, Flonase, Breo Ellipta, Arnuity Ellipta, and Flovent) and budesonide, as well as systemic corticosteroids ciclesonide, betamethasone, methylprednisolone, mometasone, and triamcinolone. Use alternative corticosteroid and monitor for signs of Cushing's syndrome. Beclomethasone and prednisone as alternative corticosteriods may be considered, particularly for long-term use. Effectiveness of oral contraceptives may be decreased; consider using other or alternative methods of contraception. Use lowest dose of digoxin; monitor and titrate. Monitoring of antidepressant response is recommended with selective serotonin reuptake inhibitors (such as paroxetine and sertraline). Coadminister bosentan, immunosuppressants, and colchicine with caution. A lower dose of colchicine is recommended. Can be used with Sovaldi and Daklinza. Avoid with Harvoni if TDF is part of HIV regimen. With Epclusa, monitor for tenofovir toxicities if TDF is part of HIV regimen. Do not take with Olysio, Viekira Pak, or Zepatier.

MORE INFORMATION

Prezista is now recommended as part of an initial regimen "in certain clinical situations" in DHHS guidelines. DHHS wrote that this change was made "in part because of greater tolerability" with the integrase inhibitor medications compared to Prezista + Norvir or Prezcobix. According to the guidelines, "An example of a situation in which a [Prezista (darunavir)]-based regimen may still be preferred is when a high genetic barrier to resistance is particularly important, such as when there is substantial concern regarding a person's adherence or when antiretroviral therapy (ART) should be initiated before resistance test results are available [go to aidsinfo.nih.gov]." Examples of people needing to start treatment immediately before resistance test results are available include newly infected individuals, pregnant women, and those who are experiencing certain opportunistic infections (an indication of advanced disease). A single-tablet, once-daily regimen containing darunavir/COBI/FTC/TAF is expected to be approved this year (see page 32). Prezista + Norvir is a preferred component in the DHHS perinatal guidelines. See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Approved in 2006, it is still the "newest" PI (tells you something about recent progress in this class of medications). It *must* always be given with a booster like Norvir or Tybost to be effective. It is approved to be given as a part of a first time ART regimen dosed once daily, or dosed twice daily (both with two NRTIs) for people on their second or more ART regimen and whose HIV has some resistance to PIs. It remains the only PI still recommended as a first-time regimen for those whose HIV treater believes they need the benefits of a PI. Its major side effects are nausea, queasiness, diarrhea, and rash. It is the first, and only, PI which has been developed as part of an STR (see DRV/COBI/FTC/TAF).

Activist Moisés Agosto-Rosario says: Darunavir is a protease inhibitor taken once a day boosted with ritonavir or cobicistat. A single-tablet PI-based regimen combined with cobicistat, TAF, and Emtriva is expected to be approved in 2018. Liver enzymes must be monitored as well as kidney functions if used with Truvada. Many drug interactions can occur when using darunavir boosted with either ritonavir or cobicistat. A conversation with the doctor about all drugs taken is necessary.

Evotaz ✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

atazanavir/cobicistat **(ATV/COBI)**

STANDARD DOSE

One tablet once daily with food. Each tablet contains 300 mg of atazanavir boosted by 150 mg cobicistat.

Use in treatment-experienced patients depends on protease inhibitor drug resistance. Co-administration with drugs containing tenofovir disoproxil fumarate (Viread, found in Atripla, Complera, Stribild, and Truvada) is not recommended if kidney function as measured by creatinine clearance is below 70 mL/min.

Not recommended in people with any degree of liver impairment or those who are treatment-experienced and on hemodialysis.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Cobicistat should be used in pregnancy only if the benefits justify the risks. There is only limited data in pregnancy. Cobicistat has not been studied separately from Genvoya and Stribild in individuals under 18 years of age; thus, Evotaz should not be used in pediatric patients.

MANUFACTURER

Bristol-Myers Squibb
evotaz.com
(800) 321-1335

AWP

$1,926.56/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the pages for the individual drugs contained in this medication: Reyataz and Tybost. The most common (greater than 10%) side effects reported in clinical trials were nausea, ocular icterus (yellowing of the eyes), and jaundice. Rash has also been reported, though less common. Cobicistat can cause a small, reversible increase in serum creatinine (SCr, which in turn affects the eGFR or estimated CrCl lab values) within the first few weeks of treatment without affecting actual kidney function (see Tybost for more information). While cobicistat does not affect actual kidney function, its effect on SCr can make monitoring of impaired kidney function more difficult or less accurate. However, patients experiencing a confirmed increase in serum creatinine of greater than 0.4 mg/dL from baseline should be closely monitored for renal safety. Serum phosphorus in patients with or at risk for kidney impairment should also be monitored. Kidney impairment, including cases of acute kidney failure and Fanconi syndrome, has been reported in patients taking both cobicistat and Viread (tenofovir DF or TDF, also found in Truvada). When used with TDF, a baseline CrCl, urine glucose, and urine protein is needed; CrCl, urine glucose, and urine protein should be monitored regularly while taking Tybost-containing regimens. Observational cohort studies reported an association between some PIs (including darunavir, found in Prezista and Prezcobix, and lopinavir/ritonavir, brand name Kaletra) and an increased risk of cardiovascular (CV) events, while this has not been seen with Reyataz (atazanavir, or ATV), found in Evotaz. Another observational cohort study of predominantly male participants found a lower rate of cardiovascular events in those receiving ATV-containing regimens compared with other regimens. Further study is needed.

POTENTIAL DRUG INTERACTIONS

See the pages for the individual drugs contained in this medication: Reyataz and Tybost. Tell your provider or pharmacist about all medications, herbals, and supplements that you're taking or thinking of taking, prescribed or not, as there are many other drug interactions not listed here. Cobicistat interacts with many drugs, because as a booster it inhibits liver enzymes involved in drug metabolism. It is important to take Evotaz only with other HIV medications recommended by your provider because Evotaz and its similar drugs are contained in other HIV medications: Genvoya, Kaletra, Norvir, Prezcobix, Reyataz, Stribild, and Tybost. Use with other protease inhibitors or with Intelence or Sustiva is not recommended. Do not take with ergot derivatives, triazolam, oral midazolam, lurasidone, pimozide, Revatio, simvastatin, lovastatin, St. John's wort, Viramune, alfuzosin, ranolazine, rifampin, dronedarone, or irinotecan. Do not take with colchicine if there is kidney or liver impairment. Do not use with Olysio, Viekira Pak, or Zepatier. Can be used with Sovaldi, Daklinza (reduce Daklinza dose to 30 mg), or Harvoni (if TDF is not part of the HIV regimen). Monitor for tenofovir toxicities with Epclusa if TDF is part of the regimen.

MORE INFORMATION

Evotaz is an alternative PI for first-time therapy in DHHS HIV treatment guidelines, and is one of two PIs that are co-formulated with the booster cobicistat (the other is Prezcobix). Since most people who take Reyataz must use it with a PK enhancer like cobicistat (Tybost) or ritonavir (Norvir), this formulation makes for greater convenience, one less pill, and one less co-pay. Tybost is not an HIV medication. Similar to ritonavir, it is used to boost blood levels of other drugs. The two PK enhancers have a long list of drug interactions. Maintaining adequate hydration is important with Evotaz.

See package insert for more complete information on potential side effects and drug interactions.

Dr. David Hardy says:
Approved in early 2015 at the same time as Prezcobix, this two-drug tablet combines Reyataz with a booster (Tybost) to ensure boosting and reduce pill number. There is not and will not be (any time soon) an STR containing Reyataz. As discussed elsewhere, the use of Reyataz as a first-time regimen has significantly decreased due to its increased side effects compared to other ART options.

Activist Moisés Agosto-Rosario says: Boosted atazanavir is the first PI to be used once a day. Compared to previous PIs, it has a lipid- friendly profile, eliminating any worries about metabolic complications. Even though cobicistat is not clinically inferior to boosting with ritonavir, it does make it easier for individuals by eliminating one more pill and an extra co-payment. AbbVie, the maker of ritonavir, never licensed ritonavir to be used in a co-formulation with other HIV drugs. Drug interactions are a concern. Medications for acid reflux can interfere with the absorption of atazanavir. With atazanavir there is an increase of bilirubin that, although it is not harmful, can cause yellowing of the eyes and skin.

Reyataz ✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

atazanavir sulfate **(atazanavir, or ATV)**

STANDARD DOSE

For most treatment-naïve (first time on HIV therapy) and treatment-experienced individuals, the dose is one 300 mg capsule plus 100 mg Norvir or 150 mg Tybost once daily with food. See package insert for dosing recommendations during pregnancy, liver or kidney impairment, and with certain drug interactions. Capsules also available in 150 mg and 200 mg. Take Norvir or Tybost at same time as Reyataz. Pediatric dose with 50 mg oral powder available based on body weight for children at least 3 months of age weighing at least 11 pounds (5 kg).

Take missed dose as soon as possible, unless it's closer to the time of your next dose. Do not double up on your next dose. Swallow capsules whole—do not open or mix with anything. Oral powder may be used by adult patients who cannot swallow the capsules.

GENERIC IS AVAILABLE.

MANUFACTURER

Bristol-Myers Squibb
reyataz.com
(800) 321-1335

AWP

150 mg and **200 mg**, 60 capsules: $1,755.91/month
300 mg, 30 capsules: $1,739.00/month
Generic atazanavir 300 mg, 30 capsules: $1,565.35/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Most common side effects may include nausea, yellowing of the skin or eyes (a result of increased bilirubin levels), reversible upon stopping the drug), and rash. Other less common side effects may include kidney stones, gallstones, abnormal heart rhythm, and elevated liver enzymes (more common in people with hepatitis B or C). Capsules do not contain phenylalanine but oral powder does; thus use with caution in individuals with phenylketonuria (PKU). Kidney laboratory testing should be performed in all patients prior to initiation of Reyataz and continued during treatment. Renal laboratory testing should include serum creatinine, est. creatinine clearance, and urinalysis with microscopic examination. Rarely, chronic kidney disease has been seen. A cross-sectional cohort study reported Reyataz with Norvir was associated with less progression to atherosclerosis (a symptom of cardiovascular disease). Large observational cohorts found an association between some PIs (DRV/r, FPV, IDV, and LPV/r) and an increased risk of cardiovascular events, while this association was not noted with Reyataz. Another observational cohort study of predominantly male participants found a lower rate of cardiovascular events in those receiving Reyataz-containing regimens compared with other regimens. Further study is needed. There can be increased bleeding in hemophiliacs.

POTENTIAL DRUG INTERACTIONS

See package inserts for Reyataz, Norvir, and Tybost. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Do not use with alfuzosin, rifampin, irinotecan, ergot derivatives, triazolam, oral midazolam, St. John's wort, Revatio, or Viramune (nevirapine). Do not use lovastatin, simvastatin, or the co-formulations containing them (Advicor and Vytorin) for treatment of high cholesterol. Alternatives for these are atorvastatin, rosuvastatin, pravastatin, pitavastatin, and fluvastatin, but should be used with caution and started at the lowest dose possible; monitor for increased side effects. Proton pump inhibitors (PPIs, like Protonix, Nexium, and Prevacid) and H2-receptor antagonists (H2RAs, like Pepcid, Zantac, and Tagamet) can stop Reyataz from being absorbed. Treatment-experienced people should not take PPIs while on Reyataz. Treatment-naïve people can take a PPI at a low dose (such as 20 mg Prilosec OTC) 12 hours before Reyataz/Norvir. H2RAs like Pepcid may be taken (no more than 20 mg twice a day if treatment-experienced or 40 mg twice a day if treatment-naïve) at the same time as Reyataz/Norvir or at least 10 hours later. When taking Reyataz without Norvir, the dose can be taken at least two hours before and at least 10 hours after an H2RA. If taking chewable antacids like Rolaids and Tums, take Reyataz two hours before or one hour after. Treatment-experienced people should not take Reyataz with Sustiva. Viread decreases the levels of Reyataz and Reyataz/Norvir increases Viread levels; monitor for adverse events. Reyataz can be taken unboosted with Epzicom if necessary. Bepridil, amiodarone, quinidine, and lidocaine should be used cautiously because of the risk of worsening heart rhythm. Monitoring may be required when used with warfarin. Calcium channel blockers should be monitored. Use caution when using the antifungals itraconazole or ketoconazole. Voriconazole is not recommended. Reducing dose and frequency of rifabutin to 150 mg every other day or three times a week is recommended. Reyataz + Norvir increases levels of fluticasone (found in Advair, Flonase, and Flovent); monitor for signs of Cushing's syndrome, including rounded face. An alternative corticosteroid is recommended. Reyataz can be taken with birth control pills that contain no more than 30 mcg of ethinyl estradiol if taking Reyataz without Norvir and at least 35 mcg if taken with Norvir. Use caution with carbamazepine, phenobarbital, and phenytoin. ED drugs should not exceed 10 mg Cialis or 2.5 mg Levitra per 72 hours, or 25 mg Viagra per 48 hours. A lower dose of trazodone is recommended. Use with caution with bosentan, salmeterol, and immunosuppressants, and use lower dose of colchicine. Use with Norvir when taking buprenorphine. Monitor before sedation. Do not take with Zepatier. Taking with Olysio is not recommended. Reyataz/Norvir is not recommended with Harvoni if tenofovir DF (TDF, in Truvada) is part of HIV regimen. With Epclusa, monitor for tenofovir toxicities if TDF is part of HIV regimen. Take Reyataz with morning Viekira Pak dose, without Norvir.

Dr. David Hardy says:
Approved in 2003, Reyataz was the first effective and better-tolerated PI alternative to the now forgotten Kaletra, a drug credited with saving many lives in the early 2000's, but loaded with significant side effects. Reyataz can be given with or without a booster (Norvir or Tybost), but due to better resistance to HIV resistance, it is almost always given with a booster. In a 3-way clinical trial to find the best first-time ART regimen, Reyataz + Norvir came in third after both Prezista + Norvir (second) and Isentress (first) due to its greater side effects (nausea, queasiness, diarrhea, and yellow eyes and skin). Its use has progressively fallen off over the past several years due to these study results. Of note, Reyataz went off patent (marketing exclusivity) in the summer of 2017 and became available as a generic form in December 2017. What effect this new and most likely cheaper version will have on Reyataz use will probably be minimal.

Activist Moisés Agosto-Rosario says: Reyataz is used with cobicistat (co-formulated as Evotaz) or ritonavir as boosters, more so if it is used in combination with Truvada. Medications for acid reflux can interfere with the absorption of atazanavir. With atazanavir there is an increase of bilirubin that, although it is not harmful, can cause yellowing of the eyes and skin.

MORE INFORMATION

Yellowing of the eyes and skin often leads to discontinuation. Reyataz plus Norvir and 2 NRTIs is still recommended as a preferred regimen during pregnancy. See Evotaz. Maintaining adequate hydration is important with Reyataz.

See package insert for more complete information on potential side effects and interactions.

Tybost ✔ USED ONLY AS A BOOSTER FOR OTHER DRUGS; RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE AS WELL AS IN CERTAIN CLINICAL SITUATIONS

cobicistat **(COBI)**

STANDARD DOSE

150 mg once a day with food taken at the same time with either Prezista 800 mg (co-formulated as Prezcobix), Reyataz 300 mg (co-formulated as Evotaz), or co-formulated in the single-tablet regimens Stribild and Genvoya.

Tybost is not an HIV drug; it is a pharmacokinetic enhancer or a "booster" used to increase the levels of Prezista 800 mg once daily, Reyataz 300 mg once daily, or elvitegravir 150 mg in Stribild and Genvoya. Tybost is not interchangeable with Norvir when used to increase the levels of other HIV medications.

Take missed dose as soon as possible (at the same time as any separate medication prescribed) unless it's closer to the time of your next dose. Tybost is not recommended for people with CrCl less than 70 mL/min when co-administered with a regimen containing TDF or people with severe liver problems.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
tybost.com
(800) GILEAD-5
(445–3235)

AWP

$263.60/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Side effects seen in clinical studies (greater than 2% of patients) include nausea, jaundice, and yellowing of the eyes. However, it was studied with Reyataz so the jaundice and yellowing of eyes were most likely due to the Reyataz. Before taking Tybost, kidney function testing should be conducted, including serum creatinine, serum phosphorus, urine glucose, and urine protein. These measurements should continue to be monitored while taking Tybost. Cobicistat can cause a small, reversible increase in serum creatinine within the first few weeks of treatment without affecting actual kidney function. The SCr increase occurred within weeks of starting cobicistat and was reversible within a few days after stopping it. While cobicistat does not affect actual kidney function, its effect on SCr can make monitoring of impaired kidney function more difficult or less accurate. The co-adminstration of Tybost and Viread (tenofovir DF or TDF, also found in Complera, Stribild, and Truvada) is not recommended if the CrCl is less than 70 mL/min.

POTENTIAL DRUG INTERACTIONS

Tybost interacts with many drugs. See package insert for the most complete list of interactions. Tell your provider or pharmacist about all medications, herbals, supplements, or over-the-counter (OTC) products you are taking or thinking of taking, prescribed or not, as there are many other drug interactions which are not listed here. Do not take with Evotaz, Genvoya, Kaletra, Norvir, Prezcobix, or Stribild, as each of these also contain Tybost or has a similar medication. Do not take with alfuzosin, colchicine, dihydroergotamine, dronedarone, ergotamine, irinotecan, simvastatin, lovastatin, lurasidone, methylergonovine, ranolazine, rifampin, pimozide, triazolam, oral midazolam, Revatio, or St. John's wort. Tybost may increase levels of nasal or inhaled fluticasone (Flonase, Advair, Breo Ellipta, Arnuity Ellipta, and Flovent). Use an alternative corticosteroid and monitor for signs of Cushing's syndrome (increased abdominal fat, fatty hump between the shoulders, rounded face, red/purple stretch marks, bone loss, possible high blood pressure, and sometimes diabetes). No significant interactions with beclomethasone. Tybost may increase levels of certain calcium channel blockers, beta blockers, HMG-CoA reductase inhibitors (statins), anticoagulants, antiplatelets, antiarrhythmics, antidepressants, sedative-hypnotics, rifabutin, bosentan, erectile dysfunction agents, inhaled corticosteroids, and norgestimate. Caution should be taken, with possible dose adjustments of these medications, when used with Tybost. Sporonox (antifungal) and Biaxin (antibiotic) may increase Tybost concentrations. Tybost may increase Biaxin levels. Rifabutin and some antiseizure medications, such as carbamazepine (Tegretol), phenobarbital, and phenytoin (Dilantin) may decrease Tybost drug levels. Do not take with Olysio, Viekira Pak, or Zepatier. Avoid Harvoni if tenofovir disoproxil fumarate (TDF) is part of the HIV regimen. Tybost has similar drug interactions as Norvir, but they are not interchangeable and there may be some drug interactions with Tybost that are not seen with Norvir. Tybost may increase levels of methamphetamines.

MORE INFORMATION

Tybost is not an HIV medication. It is used to boost blood levels of Prezista and Reyataz and is available in fixed-dose tablets with those medications (see Evotaz and Prezcobix). Cobicistat is also part of the single-tablet regimens Genvoya and Stribild, both recommended therapies in the DHHS treatment guidelines. Tybost shares some of the same side effects of increased cholesterol and increased triglycerides as Norvir; however in clinical trials they were less pronounced. Tybost should only be used in pregnancy if the benefits justify the risks. Tybost has not been studied separately from Genvoya and Stribild in individuals under 18 years of age; thus Tybost should not be used in pediatric patients.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Tybost was originally developed as a booster for the integrase inhibitor elvitegravir (see Stribild and Genvoya). In a head-to-head comparison of Reyataz (plus 2 NRTIs) boosted with Tybost or Norvir, no significant differences in effectiveness or side effects was seen. In fact, on a molecular basis, the two drugs look almost identical. A few small changes in Tybost have taken away its anti-HIV activity, so it is not considered an antiretroviral, unlike Norvir. Tybost has fewer unwanted drug-drug interactions compared to Norvir.

Activist Moisés Agosto-Rosario says: Tybost or cobicistat is a drug developed to work as an enhancer to boost the level of other HIV drugs. Cobicistat is not an antiviral. This enhancer inhibits a liver enzyme used by many HIV drugs to be metabolized in the liver. Being a CYP3A4 inhibitor like ritonavir, it causes the same side effects as ritonavir: increases in triglycerides and cholesterol, as well as drug-drug interactions with many other medications. One good thing about cobicistat: in contrast to the greedy manufacturer of ritonavir (who raised the price 400% when the only use of the drug was as a booster), it is less expensive and licensed for use in fixed-dose combinations by other companies.

