POSITIVELY AWARE

HIV TREATMENT, PREVENTION, AND SUPPORT FROM TPAN
JULY+AUGUST 2017

HEPATITIS TREATMENT
WHICH ONE IS RIGHT FOR ME?

HEPATITIS B
WHAT YOU SHOULD KNOW

PLUS
10 WAYS TO LOVE YOUR LIVER

CAN'T STOP THE MUSIC:
Sherri Lewis,
LONG-TERM HIV SURVIVOR, CURED OF HEPATITIS C

THE 5TH ANNUAL
HEPATITIS B&C DRUG GUIDE

THERE'S SOMETHING EVERYONE CAN DO.

Here are two resources that can help.

STOP THE VIRUS.

Watch videos, find a testing location,
and reset what you know about HIV.

HelpStopTheVirus.com

YouTube.com/HelpStopTheVirus

HIV ANSWERS

Get the answers you need,
privately, on your phone.

HIVanswers.com/app

Ask a healthcare provider about all the ways you can help prevent HIV.

GILEAD

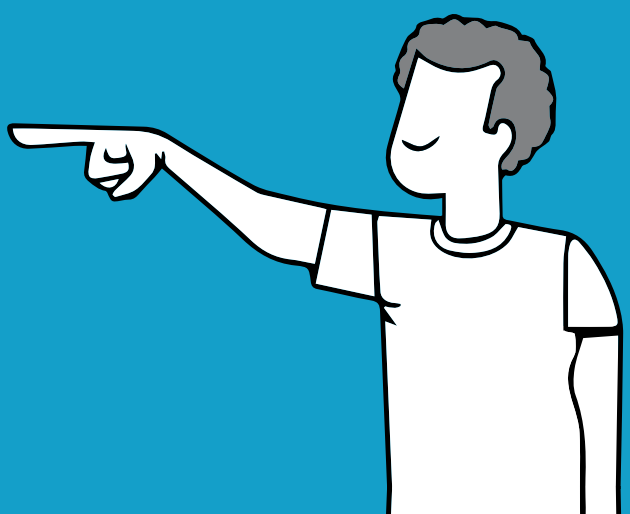
SHOULD HIV PREVENTION MATTER TO ME?

I AM LIVING WITH HIV.

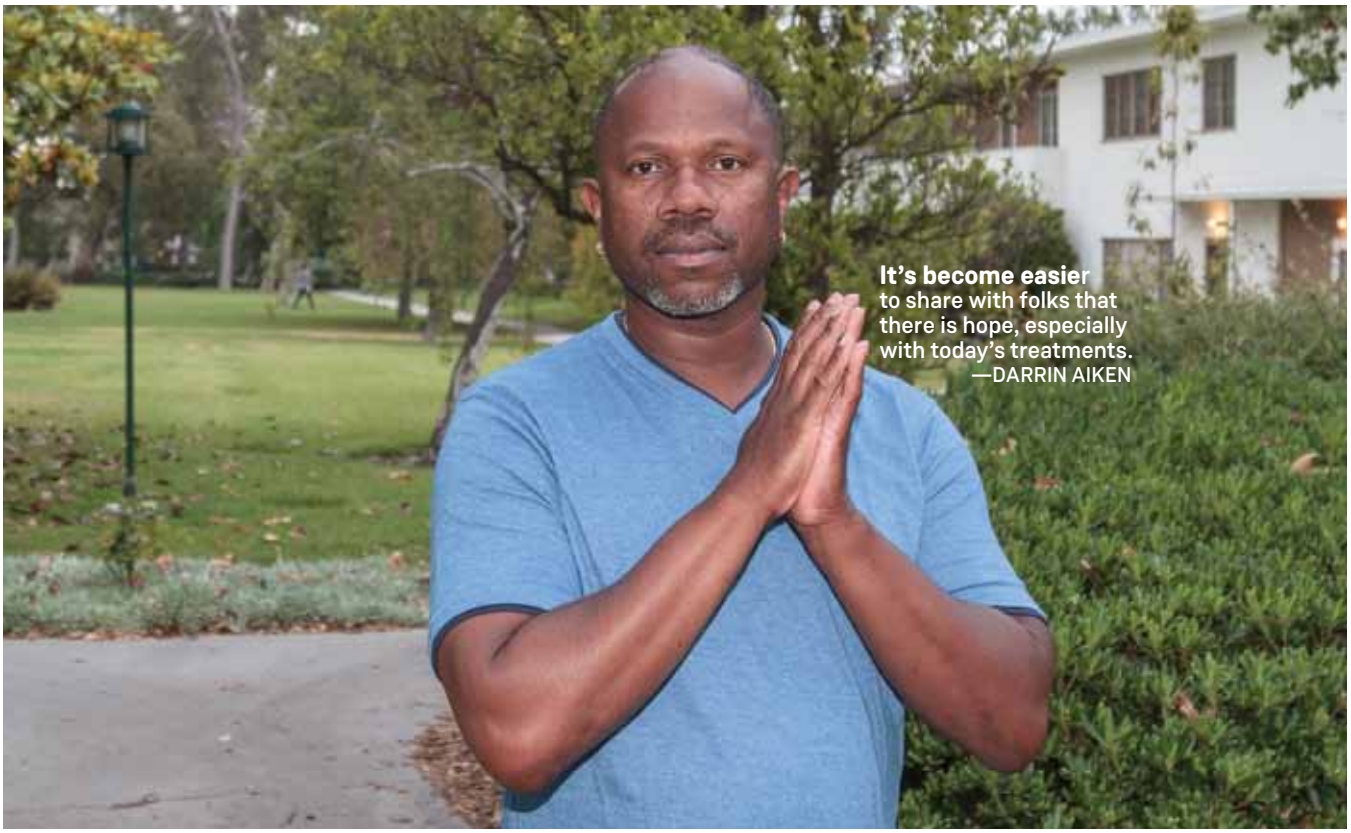
I AM HIV NEGATIVE.

YES!

See how we can all help stop the virus in our bodies and communities.



STOP THE VIRUS.



A long-term HIV survivor, Darrin Aiken was also in recovery when he learned in early 1996 that he had hepatitis C. Aiken shared some of his thoughts about his hep C experience in an email exchange.

When and how did you learn you had hepatitis C? Were you surprised?
I started living a new life in recovery in November 1994. As part of that, I began working for a graphics company that provided health insurance, and I was starting to take care of myself. It was late 1995 or early 1996 when my doctor told me I had hepatitis C. I suppose I was somewhat surprised, but didn't think too much about it at the time.

How did you feel when you learned you had hepatitis C?
I felt good about myself because I had some information about my health that was vital to me moving forward. God, the Creator, Energies, a Higher Power—whatever folks want to call it—is loving and wants the best thing for you. It's great to have that in your life. I call mine God, and I have connected to him daily for many years; that's how I make it through the difficult times. Living a life of recovery, I have support from many people. My doctor suggested that we observe its progress, as my HCV viral load was low at that time. I felt empowered by the information I had to make the right decisions about living with hep C and when to begin treatment.

Has having had hepatitis C and getting treatment changed anything for you?
I have changed. I am more aware of what I come in contact with, and more conscious of what can happen. I think and observe everything around me. I am more aware when it comes to others' blood and bodily fluids. I've been able to share my experience with my family, friends, and with the clients where I work so that they can protect themselves, and protect others from exposure. It's become easier to share with folks that there is hope, especially with today's treatments.

Aiken works for APLA Health in Los Angeles, where he is the program coordinator for the African American Gay Men's Health Initiative. His work involves conversations with black gay men about HIV/STI prevention. Discussions often include such topics as homophobia and stigma, and how these can make a person vulnerable to infection.

—RICK GUASCO
PHOTOS BY LOUIS CARR

READ ABOUT SHERRI LEWIS' OWN ROAD TO RECOVERY FROM HEPATITIS C: **PAGE 11**

ON THE FOLDOUT COVER
SHERRI LEWIS AND DARRIN AIKEN PHOTOGRAPHED BY LOUIS CARR

THE 5TH ANNUAL HEPATITS B & C DRUG GUIDE IS A COLLABORATION OF POSITIVELY AWARE AND PROJECT INFORM.

PROJECT INFORM

POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

JULY+AUGUST 2017

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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.

IN EVERY ISSUE

FEATURES

THE FIFTH ANNUAL HEPATITIS B & C DRUG GUIDE

WRITTEN AND COMPILED BY ANDREW REYNOLDS, PROJECT INFORM

THE 2017 ANNUAL HEPATITIS B & C DRUG CHART

CENTERSPREAD PULL OUT SPONSORED BY

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Newly diagnosed at 49

Well, May 18, 2017 is one date I won't forget. After sitting in my general practitioner's office for an unrelated issue for four hours and having to tell them I may be HIV-positive, I came home exhausted. My phone rings; it's the local health department, where I had the preliminary prick test (positive) and the follow-up "suck me dry of blood" test. The hits just keep coming. The first test didn't faze me (I was like "I got this!), but this one has me with one foot in the grave ("Game Over!"). I managed to survive my teenage years in the '80s during the infancy of HIV/AIDS unscathed, and now at 49 I'm reeling from this diagnosis and the hoops I now have to jump through to get treatment. I'm not sure I'm up for this fight. I got in the tub earlier and unfortunately I'm too big or the tub was too small to drown myself. Wednesday it was back to the doctor to hear my treatment options. To say I'm down is an understatement, but I'm not out...hopefully. Thanks for the letters of encouragement in TPAN, it's been one hell of a day! Tomorrow the sun shall rise, and so shall I.