Norvir

✔ USED ONLY AS A BOOSTER FOR OTHER DRUGS; RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS

ritonavir (RTV)

STANDARD DOSE

Used as a boosting agent for other protease inhibitors (increases the levels of other PIs), at smaller doses of 100 to 200 mg, taken either once or twice a day with the PI and a meal.

Take missed dose as soon as possible (at the same time as the other PI prescribed) unless it's closer to the time of your next dose. Do not double up on your next dose. Do not crush or chew tablets or capsules; always swallow whole.

Approved for children older than one month with dosing based on body surface area; the use in children depends on the co-administered PI. Capsule formulation requires refrigeration, but tablet does not. Liquid formulation available (80 mg/mL) in peppermint and caramel flavor, but is not very palatable. The taste of the liquid can be improved by mixing with chocolate milk, peanut butter, Ensure, or Advera within one hour of dosing. Liquid formula should not be taken by pregnant women, as it contains 43% alcohol. New Norvir oral powder approved last year, available in 100 mg packets, is free of alcohol and propylene glycol (both of which are found in the liquid formula), and thus safer for pediatric use.

MANUFACTURER

AbbVie
norvir.com
(800) 633-9110

AWP

30 tablets:
$308.60/month

POTENTIAL SIDE EFFECTS AND TOXICITY

The side effect potential of Norvir is much lower now that it is only used as a booster at low doses. Most common side effects include stomach pain, nausea, diarrhea, and vomiting. Other less common side effects may include fatigue; tingling/numbness around the mouth, hands, or feet; loss of appetite; and taste disturbances. Norvir can also increase cholesterol and triglyceride levels.

POTENTIAL DRUG INTERACTIONS

Norvir interacts with many drugs. See package insert for the most complete list of interactions. Tell your provider or pharmacist about all medications, herbals, supplements, or over-the-counter (OTC) products you are taking or thinking of taking, prescribed or not, as there are many other drug interactions which are not listed here. Do not take with alfuzosin, amiodarone, flecainide, lurasidone, propafenone, oral midazolam, triazolam, pimozide, ranolazine, Revatio, rifapentine, rifampin, voriconazole, ergot derivatives, or the herb St. John's wort. Do not use lovastatin and simvastatin or co-formulations containing these drugs (Advicor and Vytorin) for the treatment of high cholesterol. Cholesterol-lowering alternatives are atorvastatin, rosuvastatin, pravastatin, pitavastatin, and fluvastatin, but should be used with caution and started at the lowest dose possible; monitor for increased side effects. Norvir increases levels of nasal and inhaled fluticasone (found in Advair, Flonase, Breo Ellipta, Arnuity Ellipta, and Flovent), which may lead to Cushing's syndrome. Use an alternative corticosteroid and monitor for signs of Cushing's syndrome (increased abdominal fat, fatty hump between the shoulders, rounded face, red/purple stretch marks, bone loss, possible high blood pressure, and sometimes diabetes). Trazodone concentrations may increase; a lower dose of trazodone is recommended. Norvir may decrease levels of methadone, therefore titrate dose of methadone to clinical effect. Use caution with anticonvulsants such as carbamazepine, phenobarbital, and phenytoin. Use calcium channel blockers (amlodipine, nifedipine, and others) with caution. Norvir may alter warfarin levels; additional monitoring is required. Norvir use with other blood thinners (anticoagulants), such as Xarelto, is not recommended. Norvir can increase anticoagulant concentrations (and thereby increase risk of bleeding) or decrease their concentrations (and thereby decrease effectiveness). Cialis, Levitra, and Viagra levels are increased; doses should not exceed 10 mg Cialis or 2.5 mg Levitra per 72 hours, or 25 mg Viagra per 48 hours. Monitor for increased side effects of these medications, such as visual disturbances, low blood pressure, dizziness, and prolonged painful erection lasting longer than 4 hours. Effectiveness of oral contraceptives may be decreased; consider using other or alternative methods of contraception. Levels of the street drug ecstasy are greatly increased by Norvir, and at least one death has been attributed to the combination. Using Norvir with methamphetamines can result in up to 2–3 fold increase in methamphetamine concentrations and puts user at risk for overdose. GHB, another street drug, is also dangerous with Norvir. Clarithromycin levels can increase by up to 80%. Co-administer bosentan, salmeterol, and immunosuppressants with caution. If co-administered, a lower dose of colchicine is recommended. Norvir, when combined with another PI, may be taken with Sovaldi, Daklinza (dose may need adjustment), Epclusa (monitor for tenofovir toxicity if TDF is part of regimen), and Harvoni (if TDF is not part of HIV regimen). Norvir + PI should not be taken with Olysio, Viekira Pak, or Zepatier.

MORE INFORMATION

The advantage of Norvir is its use with other PIs as a boosting agent (officially in the drug class called "pharmacokinetic enhancers"). As such, it's used to increase the levels of some HIV protease inhibitor (PI) medications. An alternative to Norvir was approved in 2014 (see Tybost page). Stomach side effects are reduced by taking Norvir with high-fat foods—however, some other HIV medicines should not be taken with high-fat foods. See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Norvir was the second protease inhibitor approved to treat HIV, in early 1996. Over a short period of time its significant side effects of nausea, vomiting, severe queasiness, and explosive diarrhea (when taking 1,200 mg/day) reduced its use as a PI. By the late 1990s, it was used as the first booster (taking 100–400 mg/day) for almost all other protease inhibitors and markedly increased the potency and reduced the number of doses of protease inhibitors. Even at lower doses, some people have side effects such as nausea, queasiness, and diarrhea.

Activist Moisés Agosto-Rosario says: Once upon a time, Norvir was approved as a treatment for HIV. It was one of the first PIs that slowed death rates. For many it was the rescuer from death. But as with other first generation PIs, it can cause many debilitating side effects, including gastrointestinal problems and increased risk for liver toxicity. Because of the way it is metabolized, ritonavir increases the blood level of other drugs. It was hard to take and difficult to manage its toxicities and drug interactions. Even though it failed as a treatment, it has proven to be, at a lower dose, a useful booster for effective and safer PIs. However, the greedy manufacturer raised the price 400% when the only use of the drug was as a booster.

Descovy ★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

emtricitabine/tenofovir alafenamide **(FTC/TAF)**

STANDARD DOSE

One tablet once daily, without regard to food. Tablet contains 200 mg emtricitabine and 25 mg tenofovir alafenamide.

For adults and children weighing at least 55 pounds (25 kg). Crushing or splitting tablets has not been studied and is not recommended; TAF is soluble in water, but has a bitter and burnt aromatic flavor profile.

Take a missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Descovy should not be used if CrCl is less than 30 mL/min or if you are on dialysis. In children weighing less than 77 pounds, taking Descovy with a boosted HIV protease inhibitor medication is not recommended. Unlike Truvada, Descovy is not approved for and should not be used for prevention (pre-exposure prophylaxis, or PrEP).

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
descovy.com
(800) GILEAD-5
(445–3235)

AWP

$2,010.95/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Overall, Descovy is well tolerated, but some may experience nausea, headache, stomach pain, or weight loss. Skin discoloration on palms and soles may also occur. May affect the bones and kidneys. In clinical trials, fewer bone and kidney issues were observed with the TAF formulation compared to the TDF formulation. Tell your provider about any pain in extremities, persistent or worsening bone pain and fractures, with or without muscular pain or weakness, as well as any concerning changes in urinary habits as these could be signs of kidney problems. If you have HIV and HBV, guidelines recommend treatment for both viruses. Descovy can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Descovy without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider.

POTENTIAL DRUG INTERACTIONS

See package insert and DHHS guidelines for a more complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions not listed here. It is important to take Descovy only with other HIV medications recommended by your provider because the components of Descovy and its equivalent medications are contained in many other HIV drugs: Atripla, Biktarvy, Combivir, Complera, Odefsey, Emtriva, Epivir, Epzicom, Genvoya, Stribild, Triumeq, Trizivir, Truvada, or Viread; also Epivir-HBV, Hepsera, and Vemlidy (TAF). Use caution with drugs that negatively affect the kidneys, including chronic use or high doses of anti-inflammatory drugs for pain like Advil or Motrin (ibuprofen) and Aleve (naproxen). Descovy should not be taken with certain anticonvulsants (including carbamazepine, oxcarbazepine, phenobarbital, and phenytoin), Aptivus/Norvir, rifabutin, rifampin, rifapentine, or St. John's wort. Can be used with hepatitis C drugs such as Epclusa, Harvoni, Sovaldi, Olysio, Daklinza, Viekira Pak, or Zepatier.

MORE INFORMATION

Descovy is the newer version of Truvada. Instead of TDF, Descovy contains TAF (tenofovir alafenamide), which reduces serum tenofovir concentration by 90%. This results in lessened impact on kidney and bone mineralization but maintains potent antiviral activity in the CD4 cell. In clinical trials, fewer kidney and bone issues were observed with TAF than with TDF, and significant improvements were seen when switching from TDF to TAF. The long-term impact of TAF on patients with osteopenia or osteoporosis is unknown. Both Descovy and Truvada are currently recommended by DHHS HIV treatment guidelines for first-time therapy for most people. However, unlike Truvada, Descovy is not approved for and should not be used for PrEP. A clinical trial called DISCOVER is currently in progress comparing Descovy to Truvada for PrEP (prevention) in HIV-negative individuals. Because both FTC and TAF are also active against hepatitis B (HBV), Descovy is recommended by DHHS for individuals co-infected with both HIV and hepatitis B. Pediatric HIV guidelines added Descovy last year as part of a preferred regimen. There is insufficient data in pregnancy for the DHHS to recommend the routine use of Descovy in pregnant women at this time. Descovy tablets are relatively small compared to Truvada and other combination tablets, which may be a plus for patients who have difficulty swallowing.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Descovy was approved in mid-2016 as the "new and improved" version of Truvada, as it maintained the Emtriva (FTC) and changed the Viread (tenofovir DF) to TAF. This change was prompted by the finding that TAF (originally discovered and developed in 2002, but then shelved for several years) produced similar HIV suppressing effects as Viread with much lower levels of the same drug in the blood. The lower tenofovir levels have been shown to have less harmful effects on the kidneys and bone mineral density (bone strength). Descovy (or its components TAF and Emtriva) is the most preferred two-nuke combination HIV treaters use when building first-time ART regimens for their patients living with HIV.

Activist Moisés Agosto-Rosario says: Descovy is the new Truvada in that it contains emtricitabine plus tenofovir alafenamide (TAF) instead of tenofovir disoproxil fumarate (TDF). What is better about combining with TAF is that it does not cause the same level of kidney problems or lower bone density that TDF does. Both Descovy and Truvada are recommended as first-line therapies in the HHS HIV treatment guidelines. Both are approved and recommended for hepatitis B. Descovy has not been approved for PrEP, however. It is important not to combine with other antivirals not prescribed by a doctor. Many new STRs already contain TAF. Drug interactions may occur, so tell your doctor about all the medications your take, including those sold over the counter.

Truvada ★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

emtricitabine/tenofovir DF **(FTC/TDF)**

STANDARD DOSE

One tablet once daily without regard to food for adults and children weighing at least 77 pounds. In children weighing 37–76 pounds, Truvada is dosed based on body weight. See package insert for weight-based dosing. Truvada tablets are available in the following emtricitabine/tenofovir DF dosages: 100/150 mg tablets, 133/200 mg tablets, 167/250 mg tablets, and 200/300 mg tablets. Tablets can disintegrate in water, grape juice, or orange juice with minor stirring and pressure from a spoon; however, no studies have been performed to evaluate the pharmacokinetics (PK) or stability of crushed vs. intact tablets.

Take a missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. The dosing frequency needs to be adjusted for people with decreased kidney function. Truvada should not be used if CrCl is less than 50 mL/min or if you are on dialysis.

APPROVED AS GENERIC; NOT YET COMMERCIALLY AVAILABLE.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
truvada.com
(800) GILEAD-5
(445–3235)

AWP

$2,010.95/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the pages for the individual drugs contained in Truvada: Viread and Emtriva. Overall, it is well tolerated, but some may experience nausea, headache, gas, stomach pain, or weight loss. Skin discoloration on palms and soles may also occur. The TDF in Truvada is associated with long-term decreases in bone mineral density (BMD). BMD monitoring should be considered in people who have a history of bone fracture due to disease or are at risk for osteopenia or osteoporosis. While calcium and vitamin D levels can be checked to assess the need for these supplements, talk with your provider before starting on your own. Truvada can cause kidney toxicities. Tell your provider about any pain in extremities, persistent or worsening bone pain and fractures, with or without muscular pain or weakness, as well as any concerning changes in urinary habits, as these could be signs of kidney problems. Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein should be performed in all individuals with mild kidney impairment. If you have HIV and HBV, guidelines recommend treatment for both viruses. Truvada can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Truvada without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider. Truvada is associated with lower lipid levels than Ziagen or tenofovir AF (TAF) due to tenofovir DF's favorable effect on cholesterol. Truvada contains lactose, which can cause some abdominal discomfort, especially in patients sensitive to lactose.

POTENTIAL DRUG INTERACTIONS

See the pages for the individual drugs contained in Truvada: Viread and Emtriva. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. It is important to take Truvada only with other HIV medications recommended by your provider because the components of Truvada and its equivalent medications are contained in many other HIV drugs: Atripla, Biktarvy, Combivir, Complera, Odefsey, Descovy, Emtriva, Epivir, Epzicom, Genvoya, Stribild, Triumeq, Trizivir, or Viread; also Epivir-HBV, Hepsera, or Vemlidy (TAF). Tenofovir decreases the concentration levels of Reyataz, therefore when Reyataz is taken with Truvada or Viread, it is recommended that Reyataz 300 mg is taken with Norvir 100 mg or Tybost 150 mg (all as a single daily dose with food). In addition, Reyataz/Norvir, Prezista/Norvir, and Kaletra increase tenofovir concentrations. It is recommended that patients taking Reyataz/Norvir, Prezista/Norvir, or Kaletra with Truvada should be monitored for Truvada-associated adverse events, particularly decreases in kidney function. Avoid taking Truvada with drugs that negatively affect the kidneys, including chronic use or high doses of anti-inflammatory drugs for pain like Advil or Motrin (ibuprofen) and Aleve (naproxen). Truvada may be used with hepatitis C drugs such as Daklinza, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier, depending on the third drug in the HIV regimen. Monitor for tenofovir toxicities if used with Epclusa.

MORE INFORMATION

Current DHHS HIV treatment guidelines recommend Truvada (or Descovy) over Epzicom as the preferred NRTI component for initial therapy (unless Epzicom is paired with Tivicay). The new version of Truvada, called Descovy, was approved in 2016. The ACTG A5202 study reported that while both Epzicom and Truvada reduced viral load, for those people who started treatment with a viral load of more than 100,000 copies/mL, the times to virologic failure and the first adverse event were both significantly shorter in patients taking Epzicom compared to Truvada. In studies using Tivicay in the regimen, however, Truvada and Epzicom were equally effective regardless of baseline viral load. Kidney function must be monitored before and during treatment with Truvada and it may not be a good option for patients with underlying kidney problems. Fewer kidney and bone issues were seen with the TAF formulation compared to TDF in clinical trials. Approved in 2012 for HIV prevention (pre-exposure prophylaxis, or PrEP) in confirmed HIV-negative adults; see Truvada for PrEP page. Truvada is recommended by DHHS as one of the preferred NRTI combination components of an ART regimen in pregnancy.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Approved on the same day in 2004 as Epzicom, Truvada is also a two-drugs-in-one-pill, two-nuke combination "backbone" to which a third drug is added to create a three-drug combination or "cocktail" ART regimen. Truvada was the most commonly prescribed antiretroviral until Descovy was approved in 2016. This was due to Truvada's solid track record as a potent, well-tolerated, and durable two-nuke combination. Data show higher potency over Epzicom and concerns (still controversial) about Epzicom's cardiovascular side effects. Truvada's use has steadily declined since the approval of three TAF-containing medications (Genvoya, Odefsey, Descovy) due to fewer long-term side effects (kidney and bone strength). Truvada became the first, and still only, medication approved for pre-exposure prevention (PrEP) of HIV, in 2012. In mid-December 2017, a generic form of Truvada was made available in the U.S. With the availability of TAF-containing medications, the use of generic Truvada, while probably less expensive, has yet to be seen.

Activist Moisés Agosto-Rosario says: Truvada is a fixed-dose combination containing emtricitabine and tenofovir disoproxil fumarate, or TDF. Both drugs have a long half-life. Truvada is still a component of three of the four first-line recommended regimens by the HHS HIV treatment guidelines. However, Truvada may cause kidney damage and loss of bone density. It is important to monitor kidney function and bone density. Besides that, Truvada is well tolerated and potent. It is approved for HIV-negative individuals to prevent the acquisition of HIV (PrEP).

Epzicom ★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE WHEN USED IN COMBINATION WITH DOLUTEGRAVIR (AS TRIUMEQ)

abacavir/lamivudine **(ABC/3TC)**

STANDARD DOSE

One tablet once daily, without regard to food. Tablet contains 600 mg abacavir and 300 mg lamivudine.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Approved for adults and children weighing 55 lbs (25 kg) or more. Not recommended for those with decreased kidney function (creatinine clearance less than 50 mL/min) due to lamivudine component, or those with mild liver impairment due to abacavir component. Alternative doses may be obtained by using the individual components of this medication.

GENERIC IS AVAILABLE.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
(877) 844-8872

AWP

Truvada 600/300 mg tablet, 30 tablets: $1,550.05/month
generic abacavir/lamivudine 600/300 mg tablet, 30 tablets: $1395.00/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the individual drugs contained in Epzicom: Epivir (lamivudine) and Ziagen (abacavir). Common side effects may include headache, nausea, fatigue, depressed mood, dizziness, diarrhea, and insomnia. Of note is the hypersensitivity reaction (HSR, an allergic-like reaction) warning on abacavir (see Ziagen for details of symptoms). To minimize the risk for HSR, a blood test for HLA-B*5701 (a genetic marker) should be done prior to starting an HIV regimen containing Epzicom to identify patients at higher risk for this reaction. A negative HLA-B*5701 test does not mean you won't have HSR, but the risk is reduced to 1% from clinical studies. This test is covered by most insurance and also by LabCorp/ViiV (see company contact on co-pay chart).

An HSR can technically occur at any time, regardless of how long you have taken the medication, however, it is much more likely to occur when you start (or re-start) the medication (90% occur within the first 6 weeks of treatment). Symptoms of an HSR usually worsen, very slowly, with every dose. Treatment should be immediately discontinued and you can never take another product containing abacavir, such as Epzicom, Triumeq, Trizivir, or Ziagen, again (called "rechallenging"). Rechallenging could cause a rare life-threatening reaction. (This does not apply to a missed dose when there's no HSR, but talk with your healthcare provider and watch for symptoms if you've stopped the drug for at least a few days.)

Some observational studies suggest abacavir may increase the risk of cardiovascular events, including myocardial infarction (MI, or heart attack), in people with greater risk factors (such as smoking, diabetes, high blood pressure, older age, high cholesterol, family history of heart disease, and drug use), though other studies have found no increased risk. To date, no consensus has been reached on the association of abacavir with cardiac risk or a possible mechanism for the association. People who have high risk for heart disease should discuss risks with their provider and they should be monitored more closely. If you have HIV and HBV, guidelines recommend treatment for both viruses. The lamivudine component of Epzicom can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Epzicom without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider.

POTENTIAL DRUG INTERACTIONS

See the individual drugs contained in Epzicom, Epivir and Ziagen. It is important to take Epzicom only with other HIV medications recommended by your provider because Epzicom and its equivalent drugs are contained in other HIV medications: Atripla, Biktarvy, Complera, Odefsey, Descovy, Emtriva, Epivir, Genvoya, Stribild, Triumeq, Truvada, or Ziagen; also Epivir-HBV, Hepsera, and Vemlidy, used for hepatitis B. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. Alcohol can increase the levels of abacavir and therefore can increase the possibility of side effects.

Epzicom may be used with hepatitis C drugs such as Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier, depending on the third drug in the HIV regimen.