—**Jon,** VIA EMAIL

EDITOR JEFF BERRY RESPONDS: Dear Jon, Thank you for your email and for reaching out. Hearing the news "you're positive" is difficult at any age; I imagine it has to be especially hard after having survived the worst of the plague years. But you're not alone, I have friends and people I know who also tested positive later on in life after having made it through the '80s and '90s. Some feel guilt and shame, and there is often a belief by others that they should have known better.

But HIV and AIDS are not a punishment, or for those who are guilty of something. It's a virus, plain and simple. I'm glad to hear you are considering starting treatment, and have a positive outlook (no pun intended).

Sharing people's stories of how they came to terms with living with HIV is what we do, and I've come to learn that it can be the most powerful instrument of change for many who are struggling, just like you. Thank you for sharing your story, and I'm glad we could be there to offer encouragement during this difficult time. Please don't hesitate to reach out if you have any questions, or just need someone to talk to. Best regards.

JON RESPONDS: Dear Jeff, Thanks for the quick response. I will get on the mailing list, but only after my family has been informed and gets accustomed to my diagnosis. I live in the South, things are different here. ..but attitudes are changing—slowly. I did pick your publication up at my doctor's office yesterday and it helped to read the stories of others because I seriously thought about ...well, you know. I know this next week will be pure hell with appointments and lots of stress, plus thinking of my family and how to tell them about my diagnosis. Thanks for everything, Jeff. TPAN really helped me through yesterday. I'm down, but I'm not out.

YOU ARE NOT ALONE

Thank you all so much. I really do enjoy reading POSITIVELY AWARE. It helps me out and makes me feel like I'm not alone. I love it.

—**KELVIN STOKELING**
TRION, GEORGIA

COVER TO COVER

We are all truly grateful for your efforts in producing POSITIVELY AWARE, but especially for the special drug guides for HIV and hepatitis C. By reading from cover to cover, we all are staying up to date with the latest information concerning HIV and what possibilities lie ahead for the future with new treatments and potential cure. We look forward to receiving POSITIVELY AWARE.

—**STEVE PALERMO, RN, MBA, CPHQ,**
FLORIDA DEPARTMENT OF HEALTH-HILLSBOROUGH
TAMPA, FLORIDA

HEPATITIS C

I have written about being a long-term survivor. What I didn't talk about was my cure from hepatitis C (genotype 1-A). I took the relatively new drug called Harvoni. The side effects were diabetes and being flushed with red. I looked as if I spent the previous day in the sun without solar block. I went to the ER and was given some drugs to combat the redness. Ever since then I have had dermatitis. I am glad there are new drugs available for hep C. Just taking a drug as if it is safe is not a good idea with any drug one takes. I am glad to finally be cured of hepatitis C, but I know that I can catch it again.

—**BOB BROWN**
FORMER TPAN VOLUNTEER

EDITOR'S NOTE: Bob may also have received ribavirin, which is associated with rash.

JOIN THE CONVERSATION

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GUEST EDITOR'S NOTE
ANDREW REYNOLDS

The promise of eliminating viral hepatitis

Welcome to the 5th Annual POSITIVELY AWARE Hepatitis B and C Drug Guide. In last year's Guest Editor's Note, I wrote "we stand at the beginning of the end of hepatitis C" and "the only question is how fast we can end it?" Fast forward a year and we may have our answer: 2030.

Before looking ahead, it's worth looking back to see how far we've already come. For the longest time, people with hepatitis C (HCV) only had interferon and ribavirin as their treatment option. This treatment was long, miserable, and not very effective. Beginning in 2011, we started to see new, more effective (but still long and difficult) treatments for HCV. Then, beginning in 2013 the floodgates opened and several new HCV drugs and drug combinations came onto the scene each year, potentially curing 90–100% of people living with HCV in 12 weeks with mild side effects. Indeed, this year we will see two more drug combinations made available, creating a scenario where we can treat and cure just about everyone.

Progress has been much slower on the hepatitis B side. Unlike HCV, we have not found a cure for it yet. There are medications that one can take to reduce liver damage and long-term risks. Also unlike HCV, we *do* have a vaccine to prevent HBV. And while there has been significant progress in vaccinating against HBV, there are still groups of people we are missing. We can, and must, do better.

This year the National Academies of Sciences, Engineering and Medicine released a report entitled "A National Strategy for the Elimination of Hepatitis B and C." In it, they make a series of recommendations that, if followed, serve as a blueprint to prevent new infections, cure existing HCV infections and treat and manage hepatitis B until a cure is discovered.

The time to act on this is now! The United States is in the midst of an opioid crisis, leading to an increase in HCV and HBV infections among people who inject drugs. We have limited access to harm reduction services such as syringe access and medication-assisted therapy (methadone and buprenorphine), two interventions proven to reduce new infections. The cure for HCV is at hand, but the insurance restrictions and high cost of treatment serve as significant barriers for most people.

And yet, we appear to be moving backwards. The repeal of the Affordable Care Act will leave millions of people, including people with HCV and HBV, without health insurance and reduce access to drug treatment. Access to safer injecting equipment and other harm reduction interventions remains out of reach for most. Indeed, the current presidential administration has indicated that they will ramp up the failed war on drugs, a policy that has driven the HCV epidemic, led to significant suffering among people who use drugs, and decimated communities of African American and Latino men and women thrown into prisons, due to increased policing, minor drug offenses and racist sentencing laws.

We know what works, and we know what doesn't. Restricting access to healthcare and drug treatment, limiting prevention measures, and trying to incarcerate our way out of our drug problem are not solutions to HBV and HCV prevention, care, and treatment.

POSITIVELY AWARE and Project Inform are committed to ending viral hepatitis. In addition to this expanded "Hepatitis B and C Drug Guide" and the inclusion of HBV, we will continue to publish new articles online and in print. We will report news and updates on innovative treatments and prevention, as well as policies that can improve the health of people living with viral hepatitis. That is our promise to you.

Once again, I thank Jeff Berry and Enid Vázquez for their kind and gentle editorial guidance. I tend to write a lot, and were it not for them there's no telling how large this issue would be. Rick Guasco did another fabulous job designing the issue. With their support and effort, we've made this hepatitis drug guide more comprehensive, easier to read, and, I hope, more useful to people living with, or at risk for, HBV and HCV.

And finally: Let's see if we can meet the goal of eliminating viral hepatitis before 2030. We have the tools to do it already. What we need is the will to put those tools into action. Patients are ready. Medical providers are ready. Advocacy and policy experts are ready.

Let's do this!

We know what works, and we know what doesn't. Restricting access to healthcare and drug treatment, limiting prevention measures, and trying to incarcerate our way out a drug problem are not solutions to HBV and HCV prevention, care, and treatment.

BRIEFLY

ENID VÁZQUEZ @ENIDVAZQUEZPA

Generic Truvada approved for treatment and PrEP

On June 9, the FDA in a surprise move approved a generic version of the commonly-taken HIV med Truvada, a fixed-dose combination of emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF). FTC/TDF is most commonly used as part of the single-tablet regimens (STRs) Atripla, Stribild, Complera, Genvoya, and Odefsey. The approval included an indication for PrEP (HIV prevention) as well as HIV treatment.

When drugs go generic, using them may lead to more cumbersome regimens. For instance, some medical systems may switch patients off an STR to put them on multiple pills.

Activists scrambled to understand the ramifications of the announcement the same day, and called for Teva Pharmaceuticals USA, who will produce the new generic, to set up a patient assistance program, as is currently available from Gilead Sciences for its Truvada. This is especially important because generics do not necessarily save a lot of money over the original formulation. The cost savings may be a mere 10 to 15%. Truvada has a monthly AWP (average wholesale price) of $1,760, and some insurance plans require participants to pay a percentage of the price of the drug. In 2013 Gilead and Teva settled a patent lawsuit over the licensing of generic Viread (TDF), which will become available in December 2017.

Truvada also has a new version from Gilead that is kinder to the kidneys, Descovy (emtricitabine/tenofovir alafenamide, or FTC/TAF), that was approved by the FDA last year. Descovy has yet to receive the go-ahead for use in PrEP. Activists also raised the issue that it will be important for Gilead to keep in place its co-pay and patient assistance programs for Truvada even after a generic becomes available, especially for those on PrEP. Gilead issued a statement that a "generic version of Truvada will not be immediately available." The patent for tenofovir disoproxil fumarate (TDF), a component of Truvada, expires July 2017 and has pediatric exclusivity until January 2018. The patent for emtricitabine, a component of Truvada, expires in 2021.

"Gilead believes Truvada for PrEP is an important HIV prevention tool and we remain committed to helping ensure access to our medications for people both at risk of or living with HIV."

The question remains as to when a generic FTC/TDF will come to market, and whether Teva will have exclusivity in making it. Activist Peter Staley told POSITIVELY AWARE the day after the announcement that, "Yesterday was horribly frustrating, and an emotional rollercoaster. We were misled by the FDA, and stonewalled by Teva and Gilead. AIDS and PrEP activists deserve better."

Isentress HD, a new once-daily formulation, now available

In May, the FDA approved the new once-daily formulation of Isentress, called Isentress HD. **Isentress HD is taken as two 600 mg tablets once daily, with or without food**, in adults and pediatric patients weighing at least 88 pounds (40 kg). The original Isentress is taken twice daily. Raltegravir, which makes up both medications, is an integrase strand transfer inhibitor (INSTI). INSTIs are king of the hill in HIV therapy today. U.S. treatment guidelines list all the INSTI drugs on the market as "preferred" medications for initial HIV therapy (along with one protease inhibitor medication, Prezista). Isentress HD is expected to join that list. Approval was based on the results of the ONCEMRK study.

Coming soon: A new single-tablet regimen

On June 12, Gilead Sciences submitted a New Drug Application (NDA) for the approval of a single-tablet regimen containing **bictegravir (BIC), emtricitabine (FTC), and tenofovir alafenamide (TAF)**. Bictegravir is a new INSTI (integrase strand transfer inhibitor) that does not require boosting.

First-of-its-kind HIV therapy

In May, TaiMed Biologics applied to the FDA for a biologics license application (BLA) for ibalizumab (IBA), an HIV treatment given by infusion once every two weeks.

IBA is the first HIV medication of its kind, a biologic. It would also be the first long-acting drug in HIV. A biologic is a treatment or vaccine that was made in a living cell, instead of made from a chemical process putting molecules together outside of a living cell (which are most drugs, including all of the current oral HIV drugs). That doesn't make IBA necessarily better, but different.

The important difference is that IBA works against multidrug-resistant HIV. The infusion takes about 15 minutes. IBA is still expected to be given with at least one new medication to which the patient's virus is not resistant.

"While some people can suppress their viral loads with currently-approved treatments, there is an urgent need for new options among those with multidrug resistance," said Christian

ISENTRESS HD COURTESY OF MERCK GENERIC TRUVADA: IPHOTO/GUASCO

AIDSOURCE NOW IN SPANISH The National Library of Medicine's AIDSource website is now available in Spanish. According to the government's AIDSInfo website, "The mission of AIDSource is to serve as **a reliable source for easy access to HIV/AIDS-related information** from federal and non-federal resources." AIDSource includes a widget to find testing sites. Go to aids.nlm.nih.gov/espanol.

Marsolais, PhD, Senior Vice President and Chief Medical Officer for Theratechnologies, a partner with TaiMed, in a press release.

Because of that urgent need, **IBA is already available through expanded access**: go to ibalizumab-eap.com. For more on ibalizumab, see "Back to the Future" in the January+February issue.

New Norvir powder safer for pediatrics

On June 7, the FDA approved a new Norvir (ritonavir) oral powder formulation, a 100 mg packet. According to the FDA, "**Norvir oral powder dosage form is free of alcohol and propylene glycol**, both of which are present in the currently marketed Norvir oral solution, making it safer for use in the pediatric population." Information on the new powder formulation was added to the drug labels of the Norvir tablet and oral solution. Note: The taste of Norvir liquid is infamously bad. POSITIVELY AWARE has not heard from anyone about the taste of the new powder formulation.

Maintenance HIV drug on the way

There's a new HIV drug on the way, and it comes with a twist.

For the first time a new HIV drug will be used for maintaining undetectable viral load in people who've already achieved that status. Previously, HIV medications were brought to market to help people get to undetectable HIV viral load in the first place.

In the past several years, new HIV drugs were either single-tablet regimens or meant to be used in a combination consisting of two or more pills.

The new drug instead consists of two quite powerful medications in one pill, for use only in people who have already achieved undetectable viral load and are switching to the new med for what's called "maintenance therapy."

On June 1, ViiV Healthcare submitted a New Drug Application to the FDA for **a pill that combines ViiV's dolutegravir (brand name Tivicay, found in Triumeq) with rilpivirine (brand name Edurant, found in Complera and Odefsey) from Janssen Sciences**. Dolutegravir/rilpivirine must be taken with a meal (because of the rilpivirine).

The application rests on the results of the SWORD studies of more than 1,000 participants who successfully maintained undetectable viral loads after switching to dolutegravir/rilpivirine from a three- or four-medication regimen. Read more about the SWORD studies in the May+June issue.

Generic Combivir approved

Although no longer recommended by treatment guidelines, the generic version of Combivir—zidovudine plus lamivudine—was **approved by the FDA in late March**. Zidovudine is also known as AZT. Generics may be used to save money, however, they can come with the inconvenience of more pills as well as toxicity that's no longer acceptable.

Pediatric HIV guidelines updated

In April, U.S. treatment guidelines for pediatric HIV received many updates. Some of them are listed below. Go to aidsinfo.nih.gov for more information, including the section "What's New in the Guidelines".

Preferred regimens have been updated. Of note, Tivicay and Descovy were added as part of a preferred regimen. Descovy was added as a preferred NRTI.

Downgraded from "preferred" to "alternative" initial regimen were Kaletra and Sustiva (each taken with two NRTIs) for children ages 3 to 12. For children ages 6 to 12, Isentress and Prezista (twice daily boosted) were also lowered from preferred to alternative initial regimens. (They also are given with two NRTIs.)

Among other changes:

- Recommendations for testing infants for HIV were clarified and an illustrated algorithm added.
- Age and weight limitations were added to treatment recommendations.
- Examples of new options for treatment have been added to the regimen modification section.
- Following FDA approval for pediatric use in children 2 years of age or older weighing at least 22 pounds (10 kg), Selzentry new dosages and pediatric dosing have been added.
- An investigational dose of Isentress for neonates of at least 37 weeks of gestation, weighing at least 2 kg, was added.

Updated HIV guidelines include hepatitis C drug interactions

In March, U.S. **HIV treatment guidelines were updated with drug interactions with hepatitis C medications** and side effect information. Go to aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/358/drug-drug-interactions and aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/359/adverse-drug-reactions.

Stribild and Tybost labels updated on corticosteroids

In May, the FDA updated corticosteroid information on the Stribild and Tybost drug labels. For both medications, **the FDA added beclomethasone and prednisolone as drugs that do not have clinically significant interactions with Stribild or Tybost**. Otherwise, Stribild and Tybost can either not be taken with corticosteroids, or dose adjustments are needed.

Treatment guidelines updated on TB

U.S. HIV treatment guidelines were updated in May regarding tuberculosis (TB). **Information was added on new diagnostic tests and changes to preferred and alternative treatment** of commonly used TB drugs, among other updates. Go to aidsinfo.nih.gov.

NASTAD issues new resources

NASTAD, a national nonprofit organization serving

BRIEFLY

Fred Says enjoy Dogs & Daddies
Do you like dogs? Do you like daddies? The charity Fred Says now allows you to enjoy both at once! The 80-page, full-color photography book *Dogs & Daddies* by photographer inkedKenny features portraits of men with their dogs. The book's $60 cost goes toward the care and support of youth living with HIV. The book is available at **fredsays.org**. P.S. The other daddies wear way less clothes.

city and state health department staffs, has created documents aimed at **educating Congress members on the importance of Medicaid and ACA insurance** protections for people living with and at risk for HIV and hepatitis. For copies or questions, contact Amy Killelea, akillelea@nastad.org.

AIDS.gov becomes HIV.gov

On June 5, the U.S. Department of Health and Human Services officially changed the name of AIDS.gov to HIV.gov. "The announcement coincides with the 36th anniversary of the Centers for Disease Control and Prevention's first report of the initial cases of what would become known as AIDS," the agency reported in a press release. "**The name change reflects major scientific advances** that have transformed an almost universally fatal disease to a condition that, if diagnosed and treated early and continuously, can be controlled and prevented from progressing to AIDS. In fact, there are more people living with HIV in the United States now than people living with AIDS." Read the press release at hhs.gov/about/news/2017/06/05/more-name-change-aidsgov-becomes-hivgov.html.

#ShowYourFace for World Hepatitis Day

July 28 marks World Hepatitis Day, providing an opportunity to raise awareness, particularly among those who may not be aware they have the liver disease. According to the World Hepatitis Alliance, organizers of the campaign, hepatitis kills 1.34 million people a year globally. Hepatitis B (HBV) and C (HCV) cause a combined 80 percent of the world's liver cancer cases. **It's estimated that 90 percent of people living with HBV and 80 of those with HCV are aware they have it.**

"Eliminate Hepatitis" is the theme this year, highlighted by #ShowYourFace, a social media campaign inviting people to join by submitting their picture. For more information about World Hepatitis Day, go to worldhepatitisday.org.