MORE INFORMATION

Triumeq, a single-tablet regimen (STR) containing Tivicay and Epzicom, is a DHHS recommended initial therapy in most people. Otherwise, the guidelines recommend Descovy or Truvada over Epzicom as the backbone for the NRTI component of an HIV drug combination for first-time therapy, with Epzicom listed as an alternative NRTI backbone. One of the reasons abacavir is a DHHS alternative drug is that the ACTG A5202 study found that abacavir/lamivudine (Epzicom) was inferior to tenofovir/emtricitabine (Truvada) in getting people undetectable when their pre-treatment viral load was over 100,000 copies/mL. However, when combined with Tivicay (dolutegravir), Epzicom performed just as well as Truvada in people with high viral loads (over 100,000 copies/mL). Hence, Triumeq is the only abacavir-containing regimen recommended by DHHS as initial therapy for most people. The lamivudine portion of Epzicom is also used to treat the hepatitis B virus (HBV); see Epivir. Epzicom is recommended by DHHS as one of the preferred NRTI combination components of an ART regimen in pregnancy.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Approved on the same day in 2004 as Truvada, Epzicom is also a two-drugs-in-one-pill, two-nuke combination "backbone" to which a third drug is added to build a three-drug combination or "cocktail" ART regimen. Because Epzicom contains Ziagen (abacavir), a one-time blood or mouth swab test must be done to look for a genetic marker (HLA-B*5701) which predicts a severe allergic reaction if present. In 2008, a European cohort study raised concern about an association of Ziagen with the occurrence of heart attacks. Although many other studies have weighed in, trying to confirm or refute this finding, there remains controversy whether cardiovascular disease (heart attacks) is a true side effect of Ziagen or a false association. Not long after this, a large clinical trial comparing first-time ART regimens with either Epzicom or Truvada found that Epzicom was not as potent for high viral loads (more than 100,000 copies/ml). These two findings diminished the use of Epzicom and Ziagen in favor of Truvada. A generic version of Epzicom has been available in the U.S. since September 2016. Today most Epzicom use is prescribed as two of the three medications in Triumeq.

Activist Moisés Agosto-Rosario says: Epzicom is used as an alternative to Truvada in patients who can't tolerate TDF because of its kidney toxicity or loss of bone density. Epzicom may increase the risk of heart attack and cardiovascular disease due to abacavir. In patients with a viral load above 100,000 copies/mL, it is not as effective. Epzicom is recommended as a first-line treatment in combination with dolutegravir. It is combined with dolutegravir in the fixed-dose single-tablet regimen Triumeq.

Emtriva ★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

emtricitabine **(FTC)**

STANDARD DOSE

One 200 mg capsule once daily without regard to food. Dosing needs to be adjusted for adults and children who have decreased kidney function (creatinine clearance less than 50 mL/min). See package insert for guidance on dosing in the setting of kidney impairment.

Indicated for adults and children regardless of age. Emtriva is dosed based on body weight for children. See the package insert for weight-based dosing.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. It is also available as an oral solution (10 mg/mL) (cotton candy flavor) for children any age and adults who are not able to swallow the capsules. Can be used interchangeably with Epivir.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
(800) GILEAD-5
(445-3235)

AWP

200 mg, 30 capsules:
$643.82/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Emtriva is very well tolerated. The most common side effects (rarely reported) may include headache, diarrhea, and nausea. If you have HIV and HBV, guidelines recommend treatment for both viruses. Emtriva can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Emtriva without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider. Skin discoloration (darkening of the skin on the palms and the soles) can occur and was more frequent in children, but is generally mild and not concerning.

POTENTIAL DRUG INTERACTIONS

No significant drug interactions. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. It is important to take Emtriva only with other HIV medications recommended by your provider because Emtriva or anequivalent drug is contained in other HIV drugs: Atripla, Biktarvy, Combivir, Complera, Descovy, Epivir, Epzicom, Genvoya, Odefsey, Stribild, Triumeq, Trizivir, or Truvada; also Epivir-HBV, Hepsera, or Vemlidy (TAF), all three used for hepatitis B. Emtriva may be used with hepatitis C drugs such as Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier, depending on the other components in the HIV regimen.

MORE INFORMATION

Emtriva (emtricitabine) is similar to Epivir (lamivudine): both treat HIV and HBV and have the same resistance profile, meaning that if your virus is resistant to one drug, it will be resistant to the other. If your HIV develops resistance to Epivir or Emtriva, it does not mean that your HBV is also resistant to them. Both Descovy and Truvada (both contain Emtriva) are currently recommended by DHHS HIV treatment guidelines for first-time therapy for most people. Emtriva is also found in several single-tablet regimens (Atripla, Complera, Genvoya, Stribild, and Odefsey, with more to come). Sometimes, drug resistance that the virus develops against emtricitabine makes the virus reproduce at a slower rate. This drug resistance can also improve the antiviral activity of Retrovir (zidovudine) and Viread (tenofovir), and for that reason, some providers continue Emtriva treatment in combination with other antiretrovirals after resistance develops. Emtriva oral solution should be kept in the refrigerator. If kept at room temperature, the oral solution should be used within three months. The capsule is relatively small, an advantage for people with difficulty swallowing.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Emtriva is a closely related medication to Epivir (lamivudine or 3TC). Note the similar chemical names FTC and 3TC. For many HIV treaters, ART guidelines writers, and even the FDA, the two medications are interchangeable. Emtriva is almost always used in combination with Viread (Truvada) or with TAF (Descovy). It is a potent antiretroviral, but its anti-HIV activity is almost completely lost when a very common, single mutation (M184V) occurs in the virus. It has very few, if any, significant side effects and therefore is almost always included in most ART regimens.

Activist Moisés Agosto-Rosario says: Emtriva is a very safe and well-tolerated drug. Its chemical structure is the same as lamivudine. They both show equal safety profile and effectiveness. The only difference is that emtricitabine has a longer half-life. Emtriva is one of the two drugs in Truvada, which became an alternative to Combivir. It is also in several single-tablet regimens, including new drugs containing TAF and an integrase inhibitor or PI. It is also used to treat HIV/hepatitis B co-infection.

Epivir

★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE WHEN USED IN COMBINATION WITH DOLUTEGRAVIR AND ABACAVIR (AS TRIUMEQ)

lamivudine **(3TC)**

STANDARD DOSE

One 300 mg tablet once daily (or one 150 mg tablet twice daily), without regard to food. Dosing needs to be adjusted for adults and children who have decreased kidney function (creatinine clearance less than 50 mL/min). See package insert for guidance on dosing in the setting of kidney impairment.

Indicated for adults and children at least 3 months of age and older. Epivir for children is dosed based on body weight. See the package insert for weight-based dosing.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. The 150 mg tablets are scored and may be split. Based on drug properties, tablets may be crushed and added to a small amount of semi-solid food or liquid for immediate consumption. Epivir is also available as an oral solution (10mg/mL) (strawberry-banana flavor) for children any age and adults who are not able to swallow the tablets. Can be used interchangeably with Emtriva.

GENERIC IS AVAILABLE.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
(877) 844-8872

AWP

Epivir 300 mg tablets, 30 tablets: $498.89/month
generic lamivudine 300 mg tablets, 30 tablets: $324.33-$429.66/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Epivir is very well tolerated. The most common side effects (rarely reported) may include headache, nausea, fatigue, insomnia, malaise (general ill feeling), nasal symptoms, and cough. If you have HIV and HBV, guidelines recommend treatment for both viruses. Epivir can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Epivir without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider.

POTENTIAL DRUG INTERACTIONS

No significant drug interactions. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. It is important to take Viread only with other HIV medications recommended by your provider because Viread and its equivalent drugs are contained in many other HIV medications: Atripla, Biktarvy, Complera, Descovy, Emtriva, Epivir, Epzicom, Genvoya, Odefsey, Stribild, Triumeq, and Truvada; also Epivir-HBV, Hepsera, and Vemlidy (TAF), all three used for hepatitis B. Epivir may be used with hepatitis C drugs such as Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier, depending on the other components in the HIV regimen.

MORE INFORMATION

Epivir (lamivudine) is similar to Emtriva (emtricitabine): both treat HIV and HBV and have the same resistance profile, meaning that if your virus is resistant to one drug, it will be resistant to the other. If your HIV develops resistance to lamivudine, it doesn't mean that your HBV is also resistant to it. Sometimes, drug resistance that the virus develops against lamivudine makes the virus reproduce at a slower rate. This drug resistance can also improve the antiviral activity of Retrovir (zidovudine) and Viread (tenofovir), and for that reason, some providers continue Epivir treatment in combination with other antiretrovirals after resistance develops. Lamivudine is also available in four combination products: Combivir (with zidovudine), Epzicom (with abacavir), Trizivir (with zidovudine and abacavir), and Triumeq (with dolutegravir and abacavir). Epivir as part of the combination tablet Combivir is recommended as an alternative NRTI combination component of an ART regimen during pregnancy. Epivir is available as generic lamivudine, which should be as effective and well tolerated as the brand name drug Epivir. Some insurers may require patients to take regimens containing generics rather than brand name drugs, including simpler co-formulated products. For example, since both zidovudine (Retrovir, AZT) and lamivudine are available in generic form, a person might have to take these two generic pills instead of the fixed-dose combination tablet Combivir. The availability of generics might also limit choices of therapy. For example, newer brand name drugs and co-formulations, such as Genvoya or Triumeq, might be restricted to patients who can't physically tolerate generic regimens.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Due to its high potency and excellent tolerability (it has virtually no side effects), Epivir has survived as a commonly used drug where most other nukes approved during the same time have fallen by the wayside due to toxicity. It has been available as a generic lamivudine since 2011. Due to their almost identical properties, Emtriva and Epivir are almost interchangeable, including their high susceptibility to the very common M184V mutation in the virus.

Activist Moisés Agosto-Rosario says: Epivir is the oldest antiretroviral still in use today. It is well tolerated, very effective, and has no drug-drug interactions. It has been used in combination with other NRTIs and is a component of the single-tablet regimen Triumeq. It is used to treat individuals co-infected with HIV and hepatitis B (HBV); if discontinued for HIV it may cause a flare-up of HBV disease. A downside of Epivir is its drug resistance profile. One mutation (M184V) can reduce its effectiveness.

Viread ★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE

tenofovir disoproxil fumarate **(TDF)**

STANDARD DOSE

One 300 mg tablet once daily, without regard to food in adults and children at least 2 years old weighing at least 21 pounds (10 kg). Viread tablets are also available in the following dosages: 150 mg, 200 mg, 250 mg tablets, and oral powder (40 mg/g in 60 g packets). Based on a company study, tablets can be disintegrated in water, grape juice, or orange juice with minor stirring and pressure from a spoon. In children, Viread is dosed based on body weight. See package insert for specific weight-based dosing.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Dosing frequency needs to be adjusted for adults and children with decreased kidney function (for creatinine clearance, or CrCl, less than 50 mL/min). See package insert for guidance on dosing in the setting of kidney impairment. FDA approved for chronic HBV in patients 12 years and older weighing at least 77 pounds (35 kg).

GENERIC IS AVAILABLE.

MANUFACTURER

Gilead Sciences, Inc.
Gilead.com
(800) GILEAD-5
(445-3235)

AWP

200 mg and **250 mg** tablets: $1,268.06/month
300 mg tablets: $1,368.26/month
Generic 300 mg tablets: $1,215/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Generally well tolerated, but some may experience nausea, diarrhea, vomiting, and gas. Decreases in bone mineral density (BMD) have been observed. BMD monitoring should be considered in people who have a history of bone fracture due to bone disease or are at risk for osteopenia or osteoporosis. Viread may cause kidney toxicities. Creatinine clearance (CrCl) should be assessed before initiating treatment. In addition to CrCl, glucose and protein in the urine and serum phosphorus should be monitored more often in patients at risk for kidney problems. Tell your provider about any pain in extremities, persistent or worsening bone pain and fractures, with or without muscular pain or weakness, as well as any concerning changes in urinary habits, as these could be signs of kidney problems. Viread is associated with a favorable effect on LDL cholesterol. If you have HIV and HBV, guidelines recommend treatment for both viruses. Viread can be used to treat HIV and HBV simultaneously. If you are co-infected with HBV and HIV, you should not stop Viread without medical supervision because it can cause your HBV to flare and cause you to experience signs and symptoms of acute hepatitis. HBV should be closely monitored by your provider. The Viread formulation contains lactose, which can cause some abdominal discomfort, especially in patients sensitive to lactose.

POTENTIAL DRUG INTERACTIONS

Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. It is important to take Viread only with other HIV medications recommended by your provider because Viread and its equivalent drugs are contained in many other HIV medications: Atripla, Biktarvy, Complera, Odefsey, Descovy, Emtriva, Epivir, Epzicom, Genvoya, Stribild, Triumeq, and Truvada; also Epivir-HBV, Hepsera, or Vemlidy (TAF), all three used for hepatitis B. Viread decreases the levels of Reyataz; therefore, Reyataz 300 mg must be boosted with Norvir 100 mg or Tybost 150 mg (taken together with food) when used in combination with TDF. Kaletra, Prezista/Norvir, and Reyataz/Norvir increase Viread levels, but there is no dose adjustment needed. Patients taking Kaletra, Prezista/Norvir, or Reyataz/Norvir with TDF should be monitored for Viread side effects (including kidney disorders) due to the higher TDF levels. Do not take Viread with adefovir. Avoid taking Viread with drugs that negatively affect the kidneys, including chronic use or high doses of NSAIDS (nonsteroidal anti-inflammatory drugs for pain, such as Advil or Motrin (ibuprofen) and Aleve (naproxen). Viread may be used with hepatitis C drugs such as Daklinza, Harvoni, Olysio, Sovaldi, Viekira Pak, or Zepatier, depending on the other components in the HIV regimen. Monitor for tenofovir toxicities if used with Epclusa.

MORE INFORMATION

TDF with emtricitabine, as Truvada, is a recommended NRTI combination by DHHS HIV treatment guidelines for first-time therapy. A new version of tenofovir, called tenofovir alafenamide (TAF), replaced TDF in certain fixed-dose combinations. Genvoya and Odefsey are two single-tablet regimens containing TAF instead of TDF. Descovy is another version of Truvada, combining emtricitabine with TAF instead of TDF. In clinical trials, TAF had fewer kidney and bone issues than TDF. The NIH reported last year that infants exposed in the womb to TDF may have lower bone mineral content than those exposed to other antivirals. Tenofovir DF was approved in 2012 as part of Truvada for HIV prevention as PrEP (pre-exposure prophylaxis; see Truvada for PrEP page). TDF is part of the single-tablet regimens Atripla, Complera, and Stribild. Viread as part of the combination tablet Truvada is recommended by DHHS as one of the preferred NRTI combination components of an ART regimen in pregnancy.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Because of its different HIV resistance mutation pattern, Viread continued to be potent when other nukes had failed and became a common part of most ART regimens from 2001 to 2015. Its most common short-term side effects are mild nausea, queasiness, and mild diarrhea; on a long-term basis it can cause kidney damage and weakening of bones (osteoporosis or bone demineralization) in a small number of people. It is increasingly being replaced by TAF-containing regimens. A generic form of Viread became available in the U.S. in December 2017.

Activist Moisés Agosto-Rosario says: Viread, or TDF, is potent, well tolerated, and has a long half-life. Monitoring kidney functions is important while taking TDF. It has been shown to cause kidney toxicity as well as a loss of bone density. These side effects tend to disappear when discontinued. It is a component of the single-tablet regimens Complera and Stribild, as well as Truvada, a widely used fixed-dose combination as a nuke backbone and as a prophylaxis for HIV infection. Its manufacturer has developed an improved version of TDF known as TAF, or tenofovir alafenamide fumarate. TAF is a component of the single-tablet regimens Genvoya and Odefsey, and eventually will replace TDF in all fixed-dose combination and single-tablet regimens using it.

Ziagen

★ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN FOR MOST PEOPLE WHEN USED IN COMBINATION WITH DOLUTEGRAVIR AND LAMIVUDINE (AS TRIUMEQ)

abacavir **(ABC)**

STANDARD DOSE

Two 300 mg tablets once daily (or one 300 mg tablet twice daily), without regard to food.

For adults and children at least 3 months of age and older. In children Ziagen is dosed based on body weight. See the package insert for weight-based dosing. Tablets may be crushed or split and added to a small amount of semi-solid food or liquid. Ziagen is also available as an oral solution (20 mg/mL) (strawberry-banana flavor) for children and adults who are not able to swallow the tablets.

Dose adjustment is not needed for people with kidney impairment. Dose adjustment is needed for people with mild liver impairment (200 mg twice daily). Ziagen should not be used in people with moderate or severe liver disease.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

GENERIC IS AVAILABLE.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
(877) 844-8872

AWP

Ziagen 300 mg tablet, 60 tablets: $670.57/month
generic abacavir 300 mg tablet, 60 tablets: $502.22–$603.33/month

POTENTIAL SIDE EFFECTS AND TOXICITY

The most common side effects may include nausea, vomiting, diarrhea, fatigue, headache, fever, rash, muscle aches, and trouble sleeping. In pediatric patients, the more common side effects were fever and/or chills, nausea and vomiting, skin rashes, and ear/nose/throat infections.

Approximately 8% of people who took abacavir in clinical trials (where screening for HLA-B*5701, a genetic marker associated with abacavir hypersensitivity, was not performed) experienced hypersensitivity reaction (HSR), an allergic-like reaction. To minimize the risk for HSR, a blood test for HLA-B*5701 should be done prior to starting an HIV regimen containing abacavir to identify patients at higher risk for this reaction. This test is covered by most insurance and also by LabCorp/ViiV (see company contact on co-pay chart). If the HLA-B*5701 test is positive, you are at an increased risk for HSR and you should not take abacavir. An allergy to it should be entered in your medical record. A negative HLA-B*5701 test does not mean you won't have HSR, but the risk is very low (1% from clinical studies). Symptoms of HSR usually include some combination of the following: fever, skin rash, malaise (general ill feeling), severe nausea, headache, muscle ache, chills, diarrhea, vomiting, abdominal pain, respiratory symptoms (cough, difficulty breathing, sore throat), and/or joint pain. Symptoms are listed on the patient information sheet and warning card that you receive each time you fill your prescription. You should keep the warning card with you. HSR might be confused with flu, but symptoms of HSR usually worsen, very slowly, with every dose.

People who think they are experiencing HSR must be evaluated by an experienced HIV provider right away before they stop taking abacavir. Do not use a skin patch test to confirm HSR. Symptoms usually resolve after permanent discontinuation. If you develop HSR, abacavir should be stopped and you can never take abacavir or any product containing abacavir (Epzicom, Trizivir, Ziagen, or Triumeq) again (starting again is called rechallenging). Rechallenging can cause a rare life-threatening reaction. This does not apply to a missed dose when there is no HSR, but talk with your healthcare provider and watch for symptoms if you've stopped the drug for a few days, preferably under the observation of others who can call for medical help if you develop symptoms. An HSR can technically occur at any time, regardless of how long you have been taking the medication, however, it is much more likely to occur when you start (or re-start) the medication (90% occur within the first 6 weeks of treatment).

Some observational studies suggest abacavir may increase the risk of cardiovascular events, including myocardial infarction (MI, or heart attack), in people with risk factors (such as older age, smoking, diabetes, high blood pressure, high cholesterol, family history of heart disease, and drug use), especially within the first 6 months of therapy. However, other studies, including a large meta-analysis, have shown no increase in cardiovascular risk. To date, no consensus has been reached on the association of abacavir with cardiac risk or a possible mechanism for the association. People who have high risk for heart disease should discuss risks with their provider and they should be monitored more closely.

POTENTIAL DRUG INTERACTIONS

Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking about taking, whether they are prescribed or not, as there are other drug interactions not listed here. It is important to take Ziagen only with other HIV drugs recommended by your provider because Ziagen is contained in other HIV medications: Epzicom, Triumeq, and Trizivir. Alcohol can increase abacavir levels and therefore can increase the possibility of side effects.

MORE INFORMATION

ACTG A5202 study found that abacavir/lamivudine (Epzicom) was inferior to tenofovir/emtricitabine (Truvada) in getting people undetectable when their pre-treatment viral load was over 100,000 copies/mL. However, when combined with Tivicay (dolutegravir), Epzicom performed just as well as Truvada in people with high viral loads (over 100,000 copies/mL). Hence, Triumeq is the only abacavir-containing regimen recommended by DHHS as initial therapy for most people. It is recommended that people with symptoms of acute respiratory disease consider HSR even if another diagnosis such as pneumonia, bronchitis, or flu is possible. But again, a simple test reveals whether you are at risk for the allergic reaction. FDA researchers reported finding a mechanism for autoimmune drug reactions, including abacavir HSR, and hope it helps improve drug safety in the future. Abacavir is part of Epzicom, Trizivir, and Triumeq; see those pages. Ziagen as part of the combination tablet Epzicom is recommended by DHHS as one of the preferred NRTI combination components of an ART regimen during pregnancy.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Ziagen was approved in 1998 at a time when HIV resistance to antiretrovirals and treatment failure were very common. It provided a new option for treatment. From the beginning, this medication has had its challenges. As the drug was being studied in the late 1990s, a severe and possibly fatal allergic reaction (hypersensitivity) was discovered. Super elegant (cool) pharmacogenetic studies linking a PLWH's genetic code to the occurrence of this side effect found a specific gene which was associated with the allergic reaction. A simple blood or mouth swab can be used to detect the gene and determine if the medication can be safely taken. Next, a European cohort study linked Ziagen to heart attacks and a U.S. study showed it to be less potent than Viread. Despite these challenges, Ziagen has survived, a bit tattered, a nuke still used today, almost exclusively in the single-table regimen Triumeq. A generic form of Ziagen has been available in the U.S. since 2012.