New link found between HIV and emphysema

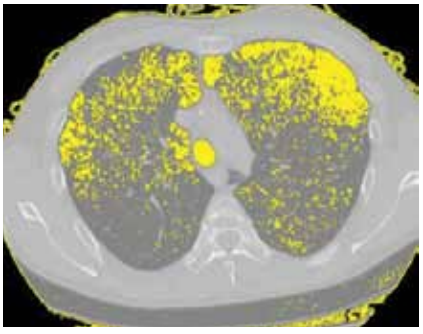
Researchers at Cornell University have discovered a mechanism which HIV uses to attack the lungs, which may help explain why the chronic lung disease emphysema is seen in up to 30 percent of people who are on ART.

Published May 9 in *Cell Reports*, the Cornell study found that HIV binds to stem cells (also known as basal cells), which transform into other types of cells that line airways of lungs. **HIV reprograms the basal cells so that they release enzymes known as proteases, which can destroy lung tissue** and tear holes in the walls of air sacs.

"This research is important because although antiretroviral agents have turned HIV into a chronic, rather than deadly, disease, the viral reservoirs that remain in the lungs and other tissue continue to cause serious side effects," said senior author Dr. Ronald Crystal, chairman of Cornell's department of genetic medicine, and a pulmonologist at New York-Presbyterian/Weill Cornell Medical Center. "Now that we have more information about how the HIV virus might cause emphysema, we can learn more about this potential enzyme target and work toward developing a therapy to prevent this lung damage from happening."

READ THE ORIGINAL ARTICLE: cell.com/cell-reports/pdf/S2211-1247(17)30520-X.pdf.

—RICK GUASCO



A CT scan of a section of lungs from an HIV-positive man; the highlighted portions show areas of emphysema.

DOGS & DADDIES: INKEDKENNY CT SCAN: DR. RONALD CRYSTAL, WEILL CORNELL MEDICINE

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CAN'T STOP THE MUSIC

Sherri Lewis and her long road to hepatitis C recovery

BY **MICHELLE SIMEK**

Sherri Lewis doesn't enter a room—she explodes into it, like a bomb of positive energy. A brown-eyed brunette, she attracts people to her—everyone wants to be her friend. Petite yet powerful and looking decades younger than her 63 years, Sherri is HIV-positive, has been clean and sober since 1987, and was cured of hep C in 2015. "I wasn't giving up, I was like a pit bull...you have to fight for it, they're not going to just give it to you, those bastards," says Sherri about her battle for hep C treatment.

Born and raised in New Jersey (and the accent remains), she now calls Los Angeles home. She was brought up in a dysfunctional Jewish family. Her father was "the husband who didn't come home" and her mother spent her time "obsessing and chasing him" and yelling at Sherri. Incest was also part of the home life. "My family had no physical boundaries...and was touchy-feely in all the wrong places." Even young Sherri knew that this was not appropriate. "I don't think this is right, what's going on here." As a teenager, Sherri was molested by an uncle, but no one talked about it. She coped with the pain of being abused by using drugs, both street-based as well as her mother's diet pills.

However, Sherri's addiction story may have started when she was a young girl. She was given a tincture of opium (yes, this used to be a thing) for her anxiety caused by dealing with her family. "My mother left me alone with it and said 'don't forget to take your medicine.'" She made an innocent mistake and, instead of taking 10 drops from the dropper, she took 10 droppers full. She got very high ("It was a mistake but I liked it") and when her mother came home she was furious instead of compassionate. She called the doctor, who told her to walk Sherri around and make her drink black coffee; otherwise she would have to get her stomach pumped.

By her teenage years, Sherri was using many different kinds of drugs: pot, speed, quaaludes, and her mother's diet pills. She didn't really have a drug of choice so took anything that was offered her. In 1971, at 17 years old, she shot up heroin and used a "stupid old junkie needle" that someone handed her. Soon

PHOTO: LOUIS CARR

When Sherri got the news that she was cured from hep C, she didn't believe it. "I kept testing

after, she became very sick. She felt ill and exhausted and did not have "that teenage energy." She also experienced abdominal pain, jaundice, and excessive burping that tasted like sulfur. When she went to see the doctor, he told her that she had non-A/non-B hepatitis (there were no tests for hep C at this time) and that "you could die from this." She was instructed to stay away from alcohol and to be on bed rest for a year. Her reaction? "This was the worst thing to tell a troubled teen. I have to stay in bed and can't drink? Shit!" The reaction from her parents? Nonexistent. They were "preoccupied with themselves and their marriage." But Sherri did follow doctors' orders. She rested and stayed away from alcohol and other drugs for a year. Then, she returned to her "wild child life" and "went on my merry hell-driven way." But no matter how high or drunk she was, she never quite forgot about the hepatitis. Her liver was always in the back of her mind.

Sherri followed her musical dreams and by 1981 was fronting a pop music band in New York called Get Wet, with "Sherri Beachfront" as her stage name. Fueled by drugs, booze, and a lot of drive, Get Wet signed with Boardwalk Records and their single "Just So Lonely" hit the Billboard charts. But Boardwalk Records went belly up a few years later and the alcohol and other drugs once began to take their toll. Sherri ended up living in a sketchy New York apartment, with bottles, syringes, and vomit as her roommates. To quote VH1, "And then...the music stopped..."

In 1985, after a couple of attempts at rehab, Sherri got clean and sober with help from Narcotics Anonymous and their 12-step program. She got a sponsor and "one day at a time" became one of her many mantras. Once told by a therapist that her addiction was "situational" due to her family history and the incest, Sherri slightly scoffs at this. "It doesn't matter if it was situational, once you are a pickle, you never get to be a cucumber again." Once sober and stable, Sherri did begin singing again and booked some dates at hot clubs and almost got a role in an Off-Broadway show.

By 1987, she was newly engaged and ready to become a wife and mother. "I was always meant to be a mother." She went to the doctor to "get tested for everything." She wanted a "clean bill of health for her fiancée." Much to her shock, her HIV test came back positive—on her 33rd birthday no less. "No one forgets their diagnosis date; that one was particularly telling. Really? On my birthday? Gee whizz, thanks...it was clear life or death. I was born on this day, what are you trying to tell me, God? I'm kind of like Tevye (a

PHOTO: LOUIS CARR

negative, negative, negative, but I still didn't believe it."

character from *Fiddler on the Roof*), I'm always talking to God."

With her T-cells around 700 and no symptoms of HIV, Sherri refused to go on AZT, the only medication at the time. She "wanted to wait until there was something better." While she was waiting for those better medications, she changed her diet to macrobiotic (fish, grains, legumes) and cut out dairy and wheat (Sherri was gluten- and dairy-free before anyone else was, which is a testament to her hipness). She started an HIV regimen containing a protease inhibitor in 1997. By that point her T-cells had dropped to 225 and she had extreme fatigue and a rash, but she quickly bounced back once she started treatment.

When the hep C antibody test was approved by the FDA in 1992, Sherri was tested shortly thereafter and was officially diagnosed with HCV. She had always mentioned her non-A/non-B diagnosis to her healthcare providers, so this particular diagnosis was not a surprise. And in comparison to testing positive for HIV, "It was so secondary next to the death sentence and dark cloud—the humungous HIV burden. I was already working and counseling in the field...and was seeing people dying. I was trying to sell hope." It's not like she wasn't concerned, but HIV was more of a priority. Besides, Sherri had been clean and sober and macrobiotic since 1985 and living a healthy life, so she was certain that her liver was healthy, despite the virus.

She didn't want to go on interferon due to the horrible side effects she saw her friends in the injection drug community experiencing (extreme fatigue, fever, chills, major depression) so she decided to do what she did with HIV and wait for something better to come along. She also decided not to get a liver biopsy. "I kept hearing that the tissue was the issue" but she felt fine and closely monitored her hep C viral load (which was never high, which is unusual) and liver enzymes. In 2015, her HIV doctor, Dr. Judy Currier at the UCLA CARE Center, mentioned Harvoni to her and it sounded exactly like what Sherri had been waiting for.

But getting Harvoni turned out to be harder than expected—much harder. Once Sherri "learned how expensive it was, I looked for a clinical trial." She went to the offices of Dr. Peter Ruane in Los Angeles. Dr. Ruane was running an 8-week clinical trial of Harvoni. At his offices, she received a FibroScan, which checks the levels of liver fibrosis. Much to Sherri's astonishment, her liver score was F3. She had liver fibrosis. "The doctor came back to me with the sullen face and I was as shocked as I was when I was told I was HIV-positive. I think I'm fine and that I'm getting an 'A' and you're telling me that my liver is not good?" Due to her F-score, she could not join the study. Tests also revealed she had kidney damage, most likely due to taking Truvada for many years, she was told. Stunned and disappointed that she could not join the clinical trial, "I ran back to my doctor with my tail between my legs."

Due to the kidney damage, Sherri had to switch to Triumeq. Once the switch was official and her HIV labs stabilized, Dr. Currier and Sherri had a major fight ahead of them. Even with an F3 score, she was denied treatment. The rejection letters from the insurance company kept coming, which was particularly galling since Sherri pays a high premium for private health insurance. Dr. Currier finally wrote an appeal, which listed Sherri's kidney problems as yet another reason to approve the Harvoni prescription. "Dr. Currier had to play the kidney card...and just give me the damn drug." Finally, Sherri was able to get the medication (it was not yet on California's ADAP program).