Activist Moisés Agosto-Rosario says: A hypersensitivity reaction due to abacavir may occur; a blood test that can predict predisposition to this hypersensitivity is required. There is a risk for cardiovascular disease because of abacavir. Patients with a family history of heart disease or at risk must discuss this with their doctor and monitor their heart condition.

doravirine (DOR)

● DHHS RECOMMENDATION NOT YET ESTABLISHED

INVESTIGATIONAL DRUG AT PRESS TIME. PHOTO UNAVAILABLE.

DOSE USED IN STUDIES

One tablet once daily without regard to food. Tablet contains 100 mg of doravirine.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND TOXICITY

See package insert when available. In one study, side effects observed in 10% or more of 383 patients taking a regimen containing doravirine included nausea (11%), neuropsychiatric symptoms (11%, including depression, abnormal dreams, insomnia, and dizziness), diarrhea (14%), and headache (14%). Brain-related side effects (including dizziness, nightmares, and depression) were significantly less common in study participants taking doravirine than in those who received efavirenz.

POTENTIAL DRUG INTERACTIONS

See package insert when available for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not. Do not take with any other HIV antiretroviral medication unless specifically instructed to do so by expert consultation. Therefore, do not take with the following HIV medications, since these are already in this drug or they have medication from similar drug classes: Atripla, Complera, Edurant, Intelence, Juluca, Odefsey, or Sustiva.

MORE INFORMATION

Expected to receive FDA approval in 2018. Doravirine may be an option for patients who have developed drug resistance to other NNRTIs. A single-tablet regimen (STR) containing doravirine is also expected to be approved this year; see doravirine/TDF/3TC page. Doravirine was found to be non-inferior to boosted darunavir (brand name Prezista) at 48 weeks. Darunavir is one of two protease inhibitors recommended for first-time use in certain clinical situations by U.S. HIV treatment guidelines. Doravirine has not yet been compared to an integrase inhibitor (INSTI), all of which are DHHS recommended for most people taking HIV medication for the first time. Doravirine is a non-nucleoside medication, a drug class that includes rilpivirine (brand name Edurant, found in Complera and Odefsey).

In the DRIVE-FORWARD study, with people taking HIV therapy for the first time (treatment-naïve), there was a lower success rate than is expected in HIV therapy today. This was thought to be affected by the number of people who quickly dropped out of the study when given so many pills to take—they were not given a single-tablet regimen (STR). Those drop-outs were counted as virologic failures. The success rate was 80% for the darunavir group and 84% for the doravirine group (achieving undetectable viral loads of less than 50 copies per mL). Only one of 364 doravirine-treated patients developed drug resistance, a relatively low number for an NNRTI; there was no resistance in the boosted darunavir group (as could be expected). The doravirine STR is being studied in treatment-naïve individuals (first time on HIV therapy) who have virus that doesn't respond well to other NNRTIs (the DRIVE BEYOND study). It is also being studied in people with undetectable viral loads on their current treatment who are switched to the doravirine STR (the Phase 3 DRIVE-SHIFT study).

See package insert when available for more complete information on potential side effects and interactions.

Dr. David Hardy says: Doravirine is considered a "second generation" NNRTI due because of its enhanced resistance profile compared to Sustiva and other older "first generation" NNRTIs. In fact, lab studies predict that it may be effective after a first generation NNRTI has failed and left HIV resistance mutations. To date, data from two large clinical trials comparing doravirine to Sustiva and to Prezista/Norvir have shown that doravirine has similar anti-HIV potency as those two known potent medications and with fewer side effects. Doravirine is also being developed as an STR combined with Viread and Epivir. The FDA has set a target action date of Oct. 23, 2018, for both applications for doravirine and doravirine/Viread/Epivir under the Prescription Drug User Fee Act (PDUFA).

Activist Moisés Agosto-Rosario says: This new drug is effective against NNRTI drug-resistant mutations. Individuals with resistance to other NNRTIs may benefit from regimens containing doravirine. It is also contained in the new single-tablet regimen doravirine/TDF/3TC. The potency of doravirine is comparable to efavirenz and boosted darunavir when used in combination with two nucleoside reverse transcriptase inhibitors (NRTIs) in treatment-naïve individuals. Brain and central nervous system side effects are less common in individuals taking doravirine compared to those taking efavirenz. Doravirine has not yet been approved by the FDA.

MANUFACTURER

Merck and Co.
(800) 622–4477

AWP

Not yet established

Edurant

✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS IN COMBINATION WITH DESCOVY OR TRUVADA (AS ODEFSEY OR COMPLERA)

rilpivirine (RPV)

STANDARD DOSE

One 25 mg tablet once daily with a standard meal (more than 390 calories). See below. For adults and children 12 years of age and older weighing at least 77 pounds (35 kg).

Viral load (HIV RNA) must be less than 100,000 copies/mL and CD4 T-cell count must be above 200 cells/mm^3 before starting Edurant due to higher rates of virological failure in these patients.

Take missed dose as soon as possible with a meal, unless it is closer to the time of your next dose. Do not double up on your next dose. For proper absorption, it must be taken with a meal that you chew—not just nutritional drinks or protein shakes. Taking Edurant without food could result in a 40% decrease in the drug absorption and may lead to HIV resistance.

MANUFACTURER

Janssen Therapeutics
edurant.com
(800) JANSSEN (526-7736)

AWP

$1,251.76/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Moderate to severe side effects are uncommon. Most common side effects occurring in 3–5% of study subjects were insomnia, headache, rash, and depressive disorders. Tell your doctor right away if you experience feelings of sadness, hopelessness, anxiety or restlessness, or have suicidal thoughts or actions. A small study showed a higher rate of depressive disorders in adolescents (19.4%—seven out of 36 youths—vs. 9% for adults), which may or may not have been related to Edurant. Two different studies comparing Edurant to Sustiva showed that Edurant was slightly better tolerated. Edurant also has minimal negative effects on "bad" cholesterol, total cholesterol, and triglycerides when compared to Sustiva. Edurant improved "good" cholesterol slightly less than Sustiva. Liver problems can occur with Edurant (even in patients without a history of liver disease). Edurant can cause a small, reversible increase in kidney function test (serum creatinine) within the first few weeks of treatment without affecting actual kidney function.

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list. Tell your provider or pharmacist about all medications, herbs, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Edurant should not be taken with other non-nukes or Complera, Juluca, or Odefsey, as the latter three already contain rilpivirine. Cannot be taken with the anti-seizure medications carbamazepine, oxcarbazepine, phenobarbital, and phenytoin; the anti-TB drugs rifampin and rifapentine; proton pump inhibitors (Aciphex, Nexium, Prevacid, Protonix, and Prilosec); or the herb St. John's wort. Do not take with more than one systemic dose of the steroid dexamethasone. Antacids should be taken two hours before or at least four hours after Edurant. Acid-reducing drugs (Pepcid, Tagamet, Zantac, and Axid) should be taken 12 hours before or four hours after an Edurant dose. If administered with rifabutin, the dose of Edurant should be increased to two 25 mg tablets once daily with a meal. When rifabutin is stopped, Edurant dose should be decreased to 25 mg daily. Monitor for worsening of any fungal infections when Edurant is used with antifungal medications like fluconazole, itraconazole, ketoconazole, posaconazole, and voriconazole; dose adjustment for these medications may be needed. Use azithromycin when possible instead of the antibiotics clarithromycin, erythromycin, and telithromycin. Methadone levels are reduced slightly and patients should be monitored for symptoms of withdrawal. Should be used with caution when taken with medications with a known risk of torsades de pointes or QT prolongation (these abnormal heart rhythms can make the heart stop). No dose adjustment needed with hepatitis C medications Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, or Zepatier. Cannot be taken with Viekira Pak.

MORE INFORMATION

A new medication combining rilpivirine with dolutegravir was approved by the FDA in late 2017; see Juluca. Edurant is not recommended for treatment-naïve patients with a pretreatment viral load greater than 100,000 copies/mL or CD4 less than 200. A rilpivirine-based regimen may be advantageous in people with high risk for heart disease due to its relatively low impact on lipid profile. While its tolerability and safety profiles are advantages for Edurant, the greater potential for virologic failure in patients with high viral loads or low CD4 counts, food restrictions, and cross-resistance to the other NNRTIs puts Edurant at a disadvantage for first-time treatment—people may not be able to switch to another NNRTI if their HIV develops NNRTI resistant mutations to Edurant. Data for use of rilpivirine in combination with an abacavir/lamivudine background are insufficient to recommend at this time. For individuals with HIV-2, commonly found in some other countries, an NNRTI would not be recommended as HIV-2 is inherently resistant to NNRTIs. Edurant can be used during pregnancy, and is listed as a DHHS alternative NNRTI to use in pregnancy in combination with a two-NRTI backbone. According to the FDA, lower exposures of rilpivirine were observed during pregnancy, therefore, viral load should be monitored closely.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Edurant was approved in 2011 as the second "second generation" NNRTI to be used as a first-time ART regimen. Edurant has been used in two STRs, Complera and Odefsey [and more recently in Juluca]. Its upside is its excellent tolerability (side effects are uncommon); its downside is that it lacks potency for people with high viral loads (more than 100,000 copies/ml). Due to its potency concerns, it has never been considered the best choice for people starting their first ART regimens, but only those with lower viral loads (less than 100,000 copies/mL).

Activist Moisés Agosto-Rosario says: Rilpivirine is an NNRTI shown not to be inferior to efavirenz in individuals with a viral load below 100,000 copies/mL. It was first approved as a single agent but nowadays is used in various single-tablet regimens: Complera, Odefsey, and Juluca. The resistance profile of this drug is complicated. If resistance to rilpivirine develops, cross resistance to Intelence often follows. It is well tolerated and needs to be taken with food. It works well when switching regimens in individuals with undetectable viral load. It is important to know the drug-drug interactions of rilpivirine. It should not be taken with antacids because they will affect drug absorption.

Sustiva

✔ RECOMMENDED AS COMPONENT OF INITIAL REGIMEN IN CERTAIN CLINICAL SITUATIONS (AS A COMPONENT OF ATRIPLA, OR WITH DESCOVY OR TRUVADA)

efavirenz **(EFV)**

STANDARD DOSE

One 600 mg tablet once daily, preferably on an empty stomach at bedtime.

Approved for adults and children 3 months and older weighing at least 7.7 pounds (3.5 kg). For children weighing less than 88 pounds (40 kg), the dose is based on weight. See the package insert for specific weight-based dosing. For children weighing at least 88 pounds, use the standard adult dose. For those who can't swallow capsules, administer by capsule sprinkle method. See below or drug label for instructions or watch video at sustiva.com.

Take missed dose as soon as possible, unless it is closer in time to your next dose. Do not double up on your next dose. Also available in 50 mg and 200 mg capsules.

Use with caution in mild liver impairment; not recommended with moderate or severe liver impairment.

GENERIC IS AVAILABLE.

MANUFACTURER

Bristol-Myers Squibb
bms.com
sustiva.com
(800) 321-1335

AWP

50 mg, **200 mg**, and **600 mg** tablets: $1,176.74/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Central nervous system (CNS) symptoms (dizziness, insomnia, impaired concentration, abnormal or vivid dreams, and hallucinations) are most common at the start of treatment and usually diminish in two to four weeks. Bedtime dosing on an empty stomach can help reduce symptoms. Less common psychiatric symptoms (catatonia, depression, suicidal thoughts or actions, aggression, paranoid/manic reactions) may also occur. A 2014 study reviewed four previously published AIDS Clinical Trials Group (ACTG) studies regarding efavirenz and suicidal ideation and re-emphasized the fact that efavirenz has an association with suicidality (reported suicidal ideation or attempted or completed suicide), and should be used with caution in patients with severe or uncontrolled depression and/or a history of suicidality. Additional side effects may include rash, nausea, vomiting, diarrhea, and fever. Rash in children is more common and more severe. Efavirenz may raise levels of triglycerides (fat in the blood) and cholesterol. Efavirenz can cause a false positive for marijuana on certain drug tests. A more specific confirmatory test can be done. A link to birth defects in humans has not been supported in meta-analyses. The pregnancy recommendation is that women in their first trimester continue taking efavirenz as long as their viral load remains undetectable; however, efavirenz should only be used if the potential benefit outweighs the potential risk, as when other treatment options are not available. Because of the association with suicidality and neuropsychiatric effects, it is also recommended to screen for antenatal and postpartum depression in women with HIV who are taking a regimen containing efavirenz. Regular monitoring for increased liver enzyme levels is recommended initially and during treatment for people with hepatitis B/C or liver disease.

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list. Tell your provider or pharmacist about all medications, herbals, supplements, and over-the-counter products you are taking or thinking of taking, prescribed or not, as there are other drug interactions not listed here. Sustiva should not be taken with other NNRTIs or medications that contain them (Atripla, Edurant, Complera, Odefsey, or Juluca). Do not take with midazolam, pimozide, ergot derivatives, St. John's wort, or triazolam. May affect warfarin levels. Can decrease levels of buprenorphine and methadone—monitor for withdrawal. Increase Kaletra to two 200/50 mg tablets plus one 100/25 mg tablet twice daily (total 1000/250 mg per day) with food when taken with Sustiva. Kaletra cannot be taken once daily with Sustiva. When using with Tivicay, increase the Tivicay dose to 50 mg twice daily. Treatment-experienced people should not take Reyataz with Sustiva, but for treatment-naïve people, Reyataz once-daily dose should be 400 mg with Norvir boost. Boost once-daily Lexiva with 300 mg Norvir. Increase Selzentry to 600 mg twice daily. Increase the Sustiva dose to 800 mg once daily with rifampin for people weighing 110 pounds (50 kg) or more. Rifabutin can be used as an alternative, but dose adjustment is needed. When taken with carbamazepine, phenobarbital, or phenytoin, periodic monitoring of anticonvulsant and Sustiva levels should be done or alternative anti-seizure drugs, such as levetiracetam, should be considered. Effectiveness of birth control pills may be decreased; consider the use of other contraceptives. Closer monitoring and dose adjustments may be required with posaconazole (avoid unless benefit outweighs potential risk) and itraconazole (should consider an alternative, as no dose recommendation can be made). The dose of voriconazole should be increased to 400 mg every 12 hours and the Sustiva dose should be decreased to 300 mg once daily using capsules; tablets should not be broken. Monitor effectiveness of clarithromycin or consider azithromycin. Levels of immunosuppressants should be monitored when starting or stopping Sustiva. Cardizem, Lipitor, Pravachol, and Zocor doses may need to be adjusted. Titrate dose of bupropion and sertraline based on clinical response. Should not be taken with other medications that prolong QT interval or medications with a known risk of torsades de pointes. No dose adjustment with Harvoni or Sovaldi. Increase Daklinza dose to 90 mg with Sustiva. Don't take with Epclusa, Olysio, Viekira Pak, or Zepatier.

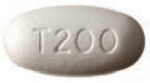
MORE INFORMATION

If you can't sleep, ask your doctor about gradually adjusting the timing of your dose until it's taken during the day. A rare genetic trait affecting drug metabolism of Sustiva, leading to a higher rate of side effects, occurs more in African Americans. In pediatric HIV guidelines, Sustiva was downgraded in 2017 from "preferred" to an "alternative" component of an initial regimen for children ages 3–12 years. For individuals with HIV-2, commonly found in some other countries, an NNRTI would not be recommended as HIV-2 is inherently resistant to NNRTIs.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says: Approved in 1998, Sustiva was the "Queen Bee" of antiretrovirals as the "kinder and gentler" alternative to the highly potent but difficult-to-tolerate protease inhibitors of the time until the appearance of the integrase inhibitors in 2007. Although highly potent against HIV and taken just once daily, for some people, the unique side effects of grogginess, dizziness, and vivid dreams were too much to tolerate. It was thought that these side effects would go away over time, but long-term (5 years) studies with Sustiva showed that they never improve for some. Worsening of mental health conditions and increased suicide thoughts and attempts have helped to limit Sustiva's use. It is still the most commonly prescribed antiretroviral in the world.

Activist Moisés Agosto-Rosario says: Sustiva is a very potent and long-acting antiviral. Efavirenz is the anchor drug of Atripla, the first and most widely used single-tablet regimen for the last 11 years. Sustiva's central nervous system side effects are challenging. Dizziness, weird dreams, depression, and constantly feeling tired are some of the side effects reported. Some individuals tolerate it well and others manage to overcome side effects after three months. With the development of other NNRTIs and INSTIs that are more tolerable and have fewer central nervous system toxicities, Sustiva has waned in popularity.



Intelence ✔

FOR TREATMENT-EXPERIENCED PATIENTS WITH VIRAL STRAINS RESISTANT TO AN NNRTI AND OTHER ANTIRETROVIRAL DRUGS ONLY

etravirine **(ETR)**

STANDARD DOSE

One 200 mg tablet, twice daily, following a meal. Approved for adults and children 6 years and older weighing at least 35 pounds (16 kg). See the package insert for specific weight-based dosing in children. Also available in 25 mg and 100 mg tablets.

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. People unable to swallow pills (Intelence tablets are "chalky") can dissolve tablets in 1 teaspoon (5 mL) of water or at least enough liquid to cover the medication, stir well until the water turns milky, add more water if desired—use orange juice or milk as an alternative, always placing tablets in water first. Avoid grapefruit juice and warm (over 104° F) or carbonated beverages. Drink immediately, rinse the glass several times with water, orange juice, or milk and completely swallow the rinse each time to make sure the entire dose is taken. See commentary in the "More Information" section. Taking Intelence without food could result in a 50% decrease in the drug absorption and may lead to HIV drug resistance.

MANUFACTURER

Janssen Therapeutics
intelence.com
(800) JANSSEN
(526-7736)

AWP

25 mg tablets:
$380.74/month
100 mg and **200 mg** tablets:
$1,522.95/month

POTENTIAL SIDE EFFECTS AND TOXICITY

Generally well tolerated, but most common side effects may include mild rash and diarrhea. Rare side effects include severe rash and peripheral neuropathy. Levels of liver enzymes called transaminases should be monitored. Rash is associated with all of the current NNRTIs, but if you develop a rash from Intelence, you may still be able to take one of the other NNRTIs.

POTENTIAL DRUG INTERACTIONS

Refer to package insert for complete list. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, prescribed or not, as there are other drug interactions which are not listed here. Intelence should not be taken with other NNRTIs or medications that contain them (Atripla, Complera, Juluca, and Odefsey). If Intelence is taken in combination with a protease inhibitor, it must be boosted with low-dose Norvir. Avoid Intelence with boosted Aptivus or Lexiva. It should be avoided with Tivicay unless administered with one of the following combinations: Reyataz/Norvir, Prezista/Norvir, or Kaletra. Taking it in combination with Selzentry requires a Selzentry dose adjustment to 600 mg twice daily when used without a boosted PI and 150 mg twice daily when used with a boosted PI. Do not take Intelence with Tegretol, Luminal, Dilantin, Priftin, Rifadin, or the herb St. John's wort. Use with caution when combined with the antifungals Diflucan and Vfend. Dose adjustments of the antifungals ketoconazole, itraconazole, and posaconazole may be needed. Dosage adjustments of certain cholesterol medications may be needed based on clinical response, including Lipitor, Lescol, Mevacor, Livalo, and Zocor.

Monitor the effectiveness of Coumadin (warfarin) and adjust dose as needed based on clinical response. Alternatives to Plavix should be considered when used with Intelence. Alternatives to clarithromycin, such as azithromycin, should be considered for treatment of MAC. Lower Valium dose may be needed. Use caution with systemic dexamethasone or consider alternatives. Intelence can be taken with Mycobutin 300 mg daily; however, it should be avoided by those who are also taking a boosted PI. Intelence can be safely combined with methadone or buprenorphine with additional monitoring for potential signs of withdrawal. Intelence can also be safely combined with Viagra, Cialis, and Levitra, though a dosage adjustment of Viagra may be necessary. Can be taken with Daklinza (increase Daklinza dose to 90 mg). Interactions with Sovaldi and Harvoni have not been studied; but based on the metabolism, a clinically significant interaction is not expected. Taking with Olysio, Viekira Pak, or Zepatier is not recommended.

MORE INFORMATION

For patients who have had virologic failure on an NNRTI-containing regimen, do not use Intelence in combination with a nucleoside backbone alone. Although taking once daily is not FDA approved, some providers are prescribing Intelence once daily (2 of the 200 mg tablets) based on clinical trials that showed that once-daily Intelence was not inferior to Sustiva-based regimens. The once-daily dosing may improve patient adherence. Some patients complain of hard-to-swallow, large chalky pills; see dissolving instructions in dose section or package insert. For individuals with HIV-2, commonly found in some other countries, an NNRTI would not be recommended as HIV-2 is inherently resistant to NNRTIs.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Approved in 2008 as the first "second generation" NNRTI due to its improved resistance profile, Intelence has generally been used only for people whose HIV has a significant amount of resistance to other antiretroviral medications. It is approved to be given only on a twice-daily basis and generally best with boosted Prezista with or without an integrase inhibitor. It is not approved to be used as a first-time ART regimen although a couple of small studies have shown that it can work.

Activist Moisés Agosto-Rosario says: Etravirine is a second-generation NNRTI that has shown significant viral load reduction in individuals who developed resistance to the first generation of NNRTIs (efavirenz and nevirapine). Like other NNRTIs, etravirine's drug-drug interactions are many and complicated. It is important to understand the interactions and inform your doctor of all over-the-counter medications, supplements, and herbals you are taking, because they might affect the absorption of etravirine. It is well tolerated but may cause rare side effects such as rash or increased cholesterol. It is a good second-line alternative for treatment-experienced people. The size of the pill makes it hard to swallow and it leaves a chalky taste in the mouth, but there is the option of dissolving it in water.

Selzentry

▼ NOT RECOMMENDED AS COMPONENT OF AN INITIAL REGIMEN

maraviroc **(MVC)**

STANDARD DOSE

The recommended dose varies depending on other medications being taken but will be either 150, 300, or 600 mg twice daily (available in 150 mg and 300 mg tablets). Approved for adults and children at least two years old weighing at least 22 pounds (10 kg) and having a creatinine clearance of at least 30mL/min (measurement of kidney function); dose depends on weight. Available in a 20 mg/mL oral solution as well as 25 mg and 75 mg tablets. The oral solution should be administered using the included press-in bottle adapter and oral dosing syringe. Can be taken without regard to food.

Your provider or pharmacist can determine which medications will affect Selzentry levels and recommend the appropriate dose for you. See package insert for dosing guidance.

Take missed dose as soon as possible, unless it is closer in time to your next dose. Do not double up on your next dose. Before you start Selzentry, you will need a specific blood test to determine if this medication will work for you.

MANUFACTURER

ViiV Healthcare
viivhealthcare.com
selzentry.com
(877) 844-8872

AWP

25 mg tablets:
$604.36/month
75 mg, 150 mg and **300 mg,** tablets:
$1,813.04/month

POTENTIAL SIDE EFFECTS AND TOXICITY

The most common side effects occurring in greater than 8% of studied patients include cough, upper respiratory tract infections, bronchitis, fever, rash, muscle and joint pain, flatulence, bloating and distention, abdominal pain, dizziness, and trouble sleeping. Other less common side effects may include allergic reactions, liver toxicity, and heart problems in those with a history of heart disease. Rarely, Selzentry can cause dizziness or fainting when standing up due to low blood pressure. In March 2014, the FDA updated the Selzentry label stating, "Caution should be used when administering Selzentry in patients with a history of or risk factors for postural hypotension, cardiovascular comorbidities, or on concomitant medication known to lower blood pressure. Patients with cardiovascular comorbidities could be at increased risk of cardiovascular adverse events triggered by postural hypotension." Stop taking Selzentry and contact your provider right away if you develop a rash, yellowing of your eyes or skin, dark urine, vomiting, or upper stomach pain. Selzentry should not be used by people with severe or end-stage kidney disease who are taking medications that can affect the levels of Selzentry (check with your provider). Selzentry affects immune system cells and could possibly increase the risk of infections and cancer, although this has not been observed in studies up to five years of follow-up, and some data indicate it may be beneficial in cancer or for preventing metastasis (the spread of cancer to other parts of the body).

POTENTIAL DRUG INTERACTIONS

See package insert for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not, as there are many other drug interactions not listed here. Dose adjustments with other medications and anti-HIV drugs include: 150 mg twice daily if taken with medications that increase the levels of Selzentry such as boosted protease inhibitors (except for Aptivus), Stribild, Genvoya, Tybost, Rescriptor, clarithromycin, and itraconazole; 300 mg twice daily if taken with Aptivus, Viramune, Isentress, Tivicay, Triumeq, Fuzeon, and all of the NRTIs and medications that do not affect the levels of Selzentry; and 600 mg twice daily if taken with medications that decrease the levels of Selzentry such as Atripla, Sustiva, Intelence, rifampin, and some anti-convulsants such as carbamazepine (Tegretol), phenobarbital, and phenytoin (Dilantin). Likely dose with rifapentine is 600 mg twice daily, but use with caution. Not recommended with St. John's wort. Selzentry may be co-administered with the hepatitis C medications Sovaldi, Olysio, Harvoni, and Daklinza at a dose of 300 mg twice daily, however, ledipasvir (in Harvoni) may have potential to increase Selzentry levels.

MORE INFORMATION

Not recommended by DHHS as a component of an initial regimen due to requirement of CCR5 tropism prior to initiation of therapy, lack of virologic benefit when compared to other recommended regimens, and because it requires twice-daily dosing.

Selzentry is generally recommended only when other HIV medications from other classes cannot be used or when a new class of medication is needed to construct a complete and durable treatment regimen for patients who have drug resistance. Complex dosing, the need for a tropism test, and competition from newer drugs have dimmed some of the initial enthusiasm for this drug. Selzentry appears to be synergistic with ibalizumab, an experimental medication for people with extensive HIV drug resistance that is expected to be available as an orphan drug this year, helping to create a viable new regimen. See ibalizumab page. A tropism assay (Trofile, Trofile DNA, or HIV-1 Coreceptor Tropism with Reflex to UDS) is needed to determine if this medication will work for you. Results of a phenotypic tropism test (Trofile or Trofile DNA) may take up to a month. Genotypic tests are also available and may provide a faster and less expensive alternative. Selzentry only works for those people with CCR5-tropic virus. Viral tropism refers to the types of HIV that a person can have, CCR5 (R5), CXCR4 (X4), or Dual-Mix Tropic (R5 and X4). Selzentry blocks CCR5, a receptor on the outside of a CD4 cell, and shuts down this point of entry for the virus. Most people are infected with R5 virus initially, and then over time, X4 and mixed viruses may predominate. Blocking R5 with Selzentry does not cause a shift to X4 or negatively affect disease progression or CD4 count in people whose virus can use dual-mix. In the MERIT clinical trial, initial analysis suggested that Selzentry was inferior to Sustiva in reducing viral loads to below 50 copies (undetectable), but a re-analysis of the data with a more sensitive tropism test showed the regimens to be comparable in achieving undetectable viral loads in treatment-naïve participants at 96 weeks, leading to FDA approval for this group. The tropism test needed is now generally paid for by public health departments, Medicare, and private insurance. ViiV may cover the payment for the Trofile test under certain circumstances. Selzentry seems to have minimal impact on lipid levels. Not recommended for pregnant women on initial HIV medication.

See package insert for more complete information on potential side effects and interactions.

Dr. David Hardy says:
Selzentry was approved in 2007 for people with highly drug-resistant HIV, and for first-time ART treatment in 2009. Selzentry was the second antiretroviral in the entry inhibitor class to be approved (first was Fuzeon in 2003). Selzentry works uniquely by blocking the CCR5 receptor on the surface of CD4+ T cells to which HIV must attach to infect these cells. It stops HIV infection before it enters the cell. Despite favorable study results, primarily in treatment-experienced people, and an excellent safety profile, Selzentry use has been limited in the U.S. due to a costly and slow turnaround blood test which must be used to check for susceptibility to the drug and poor results in subsequent clinical trials in those starting first-line treatment. It is being studied as a possible treatment for HIV-induced brain disease (HAND).

Activist Moisés Agosto-Rosario says: Selzentry is a CCR5 antagonist that blocks one of the two receptors (CCR5) outside of the CD4 used by the virus to enter and infect the cell. A tropism test is needed to determine if the CCR5 receptor is active. In treatment-experienced patients, HIV may have adapted to target CXCR4. When this occurs, individuals are unable to benefit from a CCR5 inhibitor. Though not as popular as expected, it has become an important option for those who need to add extra help to their HIV regimen.

ibalizumab (IBA)

● DHHS RECOMMENDATION NOT YET ESTABLISHED

INVESTIGATIONAL DRUG AT PRESS TIME. PHOTO UNAVAILABLE.

DOSE USED IN STUDIES

Administered once every two weeks via intravenous infusion. Treatment begins with an IV loading (starting) dose of 2,000 mg, followed by an 800 mg IV infusion maintenance dose given every two weeks thereafter.

The first infusion takes at least 30 minutes. If no infusion-related adverse events occur, subsequent infusions take 15 minutes. Doses may be administered every two weeks at an inpatient and/or outpatient setting, including at-home infusion, if desired. Must be given with an optimized background regimen (OBR). An OBR consists of the best antiretroviral therapy that can be made for each patient based on the patterns of HIV drug resistance in their virus.

MANUFACTURER

TaiMed USA
Distributed by
Theratechnologies Inc.
theratech.com
ibalizumab-eap.com

AWP

Not yet established

POTENTIAL SIDE EFFECTS AND TOXICITY

See package insert when available. The most common adverse reactions observed in clinical studies were diarrhea, dizziness, nausea, and rash. See "More information" section.

POTENTIAL DRUG INTERACTIONS

See package insert when available for the most complete list. Tell your provider or pharmacist about all medications, herbals, and supplements you are taking or thinking of taking, prescribed or not. No interactions with other HIV drugs observed in clinical studies.

MORE INFORMATION

Essentially, this drug's niche is salvage therapy for heavily treatment-experienced people with multi-drug resistance, in addition to an optimized background regimen (OBR). A key point is that people must still take other HIV medications that have some activity—there has to be at least one HIV drug to which their virus is sensitive included in their OBR. Ibalizumab is a shiny brand new option, but it doesn't come without some rules. It will likely be expensive because the cost of the drug will be added to other expenses such as the time at the infusion center and qualified individuals to administer and handle the medication, although there will be an option for patients to receive their infusion at home. Non-adherence won't be an option—people won't be able to just show up whenever they want or be late to appointments when going to an infusion center. It will be like chemotherapy or dialysis. Patients must be on time.

A Biologics License Application (BLA) was submitted to the FDA and a response is expected by the end of April. Because of its new and unique mechanism of action, ibalizumab is already available through an expanded access program for patients who qualify. Go to ibalizumab-eap.com. Ibalizumab would become the first HIV drug that is not taken every day. Still, because it must be used with other HIV medications, antiviral treatment will still be required to be taken daily. Ibalizumab would also become the first HIV orphan drug—one that is produced for a relatively small population of patients (fewer than 200,000). It was produced for people with multi-drug resistant HIV, estimated to be fewer than 40,000 in the U.S.; the company estimates that there are fewer than 25,000. These are heavily treatment-experienced people who have multi-drug resistance, and have therefore, usually, limited treatment options. Ibalizumab has been shown to work against highly drug-resistant virus, when combined with an OBR.

Ibalizumab was studied in a relatively small Phase 3 study and patients are currently continuing to receive IBA. In these studies individuals with advanced disease and limited treatment options, significant improvements in viral load reduction and T cell increases were seen. After an initial loading dose, 83% of participants achieved a clinically significant decrease in viral load.

As a biologic, IBA is the first HIV medication made from cells rather than from chemicals. This does not make ibalizumab better, just different. All monoclonal antibodies (or mAbs, hence the last syllable of "ibalizumab"), are made this way, including biologics used to treat rheumatoid arthritis and psoriasis. Ibalizumab works differently from any other HIV drug currently on the market. It binds to a domain (location) of the CD4 receptor (in this case, domain 2), blocking viral entry into the CD4 cell. Ibalizumab works against both CCR5 and CXCR4 virus, and appears to be synergistic with all other classes of antiretrovirals. Ibalizumab is widely considered to be an HIV entry inhibitor medication, but its actual drug class is still under review. IBA is neither metabolized in the liver nor eliminated by the kidneys.

See package insert when available for more complete information on potential side effects and interactions.

Dr. David Hardy says:
If approved later this year, ibalizumab will be the first antiretroviral to be given as an intravenous (IV) infusion. This is because it is, and if approved will be, the first monoclonal (synthetically produced) antibody to prevent HIV from attaching to the CD4+ receptor on the surface of CD4+ T cells. Due to this specific inhibition process, HIV cannot grab onto and get inside of a CD4+ T cell and cause infection of that cell. A small but conclusive study showed that ibalizumab significantly dropped viral loads in people with highly drug-resistant HIV when the drug was infused by vein every 2 to 4 weeks, along with other antiretrovirals. The side effects of this investigational monoclonal antibody treatment are well tolerated. The FDA's initial target action date to complete the review of ibalizumab was January 3, 2018. The new Prescription Drug User Fee Act (PDUFA) target action date has been extended to April 3, 2018.

Activist Moisés Agosto-Rosario says: Ibalizumab is a new drug in the entry inhibitor drug class. It works in a different way from all the other antivirals. It blocks viral entry into cells by attaching to domain 2 on CD4 cells. Ibalizumab works on both CCR5 and CXCR4 virus. It is not metabolized in the liver or eliminated by the kidneys. Ibalizumab is what is known as a humanized monoclonal antibody. It will be the first medication to treat HIV that is not taken daily. It must be used in combination with other HIV medicines. This is what we know as a salvage therapy, meaning it is for people with multi-drug resistant HIV who cannot achieve undetectable levels of HIV. It is administrated by IV infusion.

Ask your doctor about once-daily ISENTRESS HD.

What is ISENTRESS HD?

ISENTRESS HD is a prescription HIV medicine used with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults, and in children weighing at least 88 pounds (40 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Important Safety Information

Some people who take ISENTRESS HD develop serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead to death. If you develop a rash, call your doctor right away. If you develop a rash with any of the following symptoms, stop using ISENTRESS HD and call your doctor or get medical help right away: fever; generally ill feeling; extreme tiredness, muscle or joint aches; blisters or sores in mouth; blisters or peeling of skin; redness or swelling of the eyes; swelling of the mouth, lips, or face; problems breathing.

Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems: yellowing of your skin or whites of your eyes; dark or tea-colored urine; pale-colored stools (bowel movements); nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of your stomach area.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

People taking ISENTRESS HD may still develop infections or other conditions associated with HIV-1 infections.

The most common side effects of ISENTRESS HD include: trouble sleeping, headache, dizziness, nausea, and tiredness. Less common side effects include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.

Tell your doctor before you take ISENTRESS HD if you have a history of a muscle disorder called rhabdomyolysis or myopathy or increased levels of creatine kinase in your blood.

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS HD. These may be signs of a rare serious muscle problem that can lead to kidney problems.

These are not all the possible side effects of ISENTRESS HD. For more information, ask your doctor or pharmacist. Tell your doctor if you have any side effect that bothers you or that does not go away.

Tell your doctor about all your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. ISENTRESS HD is not recommended for use during pregnancy. **Do not breastfeed if you take ISENTRESS HD.** Women with HIV should not breastfeed because their babies could be infected with HIV-1 through their breast milk.

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS HD. Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take ISENTRESS HD with those other medicines.

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

Please read the adjacent Patient Information for ISENTRESS HD and discuss it with your healthcare provider.

Talk to your doctor about ISENTRESS HD and visit **isentress.com**

Having trouble paying for your Merck medicine? Merck may be able to help. **www.merckhelps.com**

MERCK

I stay on top of my HIV-1 for me
and for the people who matter to me.
I have the best reasons to take care
of myself and…

I'm On It.

When you're a parent, you've got a lot to keep up with. **Once-daily ISENTRESS HD** can help fight my HIV-1. Plus, my healthcare provider said it's okay to take with my cholesterol medicine. That's important to me, **because I have more than just me to consider.**

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS HD. For more information, ask your doctor or pharmacist.

HIV Positive Model

Isentress® HD
raltegravir film-coated tablets 600 mg

Patient Information
ISENTRESS® HD (eye **sen** tris **HD**) (raltegravir) film-coated tablets

Read this Patient Information before you start taking ISENTRESS HD and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS HD?

ISENTRESS HD is a prescription HIV medicine used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults, and in children weighing at least 88 pounds (40 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Before you take ISENTRESS HD, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have a history of a muscle disorder called rhabdomyolysis or myopathy
- have increased levels of creatine kinase in your blood
- receive kidney dialysis treatment
- are pregnant or plan to become pregnant. It is not known if ISENTRESS HD can harm your unborn baby.

Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take ISENTRESS HD.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - It is not known if ISENTRESS HD can pass into your breast milk.
  - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS HD.

- **Keep a list of your medicines to show your doctor and pharmacist.**
- You can ask your doctor or pharmacist for a list of medicines that interact with ISENTRESS HD.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take ISENTRESS HD with other medicines.

How should I take ISENTRESS HD?

- Take ISENTRESS HD exactly as prescribed by your doctor.
- **Do not** change your dose of ISENTRESS HD or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor during treatment with ISENTRESS HD.
- ISENTRESS HD film-coated tablets **must be swallowed whole.**
- **Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.**
- **Do not** switch between the ISENTRESS® (raltegravir) 400 mg film-coated tablet and the ISENTRESS HD 600 mg film-coated tablet if your prescribed dose is 1200 mg.
- **Do not** run out of ISENTRESS HD. The virus in your blood may increase and the virus may become harder to treat. Get a refill of your ISENTRESS HD from your doctor or pharmacy before you run out.
- Take ISENTRESS HD on a regular dosing schedule as instructed by your doctor. Do not miss doses.
- If you take too much ISENTRESS HD, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of ISENTRESS HD?

ISENTRESS HD can cause serious side effects including:

- **Severe skin reactions and allergic reactions.** Some people who take ISENTRESS HD develop severe skin reactions and allergic reactions that can be serious, and may be life-threatening or lead to death. If you develop a rash call your doctor right away. If you develop a rash with any of the following symptoms, stop using ISENTRESS HD and call your doctor or get medical help right away:
  - fever
  - generally ill feeling
  - extreme tiredness
  - muscle or joint aches
  - blisters or sores in mouth
  - blisters or peeling of the skin
  - redness or swelling of the eyes
  - swelling of the mouth, lips, or face
  - problems breathing

Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems:

  - yellowing of your skin or whites of your eyes
  - dark or tea colored urine
  - pale colored stools (bowel movements)
  - nausea or vomiting
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of ISENTRESS HD include: trouble sleeping, headache, dizziness, nausea, and tiredness.

Less common side effects of ISENTRESS HD include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness during treatment with ISENTRESS HD. These may be signs of a rare serious muscle problem that can lead to kidney problems.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ISENTRESS HD. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ISENTRESS HD?

- Store ISENTRESS HD film-coated tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ISENTRESS HD film-coated tablets in the original package with the bottle tightly closed.
- Keep the drying agent (desiccant) in the ISENTRESS HD bottle to protect from moisture.

Keep ISENTRESS HD and all medicines out of the reach of children.

General information about the safe and effective use of ISENTRESS HD

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet.

Do not use ISENTRESS HD for a condition for which it was not prescribed. Do not give ISENTRESS HD to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about ISENTRESS HD that is written for health professionals.

For more information go to www.isentress.com or call 1-800-622-4477.

What are the ingredients in ISENTRESS HD?

ISENTRESS HD 600 mg film-coated tablets:

Active ingredient: raltegravir

Inactive ingredients: croscarmellose sodium, hypromellose 2910, magnesium stearate, microcrystalline cellulose.

The film coating contains: ferrosoferric oxide, hypromellose 2910, iron oxide yellow, lactose monohydrate, triacetin and titanium dioxide.

The tablet may also contain trace amount of carnauba wax.

usppi-mk0518-mf-1711r028
Revised 11/2017

MERCK

Egrifta

INJECTABLE FOR TREATING HIV-RELATED EXCESS BELLY FAT (LIPOHYPERTROPHY)

tesamorelin for injection

STANDARD DOSE

2 mg via subcutaneous (under the skin) injection once daily in the abdomen, rotating injection sites and avoiding scar tissue, bruises, and the navel (see step-by-step video at egrifta.com and this page for more information).

MANUFACTURER

Theratechnologies, Inc.
egrifta.com
Thera Patient Support:
1-833-23-THERA
(1-833-238-4372)

AWP

$5,520.00/month

A potential complication of HIV, antiretroviral therapy, or both may be changes in the distribution of adipose tissue (fat), otherwise known as lipodystrophy; previous reports of prevalence in the U.S. varied widely, anywhere from 2–60% of all HIV-positive patients. Abdominal lipohypertrophy (a form of lipodystrophy) is the accumulation of excess visceral adipose tissue (VAT)—deep belly fat surrounding the liver, stomach, and other abdominal organs. **Egrifta is the first, and only, FDA approved medication to reduce VAT.** This is different from subcutaneous fat. Unlike growth hormone products, Egrifta is an analogue of human growth hormone-releasing factor (GRF), which stimulates the pituitary gland to produce and secrete the body's own growth hormone. Egrifta reduces VAT while preserving subcutaneous fat. The effect of this agent appears to be greatest within the first three to six months of initiation.