"When it was finally approved, I felt like it should arrive in a Wells Fargo stagecoach with armed guard...like they were smuggling drugs or delivering platinum." Before taking her first dose, Sherri paused and looked at the big pill and thought, "I can't believe this...it's almost unbelievable that you're gonna be cured after 40 years." She took her first Harvoni pill along with her Triumeq and started her journey towards the cure. At three weeks, Sherri's hep C viral load was already undetectable but she did have side effects, including exhaustion and some headaches. The extreme fatigue forced her to take a hiatus from her beloved hot yoga classes and lasted six months post-treatment.

When Sherri got the news that she was cured from hep C, she didn't believe it. "I kept testing negative, negative, negative, but I still didn't believe it." In 2017, two years later, she finally believes it. "It all worked. It's not easy. It wasn't simple. But when it's over you look back and it wasn't all that bad either. Now you have a full life and you don't have to think about that liver 24/7."

Not thinking constantly about her liver has given Sherri time to focus on her creative side. A popular blogger on TheBody.com and a writer for *A&U* magazine, Sherri enjoys expressing herself through the written word. But music is still her primary passion. "Sherri Beachfront has come back. She was like in a trunk, she was in a coffin, but now she's unearthed. She sounds the same, but don't do a close-up!" Sherri is singing again and her new single, "Turn Up the Radio," is now available on iTunes and CDBaby. And more music from Sherri Beachfront to follow!

Says Sherri, "What it took to stay here, I would do it again. My life is richer from the journey." PA

Michelle Simek works at an HIV/AIDS research and treatment clinic in Los Angeles, California. She is also an actor, freelance writer, and literary editor. In her spare time, she knits, goes to punk rock shows, and pets her cat, Baxter.

HOW TO USE THIS GUIDE

THE POSITIVELY AWARE/PROJECT INFORM Hepatitis Drug Guide includes medications for the treatment of hepatitis B (HBV) and hepatitis C (HCV) that are FDA approved, expected to be approved this year, or are likely to be approved through June 2018. The guide also lists "off-label" recommendations (that is, treatment options that may not yet be FDA approved, but which are acceptable according to medical providers and other experts). The information provided on the FDA-approved drugs comes from the package labels, as well as other sources such as the AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C (HCV Guidance), AASLD Hepatitis B Guidance, conference presentations, and medical journals. For the yet-to-be-FDA-approved drugs, the information comes from conference presentations and scientific/medical journals.

Hepatitis C treatment comprises two or more medications—all pills—taken together. Some treatments are a fixed-dose combination (FDC) pill that contains medications from two (or more) different classes in one pill (for example, Epclusa, which is one pill containing velpatasvir and sofosbuvir), or they may be two (or more) separate pills (for example, Daklinza with Sovaldi). Some regimens may include weight-based ribavirin. There is no pegylated interferon used for the treatment of HCV any longer.

Hepatitis B is treated with one medication at a time: Either an antiviral like Viread (tenofovir) or Epivir-HBV (lamivudine), or with pegylated interferon.

WHAT'S NEW IN 2017?

The biggest change to this year's edition is the addition of hepatitis B (HBV) to the Drug Guide**.** HBV is a significant health problem in the United States—indeed, throughout the world—and as this country moves towards a viral hepatitis elimination strategy, we must include it in the guide to raise awareness and inform people who are at risk and need testing, or who are chronically infected and need monitoring or treatment.

We have seen several additional changes in hepatitis C medications since last year's publication as well. Sofosbuvir/velpatasvir received FDA approval in July 2016, and was given the brand name Epclusa. Additionally Viekira Pak was reformulated so it can be taken once daily, and its name was changed to Viekira XR. Harvoni was updated to include its new approval for its use in adolescents age 12 and older, marking the first FDA-approved DAA treatment for children.

A note on soon-to-be-approved DAAs: Gilead's next treatment regimen (sofosbuvir + velpatasvir + voxilaprevir) and AbbVie's next one (glecaprevir + pibrentasvir) will be reviewed by the FDA in July or August, well after our press date. Although we wish we could have held onto the issue until the approval of this treatment and give you the brand name and all relevant package insert information, we could not delay going to press. Upon approval, an updated drug page can be found at positivelyaware.com which you can download and print.

EACH DRUG PAGE INCLUDES:

DRUG NAMES

Drug names can be confusing. We include the brand name, the generic name, and an abbreviation. For example, Sovaldi is the brand name of sofosbuvir. Sovaldi can be abbreviated as SOV; sofosbuvir is abbreviated as SOF. Drugs that have been FDA approved will have a brand name, while those that have not yet reached that stage will only have a generic (or common) name. In some cases, it might not even have a name, but rather a series of letters and numbers (for example, MK-5172). For those drugs which have been FDA approved, the brand name will appear first, at the top of the page, followed by the common name(s); for all other drugs the common or generic name will appear first.

FDA STATUS

We will indicate if a drug is approved, and any drug that has been submitted for FDA approval will have an estimate of its approval date.

DRUG CLASS

The "direct-acting antiviral" or DAA era of HCV treatment has seen the development of several different classes of hepatitis medications. Currently, there are five classes of HCV drugs, four of them DAAs. There are currently four multi-class fixed-dose combinations. Two more are up for FDA approval in

July or August: sofosbuvir + velpatasvir + voxilaprevir (from Gilead Sciences) and glecaprevir + pibrentasvir (from AbbVie). Of this following list, only the nucleoside analogs are not DAAs:

- Nucleoside analogs
- NS3/4A protease inhibitors
- Nucleotide NS5B polymerase inhibitors
- Non-nucleoside NS5B polymerase inhibitors
- NS5A inhibitors

GENOTYPE (HCV ONLY)

Genotype (GT) refers to the strains or variations of HCV. Worldwide, there are as many as 11 distinct genotypes, but for this guide we will only refer to GT 1–6. In the U.S., GT 1–4 are most prevalent, with GT 1 the most common overall. Within each genotype, there are several subtypes that are indicated by numbers and letters (GT 1a, GT 1b, etc.). Although different genotypes can play a role in disease progression or severity, it is especially important to know one's genotype to determine the correct treatment. We will list the genotype(s) that the specific HCV medication works against, both those that are FDA approved as well as those that have enough evidence to be used off-label.

APPROVED FOR HIV/HCV CO-INFECTION

We will note HCV drugs approved for use in HIV/HCV co-infected patients, both those that are FDA approved and those that are off-label.

DOSAGE

HBV drugs are either oral tablets or an injectable. All HCV drugs are oral**,** and may need to be taken at different times, and with differing food restrictions. Sometimes the same drug is taken differently depending upon a variety of factors such as genotype or liver health. This section will describe the dosage requirements for the drug, as well as provide details about restrictions and other relevant information.

MANUFACTURER

This section includes the name of the company that makes the drug.

AVERAGE WHOLESALE PRICE (AWP)

The AWP is the measure used by insurance companies—both private and public—to determine the average cost of prescription drugs. HCV drugs are very expensive, and there is great concern over the burden these high costs are going to place on programs such as Medicaid and Medicare, as well as the Veterans Administration and private insurance carriers. Patients should never have to pay for medications at this price, but it's still important to know these costs when shopping for health insurance coverage. Each of the pharmaceutical companies has a Patient Assistance Program (PAP) to help uninsured and underinsured people cover all or part of the costs. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. A list of HCV drug patient assistance and co-pay programs appears on page 35.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

This section offers information about side effects and adverse events associated with the drugs. It's not an exhaustive list, but rather a selection of the most commonly reported side effects. The information comes from the package insert and study data for the FDA-approved drugs, and clinical trial data for the ones that have yet to receive FDA approval. Since HCV medications are never taken alone, we'll cover potential side effects that are associated with the entire regimen, as opposed to a single drug. It may be hard to separate one cause of a side effect from another, and in the end, it doesn't really matter what the cause is but only that you are experiencing it. Everyone experiences side effects differently: Just because it's listed doesn't mean you will automatically have it. Talk to your medical provider about side effects before starting treatment, communicate with him or her about any you may have during treatment, and get blood tests as directed to look for side effects.

A note on the risk of hepatitis B reactivation in some patients treated with Direct-Acting Antivirals (DAAs) for hepatitis C: On October 4, 2016 the FDA made a safety announcement, also known as a "Boxed Warning," about the potential risk of HBV reactivation in some patients taking *any hepatitis C DAA*. A Boxed Warning is the most important warning the FDA can issue. In this case, there were a number of unexpected cases of hepatitis B reactivation in people who were cured of HCV using the DAAs, leading to hepatic flares, liver failure (some requiring transplant), or in some cases, death. See page 45 for more information on this warning.

POTENTIAL DRUG INTERECTIONS

This section provides information about the variety of known and potential drug interactions. Like the side effects section, it's not an exhaustive list of interactions, but rather a list of the most important ones. You can find a complete list in the package insert, but you should also talk to your medical provider and/or pharmacist about any medications you are taking so you can minimize drug interactions. The information comes from the package insert and clinical trial data for the FDA-approved drugs, and clinical trial data for the ones that have yet to receive FDA approval.