Two Phase 3 clinical trials found that Egrifta significantly lowered VAT (up to 15–20% on average) at both 26 and 52 weeks. Egrifta may also lower triglycerides (a type of cholesterol). Adverse events were more commonly seen in the groups given Egrifta than in those receiving placebos. It is important to note that excess VAT returns once Egrifta is discontinued. Egrifta should not be administered to patients who have pituitary gland tumor(s), pituitary gland surgery, or other pituitary gland problems; active cancer; hypersensitivity to either tesamorelin and/or mannitol; or who are pregnant. Egrifta should be used with caution in patients who have a history of non-malignant neoplasms (abnormal growth of tissue such as a tumor), a history of treated and stable malignancies, elevated insulin-like growth factor 1 (IGF-1), fluid retention, diabetes, or pre-diabetes.

The most common side effects include joint pain, injection site reactions (including redness, pain, and itching), pain in legs and arms, swelling in legs, muscle soreness, tingling, numbness and prickling, nausea, vomiting, rash, and itchiness. Other warnings include hypersensitivity reactions and acute critical illness. In the Phase 3 clinical studies, patients receiving Egrifta had a higher risk of developing diabetes compared to those on placebo. Despite initial thoughts that Egrifta may have significant drug-drug interactions with medications that use CYP450 (an enzyme in the liver) for metabolism, a study in healthy volunteers proved otherwise. However, it has not been studied with medications that use other enzymes in the liver; therefore, response to medications that are metabolized through the liver should be monitored for response and adverse reactions. Long-term safety data is unknown. There have been previous reports of a theoretical increased risk of cancer with elevated IGF-1 levels. Other long-term concerns include potential development of retinopathy in patients with diabetes. Each dose necessitates mixing 1-mg vials (requiring refrigeration) of Egrifta with 2.2 mL of sterile water for injection (vial stored at room temperature). Do not use an unopened vial if the solution is colored, cloudy, or contains visible particles. Once mixed, the vial should be rolled gently, not shaken, between the hands for 30 seconds to ensure reconstitution into a clear, colorless solution and administered right away. If not used immediately, the reconstituted Egrifta should be discarded.

CAP & PAP INFO

If someone is having difficulty paying for Egrifta, there are several programs available through Thera patient support at (833) 23-THERA (833-238-4372), Monday–Friday, 8 a.m.–8 p.m. EST) or at egrifta.com.

Mytesi

ANTI-DIARRHEAL APPROVED FOR USE IN THOSE WITH HIV/AIDS AND ON ANTIRETROVIRAL THERAPY

crofelemer

STANDARD DOSE

One 125 mg delayed-release tablet taken twice a day, with or without food. The tablet should be swallowed whole and not crushed or chewed.

MANUFACTURER

Napo Pharmaceuticals
Mytesi.com
(844) 722-8256

AWP

$648.00/60 tablets

Mytesi (crofelemer) is the first, and only, anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. Currently, what is typically recommended is for the patient to take medication(s) with food and/or use Imodium (loperamide) for symptomatic diarrhea.

Mytesi approval was based on a randomized, placebo-controlled study of 374 HIV-positive patients who had about 3 watery stools per day and were on anti-HIV medicines. At study entry, patients experienced an average of approximately 20 watery stools per week. To be considered a responder, watery stools had to be decreased to two or fewer per week, which occurred in 18% of Mytesi-treated patients vs. 8% of placebo-treated patients at 4 weeks. In an open label extension phase of the study, about 50% of the patients reported two or fewer watery stools per week at 3 months, an effect which was maintained until study end at 6 months. These findings suggest that it may take some time to achieve the optimal effect. Mytesi appears to work best in those who have tried and failed non-prescription anti-diarrheals, have had diarrhea for more than two years, have more than two watery bowel movements per day, and whose bowel movements tend to be "pourable" (not clumpy). Mytesi was less effective in African Americans in this clinical study.

An infectious cause should be ruled out prior to initiating Mytesi. In the placebo-controlled part of the study, side effects were comparable to placebo. The most commonly reported side effect was upper respiratory tract infection (Mytesi, 3.8% of patients vs. placebo, 2.9%). Other reported side effects included bronchitis, cough, flatulence (gas), and increased bilirubin. Based on animal data, Mytesi may cause fetal harm. Mytesi has not been studied in patients younger than 18 years old. Its usefulness in pediatrics is unknown and use in this population cannot be recommended at this time.

There were no significant drug interactions in participants in the clinical study. There was little or no change in CD4 counts and viral load throughout the study.

In a review article in *Expert Review of Clinical Pharmacology* published in 2015 by Castro *et al*, the use of Mytesi is recommended as a reasonable choice in patients not responding to over-the-counter psyllium and loperamide. Patients should be informed that the benefits of Mytesi are not immediate, possibly taking about four weeks, and if an inadequate response is seen after three months, Mytesi should be discontinued.

CAP & PAP INFO

CO-PAY PROGRAM: (877) 336-4377
Pay no more than $25, maximum benefit of $100 on each prescription.
PAP: (888) 527-6276; mytesi.com

Serostim

INJECTABLE HUMAN GROWTH HORMONE USED FOR TREATING HIV-ASSOCIATED WASTING IN THOSE ON ART

somatropin for injection

STANDARD DOSE

0.1 mg/kg via subcutaneous (under the skin) injection, which may be in the thigh, upper arm, abdomen, or buttock once daily at bedtime (up to 6 mg), rotating injection sites and avoiding scar tissue, bruises, and the navel. It is available in 4 mg, 5 mg, and 6 mg vials. The multi-use 4 mg vial is reconstituted with bacteriostatic (containing a biological or chemical agent that stops bacteria from reproducing) water for injection and may be refrigerated for up to 14 days after reconstitution. The single-use 5 mg and 6 mg vials are reconstituted with sterile water for injection and must be used immediately; after administering the dose, any unused portion should be discarded. Some loss of the dose can be expected (approximately 10%). Inject the water into the vial aiming for the glass wall. The vial should be swirled gently in a circular motion until solution is completely dissolved; it must be clear and colorless. Do not shake. Do not inject if solution is cloudy or contains particles.

MANUFACTURER

EMD Serono
serostim.com
(877) 714-AXIS (2947)

AWP

28 day supply
4 mg: $10,292.72
5 mg: $12,865.92
6 mg: $15,439.12

Serostim is recombinant (made in a lab) human growth hormone for treatment of HIV wasting (unintentional loss of weight) or cachexia (general ill health resulting from emaciation), decreased lean body mass (muscle), and loss of physical endurance. Loss of muscle can be difficult to notice or diagnose. Serostim has been shown to increase HIV replication in the test tube; therefore, patients must be taking anti-HIV therapy, known as HAART (or cART), in order to be prescribed Serostim.

Most common potential side effects include swelling (especially of the hands and feet), muscle pain, joint pain, numbness, and pain in extremities (the ends of limbs, especially the hands and feet), carpal tunnel syndrome (requiring discontinuation if unresolved by decreasing the number of doses), injection site reactions (pain, numbness, redness, or swelling), increased blood fat (triglycerides) and blood sugar (including new or worsening cases of diabetes, sometimes reversible upon stopping Serostim), nausea, and fatigue. More rarely, potential side effects include pancreatitis (watch for persistent severe abdominal pain) and intracranial hypertension (rise in pressure in the skull, with visual changes, headache, nausea, or vomiting). Serostim should be avoided in patients who are acutely ill, have an active cancer, or have diabetic retinopathy (damage to one or both retinas). Since HIV-positive patients may have an increased risk of developing new tumors, including from birthmarks or other moles, risks versus benefits of starting Serostim should always be discussed with your provider. Additionally, patients with known malignancies should be carefully monitored, because Serostim may cause increased growth or malignant changes.

Rotate injection sites to avoid injection site reactions. An injection training program is available; see the website or call the toll-free number. Do not use while experiencing cancer or cancer treatment, serious injuries, severe breathing problems, certain eye diseases related to diabetes, or after critical illness due to complications of abdominal or open heart surgery.

Based on how the drug is broken down in your body, there are some potential drug-drug interactions, though no formal drug studies have been conducted. These theoretically potential interactions include patients on glucocorticoid (such as prednisone) therapy and may require an increased prednisone dose. Others may include medications that are metabolized through the CYP450 enzyme in your liver (like some antiretrovirals, cholesterol medications, or anticonvulsants); or medications like oral estrogen, insulin, or oral diabetes drugs. Be sure to tell your provider, pharmacist, and/or other providers about all of the medications you are taking, including herbs, supplements, and over-the-counter (OTC) products, prescribed or not.

CAP & PAP INFO

If someone is having difficulty paying for Serostim, there are several programs that may be able to assist the patient with acquiring it. These programs include EMD Serono Secured Distribution Program, the AXIS Center, the Serostim Patient Assistance Program (PAP) or the Co-Pay Assistance Program (CAP). To find out more about these programs, call (877) 714-2947.

This year, the co-pay card is front-loaded. $0 initial fill (rebate form provided if you need to pay up front and are eligible), and up to $1,500 for each additional monthly fill, not to exceed $18,000/year. PAP also available if you qualify. Call AXIS Center (877) 714-AXIS (2947).

Go to serostim.com for additional information.

Truvada for PrEP

★ CDC RECOMMENDED AS COMPLETE REGIMEN FOR PREVENTION OF HIV IN COMBINATION WITH OTHER RISK REDUCTION STRATEGIES

emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)

STANDARD DOSE

For HIV-negative adults, one tablet (200 mg emtricitabine/300 mg tenofovir disoproxil fumarate) once daily, without regard to food.

Take a missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose. Truvada should not be used for prevention if eCrCl or eGFR (measures of kidney function) is less than 60 mL/min.

APPROVED AS GENERIC; NOT YET COMMERCIALLY AVAILABLE.

MANUFACTURER

Gilead Sciences, Inc.
gilead.com
(800) GILEAD-5
(445-3235)

AWP

$2,010.95/month

POTENTIAL SIDE EFFECTS AND TOXICITY

See the pages for the individual drugs contained in Truvada—Viread and Emtriva. No new serious side effects were seen when Truvada was studied for HIV prevention in clinical trials. Some patients may experience nausea, headache, stomach pain, or weight loss. Risk compensation (when people put themselves at greater risk for infection, such as anonymous or multiple sex partners, because they think PrEP will protect them) was not observed in clinical trials. The tenofovir DF (Viread) in Truvada is associated with long-term decreases in bone mineral density (BMD). BMD monitoring should be considered in people who have a history of bone fracture due to a disease or are at risk for osteopenia or osteoporosis. Truvada can cause kidney toxicities. In prevention studies, decreases in BMD and creatinine clearance or eGFR (a marker of kidney function) were rare, mild, and reversible upon stopping Truvada. Tell your provider about pain in extremities, persistent or worsening bone pain and fractures, with or without muscular pain or weakness, as well as any concerning changes in urinary habits as these could be signs of kidney or bone problems. If Truvada is discontinued abruptly in people with hepatitis B virus (HBV), flare-up of hepatitis may occur—talk to your provider before discontinuing Truvada for PrEP. In studies, there were cases of people who had unidentified HIV infection when starting Truvada for PrEP and they were more likely to develop drug resistance than those who acquired HIV while on the medication. Truvada contains lactose, which can cause some abdominal discomfort, especially in patients sensitive to lactose.

POTENTIAL DRUG INTERACTIONS

See the individual sheets for the drugs contained in Truvada—Viread and Emtriva. Tell your provider or pharmacist about all medications, herbal products, and supplements you are taking or thinking of taking, whether they are prescribed or not. Do not take with any other HIV or HBV drugs when used for pre-exposure prophylaxis (PrEP). Avoid taking Truvada with drugs that negatively affect the kidneys, including chronic use or high doses of anti-inflammatory drugs for pain like Advil or Motrin (ibuprofen) and Aleve (naproxen). Truvada, when taken for PrEP, can be used with the hepatitis C drugs Daklinza, Harvoni, Sovaldi, Olysio, Viekira Pak, or Zepatier. Monitor for tenofovir toxicities if used with Epclusa.

MORE INFORMATION

Truvada, a widely-used medication for the treatment of HIV, was approved in July 2012 by the Food and Drug Administration (FDA) to reduce the risk of HIV infection in HIV-negative adults with substantial vulnerability for HIV acquisition. Although the drug label specifies sexually-acquired infection, U.S. HIV guidelines recommend use for protecting against infection through drug use. This approach to HIV prevention is called pre-exposure prophylaxis, or PrEP ("prophylaxis" means something that prevents disease, such as a condom or a vaccine). The U.S. Public Health Service (USPHS) issued guidelines for the use of Truvada for PrEP in May of 2014. Go to cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. pdf. Truvada is currently the only drug approved for PrEP.

Descovy, which combines emtricitabine with a more potent prodrug of tenofovir, TAF, is only approved for HIV or HBV treatment and not prevention. There is no human efficacy data with Descovy, and only Truvada should be used for PrEP. A study is currently in progress comparing Descovy to Truvada for PrEP. Other medications are also being studied for use as HIV PrEP.

There are many considerations regarding Truvada for PrEP. Proper use is crucial. It is vital that people test HIV-negative within 7 days before being given a prescription. Patients should also be re-tested for HIV infection every three months while taking Truvada for PrEP. People who are already unknowingly infected when starting PrEP, or who become infected while taking it, risk developing drug-resistant virus because Truvada alone is not adequate for the treatment of HIV. (See Truvada for HIV treatment, page 46.) This resistance may complicate future HIV therapy by reducing treatment options. Drug resistance can only occur in HIV-positive individuals. Truvada for PrEP should not be given to people with symptoms of recent (acute) infection, such as fever, fatigue, sweating a lot (especially at night), rash, vomiting, diarrhea, joint or muscle aches, headache, sore throat, or enlarged lymph nodes (especially in the neck or groin). PrEP should not be started (or re-started) if any of these symptoms appear after a potential exposure to HIV unless evaluated by a doctor and possibly re-tested for HIV. People on PrEP who have these symptoms after a potential exposure to HIV should let their provider know immediately. A specific algorithm for assessing HIV status can be found in the CDC PrEP guidelines (see above). Using PrEP correctly can avoid infection and thus eliminate the risk of drug resistance.

Truvada for PrEP is not a "morning-after pill" or a weekend medication. It must be taken every day to be maximally effective. In studies, greater protection was seen with greater adherence. Truvada for PrEP works if you take it as prescribed.

While some people may use PrEP as their only prevention method, it was studied and approved as part of a more comprehensive HIV prevention strategy that includes the use of condoms and risk reduction counseling. That said, the CDC has changed the definition of protected sex to include sex without condoms, given new modalities such as PrEP. Although consistent condom use is an important part of a prevention plan for all people prescribed PrEP, lack of use of a barrier protection is not a reason to withhold PrEP. On the contrary, the PrEP label lists people who are unwilling or unable to use condoms as at-risk candidates for whom the drug is indicated. PrEP does not protect against other sexually transmitted infections (STDs) including hepatitis C or against pregnancy.

Other screening and monitoring requirements include measuring kidney function and checking for STIs and hepatitis B and C, treatment for STIs, and vaccination for HBV if warranted.

Although a PrEP prescription can be given to a wide range of people, the FDA approved Truvada for those considered at "substantial risk" for infection. The Truvada PrEP label notes that people at risk include those who engage in sexual activity in a high-prevalence area or social network and have one or more of the following: (a) inconsistent or no condom use, (b) diagnosis of sexually transmitted infections (STIs), (c) exchange of sex for commodities (money, food, shelter, or drugs), (d) use of illicit drugs or alcohol dependence, (e) history of incarceration, or (f) sexual partners of unknown HIV status with any of the above risk factors. U.S. HIV treatment

guidelines state that, "Truvada has been shown to be safe and effective at preventing HIV in healthy adults who meet recommended criteria in the following populations: MSM [men who have sex with men], heterosexually active men and women, and IV drug users."

Individuals who have used post-exposure prophylaxis (PEP) multiple times are also good candidates for PrEP because of their continuing risk for HIV. PEP is a course of HIV medications taken for 28 days after exposure to HIV to prevent infection; it must be started as soon as possible but no later than 72 hours after exposure.

Although pregnant women were not enrolled in PrEP studies, there is hope for PrEP to help serodiscordant couples (where one partner is positive and one is negative) conceive without transmitting the virus. Last year, the DHHS perinatal HIV guidelines added a section on the use of PrEP and HIV therapy to prevent transmission in sero-different couples trying to conceive; go to aidsinfo.nih.gov. The Bay Area Perinatal AIDS Center (BAPAC) is leading the charge for safer conception options, including MSM, plus a new providers list at pleasePrEPme.org; go to hiveonline.org.

Unlike HIV therapy, which is long-term, PrEP may be used just for periods of time when HIV-negative individuals are vulnerable to infection. According to the World Health Organization, it takes Truvada for PrEP 7 days to reach protective levels, whether exposure is rectal or vaginal. The CDC notes time to steady state, or maximum intracellular concentrations of TFV-DP, of 7 days for the rectal tract and about 20 days for vaginal tissue. Protective levels, however, are reached much earlier, based on pharmacokinetic (PK) models.

The two studies that led to Truvada's approval for PrEP, iPrEx (in high-risk MSM and transgender women) and Partners PrEP (in serodiscordant couples, most of them heterosexual), showed efficacy rates between 90%–92% when participants take their meds. PrEP with Truvada has also been studied in other patient populations, including younger single men and women, injection drug users, and women. In all the studies, the common theme is that PrEP is effective if you take it every day. Other drugs are being studied for use as HIV PrEP, including long-acting injection formulations requiring only one injection every 4–8 weeks.

Some providers not working in HIV are still learning about PrEP, and some continue to be reluctant to prescribe it. Read the PDF of the CDC brochure Talk to Your Doctor about PrEP. The brochure includes resources for providers. HIV specialists may be best for a PEP or PrEP prescription, as they are familiar with the medications and more supportive of PrEP; find providers at hivma.org and aahivm.org, as well as pleaseprepme.com. HIV specialists are generally in high demand, however, and advocates are looking to make Truvada for PrEP much more accessible. There is also a complex set of standards to use in prescribing PrEP that may cause many providers to turn away, including a call for safer sex counseling. Requirements for a PrEP prescription can be burdensome. Truvada for PrEP has a Risk Evaluation and Mitigation Strategy (REMS) program which can providers can access to ensure safe prescribing. The National Alliance of State and Territorial AIDS Directors (NASTAD) developed a guide to help providers bill for PrEP services available at nastad.org/resource/billing-coding-guide-hiv-prevention. Two excellent websites for finding a PrEP provider are preplocator.org and aidsvu.org. All you need to do is put in your ZIP code and a list of providers who prescribe Truvada for PrEP will appear.

Greater PrEP acceptance and use, however, appears to be increasing among communities most vulnerable to HIV. Health departments across the country are promoting PrEP as part of a strategy to end the HIV epidemic. In addition, prevention efforts are also focusing on U=U (Undetectable equals Untransmittable), promoting the awareness that people living with HIV who have undetectable viral loads do not transmit the virus to sexual partners—see details in the September + October 2017 PA. Go to preventionaccess.org.

Insurance coverage of PrEP has become less of a concern. Providers are reporting widespread acceptance of PrEP prescriptions by insurers. Gilead Sciences also helps patients work with their insurance, including pre-authorizations, as well as provides free PrEP to uninsured patients who are eligible and co-pay assistance up to $4,800 a year; contact the patient assistance hotline at (855) 330-5479 or go to gilead.com/truvada_assistance_program. Patients may also have to advocate on their own behalf; keeping good notes of conversations and other communication is a good idea. Also, check out prep4love.com.