MORE INFORMATION

This section contains information that does not fit in any of the above sections, but is still important for you to know.

THE 2017 POSITIVELY AWARE HEPATITIS B & C DRUG GUIDE IS ALSO AVAILABLE ONLINE: positivelyaware.com

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Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

YOU MATTER AND SO DOES YOUR HEALTH

That's why starting and staying on HIV-1 treatment is so important.

WHAT IS DESCOVY®?

DESCOVY is a prescription medicine that is used together with other HIV-1 medicines to treat HIV-1 in people 12 years and older. DESCOVY is not for use to help reduce the risk of getting HIV-1 infection. DESCOVY combines 2 medicines into 1 pill taken once a day. Because DESCOVY by itself is not a complete treatment for HIV-1, it must be used together with other HIV-1 medicines.

DESCOVY does not cure HIV-1 infection or AIDS.

To control HIV-1 infection and decrease HIV-related illnesses, you must keep taking DESCOVY. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

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

DESCOVY may cause serious side effects:

- **Worsening of hepatitis B (HBV) infection.** DESCOVY is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking DESCOVY, your HBV may suddenly get worse. Do not stop taking DESCOVY without first talking to your healthcare provider, as they will need to monitor your health.

What are the other possible side effects of DESCOVY?

Serious side effects of DESCOVY may also include:

- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking DESCOVY.
- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. Your healthcare provider may tell you to stop taking DESCOVY if you develop new or worse kidney problems.
- **Too much lactic acid in your blood (lactic acidosis),** which is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Severe liver problems,** which in rare cases can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.
- **Bone problems,** such as bone pain, softening, or thinning, which may lead to fractures. Your healthcare provider may do tests to check your bones.

The most common side effect of DESCOVY is nausea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking DESCOVY?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how DESCOVY works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Ask your healthcare provider if it is safe to take DESCOVY with all of your other medicines.
- **If you are pregnant** or plan to become pregnant. It is not known if DESCOVY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking DESCOVY.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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.

Please see Important Facts about DESCOVY, including important warnings, on the following page.

Ask your healthcare provider if an HIV-1 treatment that contains DESCOVY® is right for you.


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WHAT'S
INSIDE
GILEAD

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

(des-KOH-vee)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT DESCOVY

DESCOVY may cause serious side effects, including:

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

ABOUT DESCOVY

- DESCOVY is a prescription medicine that is used together with other HIV-1 medicines to treat HIV-1 in people 12 years of age and older. DESCOVY is **not** for use to help reduce the risk of getting HIV-1 infection.
- **DESCOVY does not cure HIV-1 or AIDS**. Ask your healthcare provider about how to prevent passing HIV-1 to others.

BEFORE TAKING DESCOVY

Tell your healthcare provider if you:

- Have or had any kidney, bone, or liver problems, including hepatitis infection.
- Have any other medical condition.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with DESCOVY.

HOW TO TAKE DESCOVY

- DESCOVY is a one pill, once a day HIV-1 medicine that is taken with other HIV-1 medicines.
- Take DESCOVY with or without food.

POSSIBLE SIDE EFFECTS OF DESCOVY

DESCOVY can cause serious side effects, including:

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

The most common side effect of DESCOVY is nausea.

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

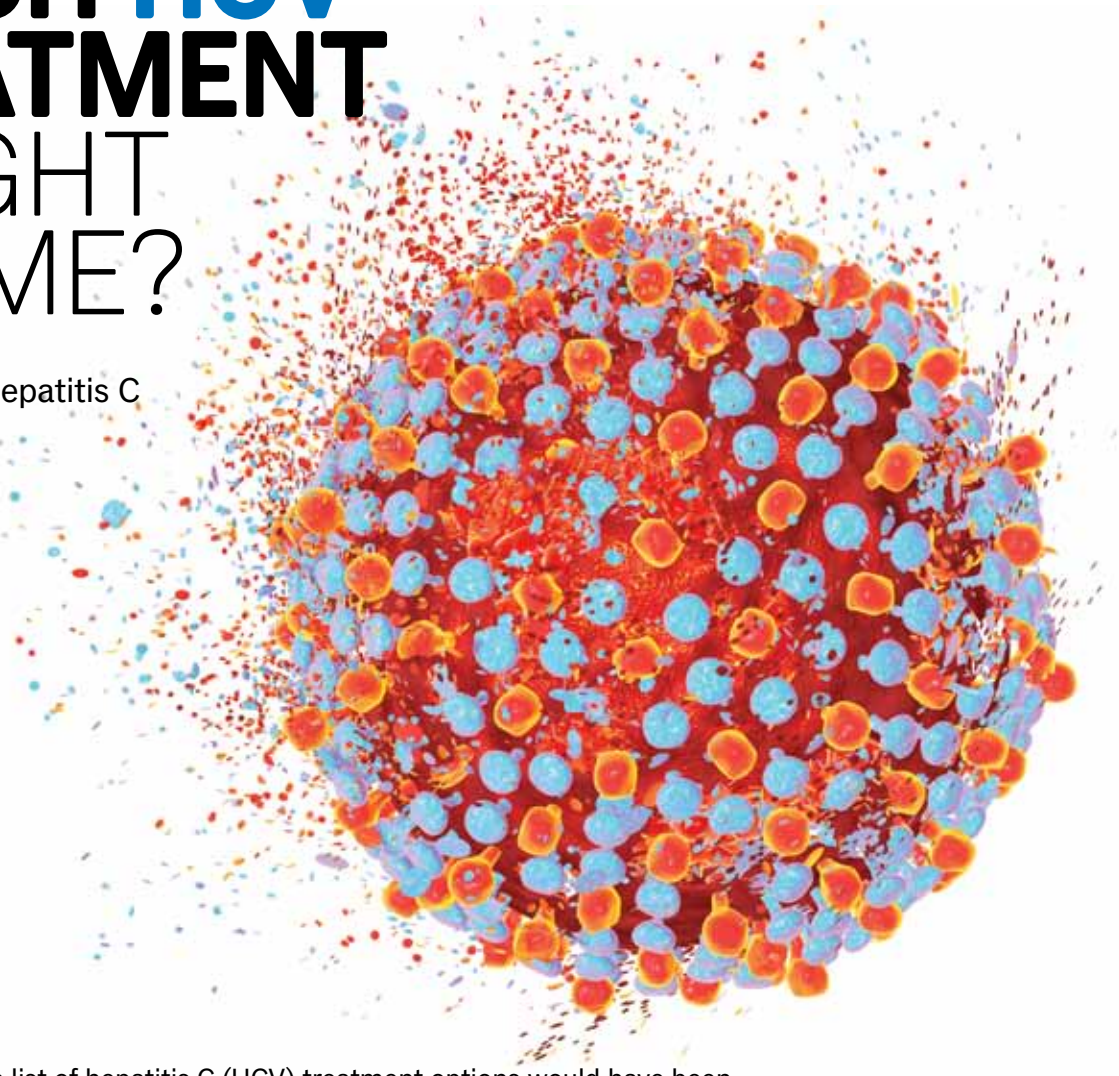
Your healthcare provider will need to do tests to monitor your health before and during treatment with DESCOVY.

GET MORE INFORMATION

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

GILEAD

WHICH HCV TREATMENT IS RIGHT FOR ME?



ISTOCKPHOTO

A quick guide to hepatitis C treatment options

BY ANDREW REYNOLDS

Five years ago, the list of hepatitis C (HCV) treatment options would have been very short. We now have eight FDA-approved direct-acting antivirals (DAAs), as well as ribavirin, for treating all HCV genotypes. With so many options, there can be confusion over what treatment to take.

AASLD/IDSA HCV treatment guidelines

There are many treatment options for people with various HCV genotypes (GT), treatment histories, levels of cirrhosis, and other co-morbidities (things like renal disease or HIV/HCV co-infection). With so many options comes confusion about which regimen is right for which genotype or treatment history and so on. This goes for patients and providers alike!

The American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) have produced a guide to help medical providers with expert guidance on screening, managing, and treating HCV. This brief article is designed to provide you with a listing of these recommendations for treating HCV in treatment-naïve patients with and without cirrhosis. All of these treatments are FDA approved, but they also include some "off-label" options (that is, not FDA approved for a particular use but shown to be effective for that condition or population) for people with HCV.

As you will see on the next page, treatments are now shorter and more effective than ever before. The treatments have the added benefit of being better tolerated with fewer side effects. For information on possible side effects, check out the individual drug pages

found in this year's guide.

This list of treatment options is not exhaustive: We cover the first-line (first-time treatment) recommendations only. There are alternatives listed in the HCV guidance, and your provider can review those with you should you need them. Of course, any treatment decision will be done with your medical provider. We hope this article provides you with a clear starting point in your journey to a cure from HCV.

What about HIV/HCV co-infection?

Everyone living with HIV and most everyone living with HCV should be treated for those infections, according to U.S. guidelines for the two conditions. Fortunately, the same hep C treatment options are available for people co-infected with both viruses.