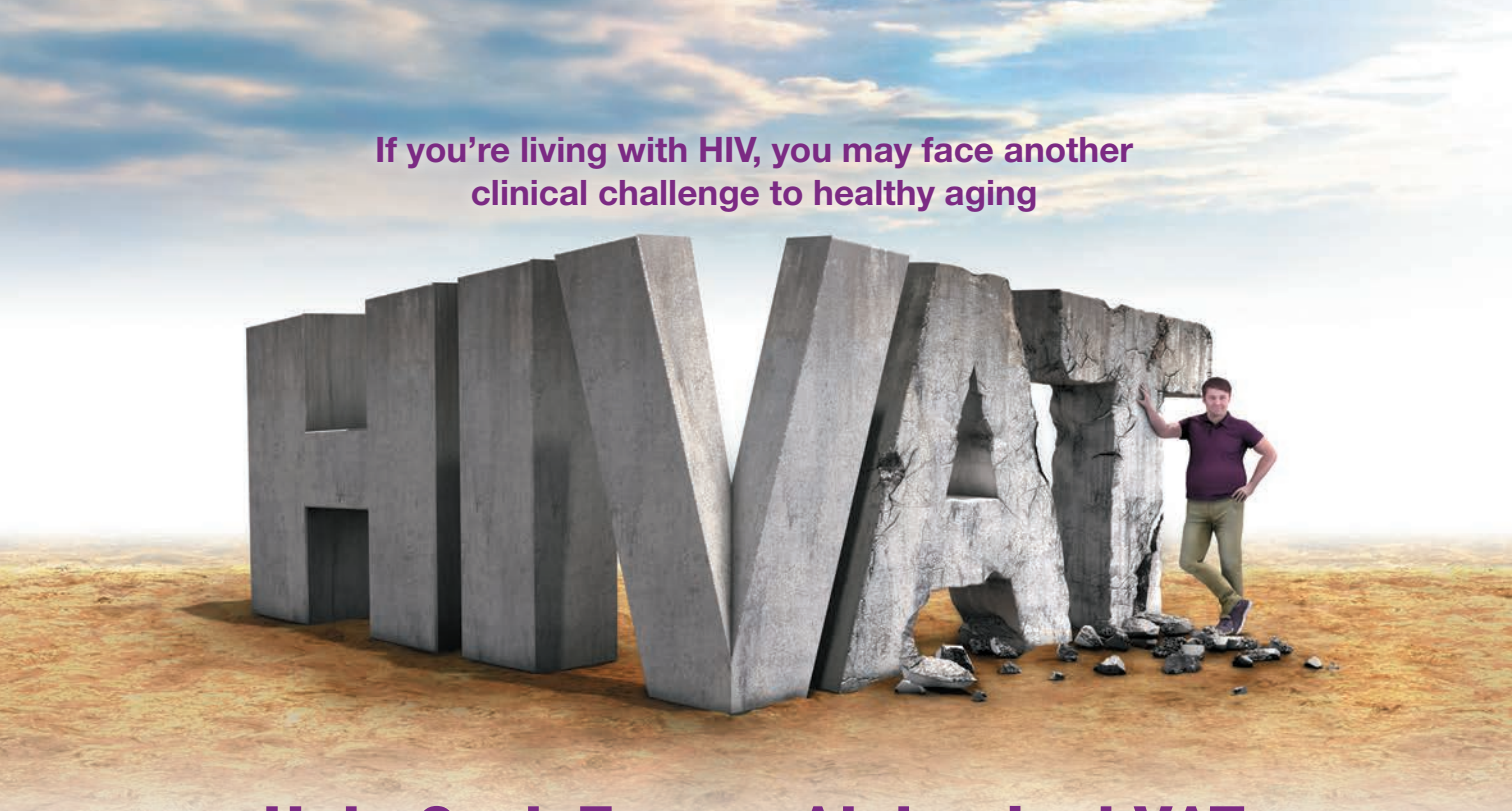
PrEP Facts: Rethinking HIV Prevention and Sex is a closed Facebook group for people interested in or currently on PrEP, and their allies. Demonstration projects providing free PrEP to study its use in the real world can be found at PrEPWatch.org from AVAC and projectinform.org/prep. Providers can use V107 as a medical billing code for PrEP (exposure to infectious disease, including HIV).

More good sources of information: cdc.gov/hiv/basics/prep; nccc.ucsf.edu/clinical-resources/pep-resources/prep; whatisprep.org; truvadaprepreams.com; and hivinsite.com.

Robert Grant, MD, principal investigator for the iPrEx study, wrote in an article for POSITIVELY AWARE, "The combination of highly active antiretroviral interventions for both HIV prevention and treatment has led to unprecedented optimism about the prospect of ending AIDS."

Read PA's special issues on PrEP at positivelyaware.com.

If you're living with HIV, you may face another clinical challenge to healthy aging



Help Curb Excess Abdominal VAT

Visceral adipose tissue (VAT) isn't regular fat. VAT is a hard fat that surrounds organs, may be associated with serious health issues, and can be difficult to control with diet and exercise alone.

EGRIFTA® (tesamorelin for injection) is the only FDA-approved treatment for excess HIV-related abdominal VAT

EGRIFTA® was shown to reduce VAT in 2 clinical trials of 816 total adult patients who received 2 mg of *EGRIFTA*® or placebo (26-week Main Phase and 26-week Extension Phase).[a]

Trial 1: 18% average reduction. **Trial 2: 14%** average reduction.

[a]For additional trial details, see the full Prescribing Information at EGRIFTA.com.

***EGRIFTA*® is not indicated to treat health issues beyond the reduction of excess abdominal VAT.**

SELECTED RISK INFORMATION

What is *EGRIFTA*®?

- *EGRIFTA*® is an injectable prescription medicine used to reduce the excess in abdominal fat in patients with HIV and lipodystrophy.
- *EGRIFTA*® causes the pituitary gland to release growth hormone, which decreases abdominal fat.
- *EGRIFTA*® is not to be used for weight loss management.
- The impact and safety of *EGRIFTA*® on cardiovascular health has not been studied.
- It is not known whether taking *EGRIFTA*® helps improve compliance with anti-retroviral medications.

EGRIFTA® may cause serious side effects including:

- **Serious allergic reactions** such as rash or hives anywhere on the body or on the skin bigger than the injection area, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fast heartbeat feeling of faintness or fainting. **If you have any of these effects, stop using *EGRIFTA*® and get emergency help right away.**
- Swelling or fluid retention. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist.
- Increase in blood sugar (glucose).
- Injection site reactions.

The most common side effects of *EGRIFTA*® include:

- joint pain, pain in legs and arms, swelling in your legs
- muscle pain
- tingling, numbness and pricking
- nausea, vomiting
- rash, itching

Please see brief summary of full Important Patient Information on next page.

Learn more at EGRIFTA.com

EGRIFTA® tesamorelin for injection

A Transformation From Within

190-02-02/18

IMPORTANT PATIENT INFORMATION

The following is a brief summary only. See complete Prescribing Information at EGRIFTA.com or request complete Prescribing Information by calling 1-833-238-4372. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is *EGRIFTA*® (tesamorelin for injection)?

- *EGRIFTA*® is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. The impact and safety of *EGRIFTA*® on cardiovascular health has not been studied.
- *EGRIFTA*® is not indicated for weight loss management.
- It is not known whether taking *EGRIFTA*® helps improve compliance with anti-retroviral medications.

Do not use *EGRIFTA*® if you:

- have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland.
- have active cancer or are receiving treatment for cancer
- are allergic to tesamorelin or mannitol.
- are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA*® and talk with your healthcare provider.

Talk to your doctor to find out if *EGRIFTA*® is right for you.

How should I use *EGRIFTA*®?

- **Read the detailed "Instructions for Use"** that comes with *EGRIFTA*® before you start using *EGRIFTA*®. Your healthcare provider will show you how to inject *EGRIFTA*®.
- Use *EGRIFTA*® exactly as prescribed by your healthcare provider.
- Inject *EGRIFTA*® under the skin (subcutaneously) of your stomach area (abdomen).
- Change (rotate) the injection site on your stomach area (abdomen) with each dose. Do not inject *EGRIFTA*® into scar tissue, bruises or your navel.

***EGRIFTA*® may cause serious side effects including:**

- Serious allergic reaction. Some people taking *EGRIFTA*® may have an allergic reaction.

Stop using *EGRIFTA*® and get emergency help right away if you have any of the following symptoms:

- a rash over your body
- hives
- swelling of your face or throat
- shortness of breath or trouble breathing
- fast heartbeat
- feeling of faintness or fainting

- Swelling (fluid retention). *EGRIFTA*® can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome).
- Increase in glucose (blood sugar) intolerance and diabetes. Your healthcare provider will measure your blood sugar periodically.
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. Call your healthcare provider for medical advice if you have the following symptoms around the area of the injection site:
  - redness
  - itching
  - pain
  - irritation
  - bleeding
  - rash
  - swelling

The most common side effects of *EGRIFTA*® include:

- joint pain
- pain in legs and arms
- swelling in your legs
- muscle soreness
- tingling, numbness and pricking
- nausea
- vomiting
- rash
- itching

These are not all the possible side effects of *EGRIFTA*®. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to THERA patient support™ toll-free at 1-833-23-THERA (1-833-238-4372).

For more information about *EGRIFTA*®, go to www.EGRIFTA.com or contact THERA patient support™ toll-free at 1-833-23-THERA (1-833-238-4372).

Manufactured by: Jubilant HollisterStier General Partnership, 16751 Trans-Canada Highway, Montreal, Québec, Canada H9H 4J4

Distributed by: Theratechnologies Inc., 2015 Peel Street, Montreal, Québec, Canada H3A 1T8.

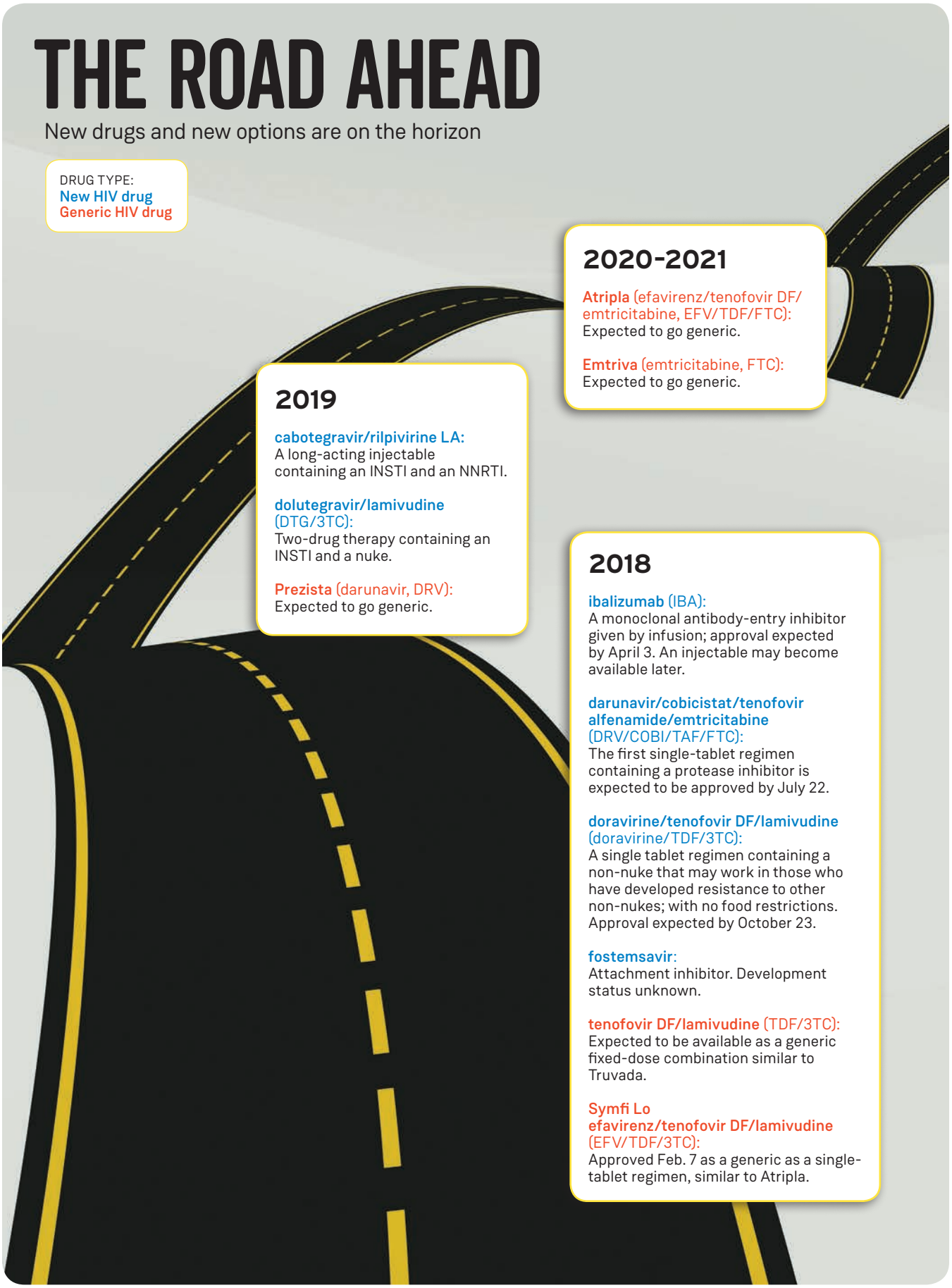
THERA technologies

EGRIFTA® tesamorelin for injection

THE ROAD AHEAD

New drugs and new options are on the horizon

DRUG TYPE:
New HIV drug
Generic HIV drug



2020-2021

Atripla (efavirenz/tenofovir DF/emtricitabine, EFV/TDF/FTC):
Expected to go generic.

Emtriva (emtricitabine, FTC):
Expected to go generic.

2019

cabotegravir/rilpivirine LA:
A long-acting injectable containing an INSTI and an NNRTI.

dolutegravir/lamivudine (DTG/3TC):
Two-drug therapy containing an INSTI and a nuke.

Prezista (darunavir, DRV):
Expected to go generic.

2018

ibalizumab (IBA):
A monoclonal antibody-entry inhibitor given by infusion; approval expected by April 3. An injectable may become available later.

darunavir/cobicistat/tenofovir alfenamide/emtricitabine (DRV/COBI/TAF/FTC):
The first single-tablet regimen containing a protease inhibitor is expected to be approved by July 22.

doravirine/tenofovir DF/lamivudine (doravirine/TDF/3TC):
A single tablet regimen containing a non-nuke that may work in those who have developed resistance to other non-nukes; with no food restrictions. Approval expected by October 23.

fostemsavir:
Attachment inhibitor. Development status unknown.

tenofovir DF/lamivudine (TDF/3TC):
Expected to be available as a generic fixed-dose combination similar to Truvada.

Symfi Lo efavirenz/tenofovir DF/lamivudine (EFV/TDF/3TC):
Approved Feb. 7 as a generic as a single-tablet regimen, similar to Atripla.

SOURCE: FAIR PRICING COALITION ILLUSTRATION" ISTOCKPHOTO/PHOTITOS

POSITIVELY AWARE

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PENNIES FROM ABOVE

HIV treatment can be costly, but there's help

ISTOCKPHOTO

Today's therapies are vastly improved over the first drugs used to treat HIV, but these advancements come at a cost. The prices of HIV drugs continue to rise every year at an average of 7–9 percent. While in the past these increases usually haven't directly affected someone who has drug coverage through their health insurance plan, increasingly individuals have to pay co-insurance (a percentage of the cost of the medication). The good news is that help is out there. ADAPs, several non-profit organizations, and the pharmaceutical companies have assistance programs in place to help you pay for the treatment you need.

The bad news is that changes may be on the way for consumers, as some big health insurers no longer allow the amount of the co-pay cards to be applied towards their deductible or out-of-pocket maximum, or steer them towards other cost-containing measures such as step therapy or individual generics that break up an STR.

A cost-sharing assistance program (CAP) is a program operated by pharmaceutical companies to offer cost-sharing assistance (including deductibles, co-payments and co-insurance) to people with private health insurance to obtain HIV drugs at the pharmacy.

A patient assistance program (PAP) is a program run through pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare, or AIDS Drug Assistance Programs (ADAPs). Each individual company has different eligibility criteria for application and enrollment in their patient assistance program.

GET DETAILS ON CAP AND PAP PROGRAMS, STARTING ON **PAGE 72**

HarborPath, a non-profit organization that helps uninsured individuals living with HIV gain access to brand-name prescription medicines at no cost, operates a special patient assistance program for individuals on ADAP waiting lists. An individual is eligible for the HarborPath ADAP waiting list program only if he or she has been deemed eligible for ADAP in his or her state and is verified to be on an ADAP waiting list in that state.

Applying for PAPs

IN 2012, the Department of Health and Human Services (DHHS), along with seven pharmaceutical companies, the National Alliance of State and Territorial AIDS Directors (NASTAD), and community stakeholders developed a common patient assistance program application form that can be used by both providers and patients. This form combines common information collected on each individual companies form to allow individuals to fill out one form. Once the form is completed, case managers or individuals then submit the single form to each individual company, reducing the overall amount of paperwork necessary to apply for a patient assistance program.

HarborPath operates as a streamlined, online portal for PAP access. HarborPath creates a single place for application and medication fulfillment. This "one stop shop" portal provides a streamlined, online process to qualify individuals and deliver the donated medications of the participating pharmaceutical companies through a mail-order pharmacy.

SPECIAL THANKS to NASTAD's Britten Pund and Amanda Bowes for much of the information listed here and to Tim Horn for his review. Adapted from **HIV Pharmaceutical Company HIV Patient Assistance Programs and Cost-Sharing Assistance Programs**: bit.ly/1XIahvN

HIV COST-SHARING ASSISTANCE PROGRAMS (CAP)

DRUGS COVERED	MANUFACTURER AND CONTACT INFORMATION	ASSISTANCE	RENEWAL
Kaletra and **Norvir**	**AbbVie** 800-441-4987, option 5; kaletra.com; norvir.com	**Kaletra:** Co-payment assistance covers the first $400 per prescription per month. **Norvir:** Covers up to $1,200 a year for co-payments.	Reapply each year
Evotaz, **Reyataz**, and **Sustiva**	**Bristol-Myers Squibb** 888-281-8981; bmscustomerconnect.com/bms3assist	**Evotaz, Reyataz, and Sustiva:** Up to $7,500 annually for co-payments, deductibles, and co-insurance in all commercially-insured plans.	Reapply each year
Atripla, **Biktarvy**, **Complera**, **Descovy**, **Emtriva**, **Genvoya**, **Odefsey**, **Stribild**, **Truvada**, and **Tybost**	**Gilead Sciences** 877-505-6986; gileadadvancingaccess.com	**Genvoya:** Covers the first $7,200 per year of co-payments. **Atripla, Complera, Odefsey, and Stribild:** Covers the first $6,000 per year of co-payments. **Descovy and Truvada:** Covers the first $4,800 per year of co-payments. **Emtriva:** Covers the first $300 per month/$3,600 per year of co-payments. **Tybost:** Covers the first $50 per month/$600 per year of co-payments.	Reapply each year
Edurant, **Intelence**, **Prezista**, and **Prezcobix**	**Janssen Therapeutics** 866-961-7169; edurant.com; intelence.com; prezista.com; prezcobix.com	Covers the first $7,500 per year of co-payments, deductibles, and co-insurance.	Reapply each year
Isentress and **Isentress HD**	**Merck and Co.** 800-850-3430; isentress.com	Covers the first $6,800 per year of co-payments, deductibles, and co-insurance for each of 12 eligible prescriptions.	Enrollment is valid until coupon expires
Juluca, **Lexiva**, **Rescriptor**, **Selzentry**, **Tivicay**, **Triumeq**, and **Viracept**	**ViiV Healthcare** 844-588-3288; ViiVconnect.com	**Juluca, Tivicay and Triumeq:** $6,000 per year/per patient maximum. **Lexiva, Rescriptor, Selzentry and Viracept:** $2,400 per year/per patient maximum.	Automatic renewal
Invirase and **Viread**	**Patient Access Network Foundation** 866-316-7263; panfoundation.org	Maximum benefit is $3,600 per year. Patients may apply for a second grant during their eligibility period subject to availability of funding.	Reapply each year

HIV PATIENT ASSISTANCE PROGRAMS (PAP)

DRUGS COVERED	MANUFACTURER AND CONTACT INFORMATION	FINANCIAL ELIGIBILITY
Kaletra, Norvir	**AbbVie** 800-222-6885; kaletra.com; norvir.com; abbviepaf.org	**Kaletra:** 500% FPL **Norvir:** No income limits
Aptivus, Viramune XR	**Boehringer Ingelheim** 800-556-8317; rxhope.com; pparx.org	500% FPL
Evotaz, Reyataz, and **Sustiva**	**Bristol-Myers Squibb** 888-281-8981; bmscustomerconnect.com/bms3assist	300–500% FPL
Atripla, Complera, Descovy, Emtriva, Genvoya, Odefsey, Stribild, Truvada, Tybost, and **Viread**	**Gilead Sciences*** 866-290-4767; gileadadvancingaccess.com	500% FPL
Edurant, Intelence, Prezista, and Prezcobix	**Janssen Therapeutics** 800-652-6227; jjpaf.org	300% FPL
Crixivan, Isentress, and **Isentress HD**	**Merck and Co.** 800-727-5400; merck.com/merckhelps; isentress.com	500% FPL
Combivir, Epivir, Epzicom, Lexiva, Juluca, Rescriptor, Retrovir, Selzentry, Tivicay, Triumeq, Trizivir, Viracept, and **Ziagen**	**ViiV Healthcare** 844-588-3288; ViiVconnect.com	500% FPL

* Patients who are insured and who do not meet their payer's coverage criteria are no longer eligible for support via Gilead's patient assistance program. This includes clients whose insurer has limited access based on: step-therapy or clinical criteria (e.g., drug and alcohol testing).

ADDITIONAL RESOURCES

THESE MAY BE OF INTEREST TO INDIVIDUALS LIVING WITH HIV

Clinical Trials
clinicaltrials.gov
A service of the U.S. National Institutes of Health, ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Fair Pricing Coalition (FPC)
fairpricingcoalition.org
As part of their advocacy work, the Fair Pricing Coalition (FPC) negotiates with companies to ensure that cost-sharing and patient assistance programs are adequately generous and easy to apply for.

Health Insurance Marketplace
healthcare.gov
The official site of the Health Insurance Marketplace, Healthcare.gov allows individuals and families to sign up for insurance coverage through the Affordable Care Act.

Treatment Action Group
treatmentactiongroup.org
Treatment Action Group collaborates with activists, community members, scientists, governments, and drug companies to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information.

FOUNDATIONS

PROVIDING ACCESS TO CARE ASSISTANCE FOR PEOPLE LIVING WITH HIV

Harbor Path
harborpath.org
Provides access to free medications for uninsured people living with chronic illnesses; administers AIDS Drug Assistance Program (ADAP) Waiting List Program.

PAN Foundation
panfoundation.org
(866) 316-7263
Provides necessary healthcare treatments to the underinsured population.

Patient Advocate Foundation
patientadvocate.org
(800) 532-5274
Provides arbitration, mediation and negotiation services to settle issues with access to care, medical debt, and job retention related to illness.

What is **Pre-exposure Prophylaxis (PrEP)**?

PRE-EXPOSURE PROPHYLAXIS (PrEP) is the use of antiretroviral (ARV) medication to prevent possible HIV transmission with HIV-negative individuals who may be at higher risk of infection. PrEP is currently recommended for sexually active men who have sex with men (MSM), heterosexual men and women, and intravenous drug users (IDU). Additional information on PrEP is available on the U.S. Centers for Disease Control and Prevention (CDC) website.

As of Feb. 9, 2018, Truvada is the only ARV approved by the U.S. Food and Drug Administration for use as PrEP.

PrEP PATIENT ASSISTANCE PROGRAM (PAP)

Gilead Sciences	877-505-6986 ; gileadadvancingacess.com	This program covers the first $400 per month/$4,800 per year of co-payments for Truvada. Automatically renews annually for enrolled patients.

PrEP COST-SHARING ASSISTANCE PROGRAM (CAP)

Gilead Sciences	877-505-6986; gileadadvancingacess.com	This program is open to those up to 500% of the Federal Poverty Level (FPL).

What is **Post-exposure Prophylaxis (PEP)**?

POST-EXPOSURE PROPHYLAXIS (PEP) involves taking antiretroviral (ARV) medicines very soon after a possible exposure to HIV to prevent becoming infected with the virus. PEP should be started as soon as possible to be effective and always within 72 hours (3 days) after a possible exposure to HIV. If your health care provider thinks PEP is right for you, you'll take 3 or more ARV medicines every day for 28 days.

Contact your care provider or local AIDS service organization for help getting started. **Clinicians can call the national PEP hotline at (888) 448-4911** for expert guidance, or go to nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis. Additional information on PEP is available at the HIV Clinical Guidelines Program and on the CDC website.

NOTE: Some of these medications are recommended for PEP only under certain conditions. The most commonly recommended regimen for PEP is Truvada plus Isentress or Tivicay.

PEP COST-SHARING ASSISTANCE PROGRAMS (CAP)

CAPs and PAPs are available for PEP, but each company has different policies for applying and delivery of medications. See detailed instructions for each pharmaceutical company below and on the following page.

DRUGS COVERED	MANUFACTURER AND CONTACT INFORMAITON	ASSISTANCE
Kaletra	**AbbVie** 800-222-6885; kaletra.com	The cost-sharing assistance covers the first $200 per Kaletra prescription.
Reyataz	**Bristol-Myers Squibb** 888-281-8981; bmscustomerconnect.com/bms3assist	The program covers up to $7,500 annually for co-payments, deductibles, and co-insurance in all commercially-insured plans for Reyataz.
Emtriva, Truvada	**Gilead Sciences** 877-505-6986; gileadadvancingaccess.com	**Truvada:** Covers the first $4,800 per year of co-payments. **Emtriva:** Covers the first $300 per month/$3,600 per year of co-payments.
Prezista	**Janssen Therapeutics** 800-652-6227; jjpaf.org	Co-payment assistance starts after the first $5 paid by the consumer, then unlimited co-payment coverage.
Isentress	**Merck and Co.** 800-850-3430; isentress.com	Covers the first $400 per month of co-payments.
Epivir, Lexiva, and **Tivicay**	**ViiV Healthcare** 844-588-3288; viivconnect.com	Covers up to $200 of co-payment on each ViiV prescription, **except Tivicay. For Tivicay**, the program covers the first $400 per-month of co-payments.

PEP PATIENT ASSISTANCE PROGRAMS (PAP)

DRUGS COVERED	MANUFACTURER AND CONTACT INFORMATION	FINANCIAL ELIGIBILITY	ACCESS INFORMATION
Kaletra	**AbbVie** 800-222-6885; kaletra.com	500% FPL	**1.** Complete an application; indicating TRAUMA on the application (this will expedite processing). **2.** Fax to: 732-584-0905. **3.** Call AbbVie, noting that you sent a fax for a TRAUMA case. **4.** AbbVie will send medications to provider. If received by 12:30 PM, will have overnight delivery (about 24 hours). If received after 12:30 PM, will have next day delivery (about 48 hours).
Reyataz	**Bristol-Myers Squibb** 888-281-8981; bmscustomerconnect.com/bms3assist	300–500% FPL	**1.** Complete an application; indicating POST EXPOSURE on the application (this will expedite processing). **2.** Fax to: 1-888-281-8985. **3.** Call Bristol-Meyers Squibb, noting that you sent a fax for a POST EXPOSURE case. **4.** Bristol-Meyers Squibb will send medications to provider or patient. Medications are shipped overnight, except on Fridays.
Emtriva, **Truvada,** and **Viread**	**Gilead Sciences** 877-505-6986; gileadadvancingaccess.com	500% FPL	**1.** Fax a letter of medical necessity to 1-800-226-2056, including: patient's name, therapy needed, date of exposure, provider's signature. **2.** Call Gilead at 1-800-226-2056 and notify them you have a patient who needs PEP Monday–Friday, 9am–8pm EST.). Tell them you faxed a letter of medical necessity. Give them time of fax, number of pages, your fax number. Have the patient's information available: name, address, phone number, date of birth, Social Security number, number of people claimed as dependents, household income, any insurance coverage, provider name, provider address, provider phone number, and parental/guardian signature of consent for any patient under 18 years of age. **3.** Gilead Sciences will give you a voucher number to place on the prescription. The patient may go to the pharmacy to fill the prescription with no out-of-pocket expense.
Prezista	**Janssen Therapeutics** 800-652-6227; jjpaf.org	200% FPL	**1.** Complete an application, selecting PHARMACY CARD on the application. **2.** Fax to: 1-888-526-5168. **3.** Call Janssen Therapeutics 1 to 2 hours after sending the fax to receive pharmacy card number. Write the number on the prescription. The patient may go to the pharmacy to fill the prescription with no out-of-pocket expense.
Isentress	**Merck and Co.** 800-850-3430; merckhelps.com	500% FPL	**1.** Complete an application; indicating PRESCRIBING PEP on the application (this will expedite processing). **2.** Fax to: 1-866-410-1913. **3.** Call Merck, noting that you sent a fax for PRESCRIBING PEP. **4.** Merck will send medications to provider. If received by 12:30 PM (PST), will have overnight delivery (about 24 hours). If received after 12:30 PM (PST), will have next day delivery (about 48 hours).
Epivir, **Lexiva,** **Tivicay**	**ViiV Healthcare** 844-588-3288; viivconnect.com	500% FPL	Call ViiV Healthcare, indicating IMMEDIATE ACCESS. Registered Advocate (i.e., on-going medical provider or case manager) must call on patient's behalf. First-time advocate can register at the same time of call for a patient. Application and all documentation for income and insurance must be faxed in after call and approval. Upon approval, patient can pick up medication that day from any retail pharmacy, with $10 co-pay.

SPECIAL THANKS to NASTAD's Britten Pund and Amanda Bowes. Adapted from **Pharmaceutical Company Patient Assistance Programs and Cost-Sharing Assistance Programs for PrEP and PEP**: bit.ly/1eFG2GU

WHAT IS PREZCOBIX® USED FOR?

PREZCOBIX® is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine always used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX® contains prescription medicines PREZISTA® (darunavir) and TYBOST® (cobicistat). PREZCOBIX® does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses. PREZCOBIX® should be taken once daily with food.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZCOBIX®?

- **PREZCOBIX® may cause liver problems which may be life-threatening. Tell your healthcare provider right away if you have any symptoms such as:**
  - Dark (tea-colored) urine
  - Yellowing of your skin or the whites of your eyes
  - Pale-colored stools (bowel movements)
  - Nausea
  - Vomiting
  - Pain or tenderness on your right side below your ribs
  - Loss of appetite
- **PREZCOBIX® may cause severe or life-threatening skin reactions or rashes. Stop taking PREZCOBIX® and call your healthcare provider right away if you develop any skin changes with symptoms below:**
  - Fever
  - Tiredness
  - Muscle or joint pain
  - Blisters or skin lesions
  - Mouth sores or ulcers
  - Red or inflamed eyes, like "pink eye" (conjunctivitis)
- **PREZCOBIX®, when taken with some other medications, can cause new or worse kidney problems, including kidney failure.**

Who should not take PREZCOBIX®?

- **Do not take PREZCOBIX®** with any of the following medicines: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®), cisapride (Propulsid®), colchicine (Colcrys®, Mitigare®, if you have liver or kidney problems), dronedarone (Multaq®), elbasvir and grazoprevir (Zepatier®), dihydroergotamine (D.H.E.45®, Migranal®), ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®, Migergot®, Wigraine®, Wigrettes®), methylergonovine (Methergine®), lovastatin or a product that contains lovastatin (Altoprev®, Advicor®, Mevacor®), lurasidone (Latuda®), oral midazolam (Versed®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®), pimozide (Orap®), ranolazine (Ranexa®), rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin (Simcor®, Vytorin®, Zocor®), St. John's Wort (*Hypericum perforatum*) or a product that contains St. John's Wort, or triazolam (Halcion®).
- **Serious problems can happen if you take any of these medicines with PREZCOBIX®.**

What should I tell my healthcare provider before taking PREZCOBIX®?

Tell your healthcare provider if you:

- have liver problems, including hepatitis B or hepatitis C, have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition
- are pregnant (if you become pregnant while taking PREZCOBIX®), breastfeeding, or plan to become pregnant or breastfeed. It is unknown if PREZCOBIX® will harm your unborn baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX®. Keep a list of your medicines to show your healthcare provider and pharmacist.
Do not start taking a new medicine without telling your healthcare provider.

What are the possible side effects of PREZCOBIX®?

PREZCOBIX® may cause serious side effects including:

- Diabetes and high blood sugar
- Changes in body fat can happen in people taking HIV-1 medications
- Immune system changes can happen in people who start HIV medications
- Increased bleeding can occur in people with hemophilia who are taking PREZCOBIX®

The most common side effects are:

- Diarrhea
- Nausea
- Rash
- Headache
- Stomach area (abdominal) pain
- Vomiting

These are not all the possible side effects of PREZCOBIX®. Tell your healthcare provider if any side effect bothers you or does not go away. For more information, ask your healthcare provider.

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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.

You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Please read accompanying Important Brief Summary for PREZCOBIX®.

Janssen Therapeutics,
Division of Janssen Products, LP

janssen Infectious Diseases

"DRUG RESISTANCE IS A RISK I TAKE SERIOUSLY."

Missing even a few doses of your HIV treatment can lead to drug resistance which can stop your medication(s) from working.

PREZCOBIX® is a treatment option that has a high barrier to drug resistance to help you keep fighting HIV.

Wisdom inspired by real people

DON'T RISK RESISTANCE

ASK

YOUR DOCTOR ABOUT

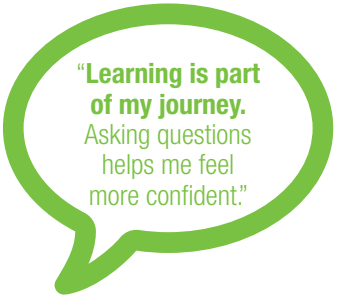
ONCE-DAILY*

PREZCOBIX®
(darunavir 800 mg/ cobicistat 150 mg) tablets

PREZCOBIX.com

*PREZCOBIX® is taken in combination with other HIV medications for the treatment of HIV-1 infection in adults.

PREZCOBIX®
(darunavir 800 mg/
cobicistat 150 mg) tablets



PREZCOBIX® (prez-koe-bix)
(darunavir and cobicistat) tablets

What is PREZCOBIX® used for?
PREZCOBIX® is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX® contains prescription medicines PREZISTA® (darunavir) and TYBOST® (cobicistat). PREZCOBIX® does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

What are the most serious warnings about PREZCOBIX®?
- **PREZCOBIX® may cause liver problems which may be life-threatening. Tell your healthcare provider right away if you have any symptoms such as:**
  - Dark (tea-colored) urine
  - Yellowing of your skin or the whites of your eyes
  - Pale-colored stools (bowel movements)
  - Nausea
  - Vomiting
  - Pain or tenderness on your right side below your ribs
  - Loss of appetite
- **PREZCOBIX® may cause severe or life-threatening skin reactions or rashes. Stop taking PREZCOBIX® and call your healthcare provider right away if you develop any skin changes with symptoms below:**
  - Fever
  - Tiredness
  - Muscle or joint pain
  - Blisters or skin lesions
  - Mouth sores or ulcers
  - Red or inflamed eyes, like "pink eye" (conjunctivitis)
- **PREZCOBIX® when taken with some other medications, can cause new or worse kidney problems, including kidney failure.**

What do I need to tell my healthcare provider?
Tell your healthcare provider if you:
- Have liver problems, including hepatitis B or hepatitis C
- Have kidney problems
- Are allergic to sulfa (sulfonamide)
- Have diabetes
- Have hemophilia
- Have any other medical condition
- Are pregnant or plan to become pregnant. (It is not known if PREZCOBIX® will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking PREZCOBIX®)
- Are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZCOBIX® because it is unknown if PREZCOBIX® can pass into your breast milk. You should not breastfeed if you have HIV-1 because of the risk of passing HIV to your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medications may prevent PREZCOBIX® from working or cause increased side effects. **Do not start taking a new medicine without telling your healthcare provider.**

Who should not take PREZCOBIX®?
- **Do not take PREZCOBIX®** with any of the following medicines: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®), cisapride (Propulsid®), colchicine (Colcrys,® Mitigare,® if you have liver or kidney problems), dronedarone (Multaq®), elbasvir and grazoprevir (Zepatier®), dihydroergotamine (D.H.E.45,® Migranal®), ergotamine tartrate (Cafergot,® Ergomar,® Ergostat,® Medihaler,® Migergot,® Wigraine,® Wigrettes®), methylergonovine (Methergine®), lovastatin or a product that contains lovastatin (Altoprev,® Advicor,® Mevacor®), lurasidone (Latuda®), oral midazolam (Versed®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®), pimozide (Orap®), ranolazine (Ranexa®), rifampin (Rifadin,® Rifater,® Rifamate,® Rimactane®), sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin (Simcor,® Vytorin,® Zocor®), St. John's Wort *(Hypericum perforatum)* or a product that contains St. John's Wort, or triazolam (Halcion®).
- Serious problems can happen if you take any of these medicines with PREZCOBIX®.

What are the possible side effects of PREZCOBIX®?
PREZCOBIX® may cause serious side effects including:
- Diabetes and high blood sugar
- Changes in body fat can happen in people taking HIV-1 medications
- Immune system changes (Immune Reconstitution Syndrome) can happen in people who start HIV-1 medications
- Increased bleeding can occur in people with hemophilia who are taking PREZCOBIX®

The most common side effects are:
- Diarrhea
- Nausea
- Rash
- Headache
- Stomach area (abdominal) pain
- Vomiting

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of PREZCOBIX®. For more information, ask your healthcare provider.

What should I know about this Brief Summary?
This information is not complete. To get more information:
- Talk to your healthcare provider or pharmacist
- Visit ***www.PREZCOBIX.com*** to read over the FDA-approved product labeling and patient information
- Call to report side effects either to the FDA at 1-800-FDA-1088 or to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Keith Marek, Shayvonna Albrecht, LeSherri James, D'Eva Longoria, Bruno Mondello, Michael McNamara, Jimmy Simpson, Angelique Munro, Chad Hendry, Terry Lewis, Samuel Hoehnle, Annette Fields, and Carlos Perez, photographed by John Gress at Slade's Barbershop in Chicago.

FRONT COVER BACKSTORY

The neighborhood barbershop can become a gathering place for a community. That was the concept for the cover of this year's annual HIV Drug Guide as 13 people living with HIV took part in our photo shoot. They shared their experiences and insights:

Keith Marek, 70, diagnosed in 1992: "Stay on your meds. And if you're not on meds, get onto treatment."

Shayvonna Albrecht, 22: "Being HIV-positive is a regular thing for me because I was diagnosed shortly after I was born. I grew up going to a summer camp for positive kids and kids with positive family members. You are not alone. There are so many other people in the same situation, and so many ways to connect with them."

LeSherri James, 35, living with HIV since 2000: "My two kids—I have a four-year-old son and a 14-year-old daughter—are what keep me going every day."

D'Eva Longoria, health educator: "Make sure you have a support system, if you don't have one, look for one—family, friends, a good community-based organization. Surround yourself with people who will keep you motivated! Empower yourself with all the right information and inform the people around you about HIV."

Bruno Mondello, 49, diagnosed in 1987: "Information is key. I get information from my doctor's office, reading publications such as POSITIVELY AWARE, volunteering at HIV organizations, and attending seminars and workshops."

Michael McNamara, 62, diagnosed in 1995: "Testing and treatment are so important. I've lost too many friends who didn't seek the medical attention I did that saved my life.

Jimmy Simpson, 53: "The love of my dog Chip keeps me going. I work hard keeping me appointments, taking my meds, and going to the gym."

Angelique Munro, 47, a transgender woman, entertainer/show director, HIV/AIDS advocate, and motivational speaker: "The state of HIV treatment is the best it has ever been and is improving every day, but the key is to know your status. Get tested regularly and learn how to protect yourself and your partners."

Chad Hendry, 38, living with HIV eight years: "Even if I could, I wouldn't change the journey that has brought me to this point. I love myself today—that wasn't something I ever thought would be possible. I will forever be grateful to have been given another opportunity at life."

Terry Lewis, 65, started treatment in 1994: "Plan on what you're going to do 20 or 30 years from now. With today's treatments, you'll probably live to see old age, and you'll need funds to live on."

Sam Hoehnle, 35, HIV prevention and research worker; living with HIV seven years: "I want to enjoy and experience life to its fullest. My diagnosis was a wake-up call—enjoy life more fully."

Annette Fields, 49, HIV-positive 24 years: "I was in a monogamous relationship with a man for about two years. During sex, we used condoms about 85% of the time. In November 1993 I found out he had died of complications from AIDS. The next month, I was diagnosed with HIV. I'm on a one-pill-a-day drug regimen and have a doctor I trust. I love that we can discuss what I need to do to stay healthy."

Carlos Perez, 58, diagnosed in 1984: "Get onto treatment, and stay on treatment. If I can do it and become undetectable, you can do it."

—COMPILED BY RICK GUASCO

TO READ more complete responses, go to positivelyaware.com.
SPECIAL THANKS to Greg Slade and Slade's Barbershop, sladesbarbershop.com.

SUBARU Loves to Care

Dining Out FOR LIFE
Dine Out, Fight AIDS

THURSDAY, APRIL 26, 2018*

Dining Out For Life, hosted by Subaru, is a restaurant-based event with a truly scrumptious call to action.

Dine out and a generous portion of your check will help fund HIV prevention, education, testing, counseling, care, and other essential services in YOUR city. Find participating restaurants and info at diningoutforlife.com.

*Check diningoutforlife.com for your city's date.