HIV/HCV-co-infected persons should be treated and retreated the same as persons without HIV infection, according to the AASLD/IDSA Guidance. Thus all the regimens listed below can be taken by co-infected people, and the cure rates show similar response rates as they do for people living with HCV alone.

Patients living with co-infection may have to adjust their HIV regimen to avoid drug-drug interactions, but no one should ever stop their HIV medications to accommodate their HCV ones. Switching HIV medications can be a very traumatic experience for someone, and if this is an issue for you, the combination of Daklinza plus Sovaldi is an option.

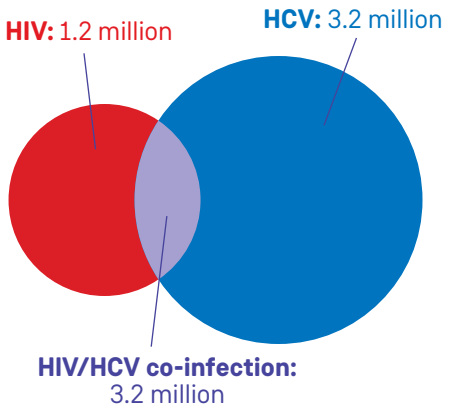
Regardless, your HIV and HCV medical provider should be in consultation with one another, and any switch in your HIV medications should be done in collaboration with your HIV care provider.

A quick note on the next medications that are likely to receive FDA approval, sofosbuvir/velpatasvir/voxilaprevir, and glecaprevir/pibrentasvir. As this issue was going to press, these medications were not yet FDA approved. When they are, they will most likely be added as treatment options for all genotypes. POSITIVELY AWARE will update the online version of this guide once this happens.

What about treatment-experienced patients, that is, people who tried treatment before, but it didn't work?

There are many options currently available for treatment-experienced patients (and several more currently in development), but it can be complicated to decide which one is right for you. Your provider will need to know your treatment history, possible HCV drug resistance, and your overall liver health before she/he can decide which regimen is right for you. The AASLD/IDSA HCV Guidance does have a long list of recommendations with each of these variables, but due to the complications and space constraints of this guide, they are not listed here. They can, however, be found in the online version of this article, at positivelyaware.com.

HIV, hepatitis C, and co-infection
AN ESTIMATED 25% OF PEOPLE LIVING WITH HIV IN THE U.S. ARE ALSO CO-INFECTED WITH HEPATITIS C.



What about the treatment options for people with other co-morbidities?

Regardless of genotype, patients who have decompensated cirrhosis, kidney (renal) disease, or are post-transplant with HCV have treatment options, but they should have enhanced monitoring by a medical practitioner who has expertise in managing that condition, ideally in a liver transplant center. If you fall into one of these patient categories, consult with your provider about the best course of care to take.

Conclusions

There are many treatment choices available for people living with HCV. The charts are a snapshot of these choices, but there are many considerations such as side effects, co-morbidities, and other matters that one must consider before making that treatment decision. Gather the help you need to make that decision: Speak with your medical provider, pharmacist, or nurse about these options. Go to a support group and speak with other patients to hear about their experiences. Project Inform and four HCV organizations staff The Support Partnership's "Help-4-Hep" national HCV phone line. Call us at (877) HELP-4-HEP, or (877) 435-7443, and speak with a trained counselor about your treatment options. See the guidelines at hcvguidelines.org.

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HEPATITIS C MEDICATIONS BY CLASS

CLASS	BRAND NAME	GENERIC/ COMMON NAME	STATUS	GENOTYPE (FDA AND OFF-LABEL)	APPROVED FOR HIV/HCV CO-INFECTION?	MANUFACTURER	SEE PAGE
NS3/4A protease inhibitor	Olysio	**simeprevir,** SMV	APPROVED	1	Yes	Janssen	30
	FOUND IN Viekira XR AND Technivie	**paritaprevir,** PTV/r	APPROVED	Viekira XR: 1 Technivie: 4	Yes	AbbVie	28, 29
	FOUND IN Zepatier	**grazoprevir,** GZR	APPROVED	1 4	Yes	Merck	26
	Brand name yet to be determined (will be combined with SOF and VEL)	**voxilaprevir,** (GS-9857)	Submitted for approval	1 2 3 4 5 6	TBD	Gilead Sciences	32
	Brand name yet to be determined	**glecaprevir,** (ABT-493)	Submitted for approval	1 2 3 4 5 6	TBD	AbbVie	31
Nucleoside and nucleotide NS5B polymerase inhibitor	FOUND IN Sovaldi; Harvoni; AND Epclusa	**sofosbuvir,** SOF	APPROVED	1 2 3 4	Yes	Gilead Sciences	25, 24, 23
NS5A inhibitor	Harvoni	**ledipasvir,** LDV	APPROVED	1 4 5 6	Yes	Gilead Sciences	24
	Daklinza	**daclatasvir,** DCV	APPROVED	1 3	Yes	Bristol-Myers Squibb	27
	FOUND IN Viekira XR AND Technivie	**ombitasvir,** OMB	APPROVED	Viekira XR: 1 Technivie: 4	Yes	AbbVie	28, 29
	FOUND IN Zepatier	**elbasvir,** EBR	APPROVED	1 4	Yes	Merck	26
	FOUND IN Epclusa	**velpatasvir,** VEL	APPROVED	1 2 3 4 5 6	No; off-label use OK	Gilead Sciences	23
	Brand name yet to be determined	**pibrentasvir** (ABT-530)	Submitted for approval	1 2 3 4 5 6	TBD	AbbVie	31
Non-nucleoside NS5B polymerase inhibitor	FOUND IN Viekira XR	**dasabuvir,** DAS	APPROVED	1	Yes	AbbVie	28
Nucleoside analog	Moderiba	**ribavirin,** RBV	APPROVED	1 2 3 4 5 6	Yes	AbbVie	33
	Ribasphere	**ribavirin,** RBV	APPROVED	1 2 3 4 5 6	Yes	Kadmon	33
	Copegus	**ribavirin,** RBV	APPROVED	1 2 3 4 5 6	Yes	Genentech	33

Epclusa sofosbuvir/velpatasvir, SOF/VEL

DRUG CLASS
sofosbuvir: **Nucleotide analog NS5B polymerase inhibitor;**
velpatasvir: **NS5A inhibitor**

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
NOT APPROVED FOR CO-INFECTION, but clinical trial results show high cure rates; off-label use is acceptable.

MANUFACTURER
Gilead Sciences

AWP
$29,904 / month

DOSAGE

A fixed-dose combination sofosbuvir 400 mg/velpatasvir 100 mg. Take one tablet once daily with or without food. Ribavirin may be included in patients with decompensated cirrohsis. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including Epclusa, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 45 for more information and consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Epclusa is a very well tolerated medication with minimal side effects. Indeed, in the clinical trials for Epclusa, there were very few people—0.2%—who discontinued treatment due to side effects. In patients without cirrhosis or in those with compensated cirrhosis, the most commonly reported side effects are headache and fatigue. Less frequently reported side effects include nausea, insomnia, and asthenia (weakness). All of these side effects are considered to be mild. In patients with decompensated cirrhosis, the above side effects can occur, with an addition of diarrhea. Again, these are all considered mild to moderate, and very few people have to discontinue treatment because of them. Lab abnormalities such as elevations in bilirubin levels and lipase levels have been observed, and although not likely to be significant, should be monitored while undergoing treatment. Epclusa has not been studied in pregnant women or nursing mothers, so we do not know what, if any impact, it would have on fetal development or nursing babies.

If used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Epclusa should not be taken within 4 hours of antacids. If taking H2-receptor antagonists, take Epclusa at the same time, otherwise you have to wait 12 hours to take it at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. You can take proton pump inhibitors comparable to omeprazole 20 mg or lower, but must have an empty stomach. Epclusa should not be taken with the following HIV medications: efavirenz or tipranavir/ritonavir. It should not be take the antimycobacterials rifabutin, rifampin or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital or oxcarbazepine. Do not take with the anti-cancer drug topotecan. It cannot be taken with St. John's wort.After FDA approval, several cases of symptomatic bradycardia (very low heart rate), and cases of fatal heart attacks and cases requiring a pacemaker have been associated with the use of Epclusa with amiodarone. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains and confusion or memory problems. Consult a medical provider should any of these occur. No sofosbuvir-based HCV regimens are to be used with amiodarone.

MORE INFORMATION

Epclusa marks an exciting development for treating HCV: One pill, once per day taken without ribavirin for 12 weeks for all genotypes with minimal side effects and high cure rates is an extraordinary achievement when one considers that the first DAA came on the scene less than 4 years ago. It also looks to be an effective and highly tolerable treatment option for people with GT3, with SVR12 rates as high as 98% for treatment-naïve patients without cirrhosis. The presence of cirrhosis looks to lower the SVR12 rates a bit (93%), but it is still an interferon and ribavirin-free option for this hard to treat patient group. The ASTRAL-4 Study, which looked at patients with decompensated liver disease resulted in an SVR12 of 83% of people taking Epclusa alone, but it increased 94% when ribavirin was added. Although it is not yet FDA approved for HIV/HCV co-infected persons, it can be used off-label: The ASTRAL-5 Study, which looked at treating HIV/HCV co-infected persons with SOF/VEL, had an overall 95% SVR12, including 100% in people with cirrhosis and 97% in treatment-experienced people.

Recommended treatment regimen and duration
In HIV-mono-infected persons with genotype 1, 2, 3, 4, 5, and 6*

PATIENT POPULATION	RECOMMENDED TREATMENT REGIMEN
Patients without cirrhosis and patients with compensated cirrhosis (Child-Pugh A)	Epclusa **for 12 weeks**
Patients with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + ribavirin **for 12 weeks**

***Though off-label, the same regimen can be used in HIV/HCV co-infected persons.

Harvoni ledipasvir/sofosbuvir, or LDV/SOF

DRUG CLASS
ledipasvir: **NS5A inhibitor;** sofosbuvir: **Nucleotide analog NS5B polymerase inhibitor**

GENOTYPE
1 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Gilead Sciences

AWP
$37,800 / month

DOSAGE

A fixed-dose combination of ledipasvir 90 mg/sofosbuvir 400 mg. Take one tablet once daily with or without food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. Duration of therapy is 12 or 24 weeks, depending upon treatment-experience and level of cirrhosis. In some cases, 8-week treatment is possible. Pediatric use approved this year for children age 12 and older weighing at least 77 pounds (35 kg). See chart for duration indications.

BLACK BOX WARNING

Before starting any DAA treatment, including LDV/SOF, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 45 for more information; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Harvoni is very well tolerated. Most commonly reported side effects are fatigue, headache, nausea, diarrhea, and insomnia, all considered mild. Discontinuation for side effects is very rare. Lab abnormalities such as elevations in bilirubin levels and lipase levels have been observed, and although not likely to be significant, should be monitored. Has not been studied in pregnant or nursing women.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit.

Sofosbuvir should not be used with amiodarone. Cases of symptomatic bradycardia and fatal heart attack, and cases requiring a pacemaker, have occurred. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. See your doctor.

Do not take within 4 hours of antacids. Take at the same time with H2-receptor antagonists, otherwise wait 12 hours to take at a dose that does not exceed doses comparable to famotidine 40 mg twice daily. May use proton pump inhibitors comparable to omeprazole 20 mg or lower, but on an empty stomach. Do not take with the HIV antiretrovirals Aptivus/Norvir, elvitegravir, cobicistat, emtricitabine, or tenofovir DF (TDF). TDF levels may be increased, and it has not been studied in terms of safety. Monitor for TDF-related adverse events if taken together. Do not take Harvoni with St. John's wort, rifampin, rifabutin, or rifapentine. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used, as they reduce the concentrations of sofosbuvir, thus reducing its effectiveness. There are no interactions with methadone.

MORE INFORMATION

This combination marks an exciting development for treating HCV GT 1: One pill, once daily potentially curing HCV in as little as 8, 12 or 24 weeks with minimal side effects is an astounding achievement. It remains commonly used to this day. In 2017, Harvoni was approved for use in children age 12 and older, or weighing at least 77 pounds (35 kg) for genotypes 1, 4, 5, and 6 with either no cirrhosis or compensated cirrhosis. This marks the first time the FDA approved a hepatitis C DAA for use in children.

Recommended treatment regimen and duration

GENOTYPE	PATIENT POPULATION AND TREATMENT DURATION
1 ADULT AND PEDIATRIC	Treatment-naïve with no cirrhosis or with compensated cirrhosis (Child-Pugh A): **Harvoni for 12 weeks***
1 ADULT AND PEDIATRIC	Treatment-experienced with no cirrhosis: **Harvoni for 12 weeks**
1 ADULT AND PEDIATRIC	Treatment-experienced with compensated cirrhosis (Child-Pugh A): **Harvoni for 24 weeks**
1 ADULT ONLY	Treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B or C): **Harvoni + ribavirin for 12 weeks**
1 ADULT ONLY	Treatment-naïve or treatment-experienced liver transplant patients with no cirrhosis or with compensated cirrhosis: **Harvoni + ribavirin for 12 weeks**
4 ADULT AND PEDIATRIC	Treatment-naïve or treatment-experienced with no cirrhosis or with compensated cirrhosis (Child-Pugh A): **Harvoni for 12 weeks**
4 ADULT ONLY	Treatment-naïve or treatment-experienced liver transplant patients with no cirrhosis or with compensated cirrhosis: **Harvoni + ribavirin for 12 weeks**
5 ADULT AND PEDIATRIC	Treatment-naïve or treatment-experienced with no cirrhosis or with compensated cirrhosis (Child-Pugh A): **Harvoni for 12 weeks**
6 ADULT AND PEDIATRIC	Treatment-naïve or treatment-experienced with no cirrhosis or with compensated cirrhosis (Child-Pugh A): **Harvoni for 12 weeks**

* In adult patients, Harvoni for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pretreatment HCV RNA less than 6 million IU/mL.

Sovaldi sofosbuvir, SOF, or SOV

DRUG CLASS
Nucleotide analog NS5B polymerase inhibitor

GENOTYPE
1 2 3 4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Gilead Sciences

AWP
$33,600 / month

DOSAGE

Take one 400 mg tablet once daily with or without food; must be taken in combination with either ribavirin and pegylated interferon, ribavirin alone, or in combination with another DAAs (see below for details). Sovaldi should never be taken by itself. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. The chart on this page summarizes the various treatment regimens.

BLACK BOX WARNING

Before starting treatment with any DAA, including Sovaldi, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 45 for more information; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. When sofosbuvir was taken with amiodarone (see interactions), several cases of serious symptomatic bradycardia (a potentially dangerous, very low heart rate) occurred, as well as cases of fatal heart attacks and cases requiring a pacemaker. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these occur. When Sovaldi is taken with pegylated interferon (drug page online only) and ribavirin (not recommended for use any longer) or ribavirin alone, the most common side effects reported by people taking this regimen are related to those two medications: fatigue, headaches, nausea, fever, chills, and arthralgia (joint pain). For more information on the side effects of each of these medications, see their respective drug pages. Pegylated interferon has been associated with depression, anxiety, and, in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting it. When Sovaldi is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit.

Sovaldi cannot be taken with the antiarythmiatic medication, amiodarone; see side effects. No sofosbuvir-based HCV regimens are to be used with amiodarone. Sovaldi cannot be taken with the HIV medication tipranavir/ritonavir, but is safe to take with other HIV medications. Sovaldi has no interactions with methadone. Do not taken Sovaldi with St. John's wort, rifabutin, or rifapentine. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used, as they reduce the concentrations of Sovaldi, thus reducing its therapeutic effectiveness.

MORE INFORMATION

Sovaldi is a drug with a lot of "firsts"—first drug of its class, first drug to receive FDA approval for use without interferon, and the first DAA to receive FDA approval for use in HIV/HCV co-infected patients. Approved in 2013, the original dosage and duration is already pretty much obsolete when compared to other HCV treatments. It can still be used in combination with Olysio or Daklinza for the treatment of genotype 1, but there are several other options that are easier to take, more effective, and likely, less expensive. Sovaldi is a key component of Harvoni and Epclusa, and will be part of the next fixed-dose combination from Gilead, sofosbuvir/velpatasvir/voxilaprevir (see drug page) for the treatment of all HCV genotypes.

Recommended adult and pediatric treatment regimens and durations

GENOTYPE	PATIENT POPULATION AND TREATMENT REGIMEN
1 4 ADULT ONLY	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A): **Sovaldi + peginterferon alfa + ribavirin for 12 weeks**
2 ADULT ONLY	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A): **Sovaldi + peginterferon alfa + ribavirin for 12 weeks**
2 PEDIATRIC ONLY	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A): **Sovaldi + ribavirin for 12 weeks**
3 ADULT AND PEDIATRIC	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A): **Sovaldi + ribavirin for 24 weeks**

Zepatier grazoprevir/elbasvir, or GZR/EBR

DRUG CLASS
grazoprevir: **HCV NS3/4A protease inhibitor;**
elbasvir: **HCV NS5A inhibitor**

GENOTYPE
1 4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Merck

AWP
$21,840 / month

DOSAGE

A fixed-dose combination of grazoprevir 100 mg/elbasvir 50 mg. Take one tablet once daily with or without food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including Zepatier, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 45; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Zepatier is very well tolerated. The most commonly reported side effects are fatigue and headaches, but both are considered mild. In smaller numbers, nausea, insomnia, and diarrhea were reported. In clinical trials, very few people—around 1%—discontinued treatment due to side effects. If used with ribavirin, cannot be taken by pregnant women or women who are trying to become pregnant; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit.

Do not take with atazanavir/ritonavir, darunavir/ritonavir, efavirenz, or lopinavir/ritonavir. No dose adjustments needed when taken with raltegrevir, ritonavir, or tenofovir; other HIV medications to be deterimined; no dose adjustments needed when taken with buprenorphine, methadone, or naloxone; safe to use with oral contraceptives. Further data is needed on interactions with rifampin, so avoid co-administration for the time being.

MORE INFORMATION

This regimen was studied in a number of patient populations that can be complicated to treat: HIV/HCV co-infected patients, patients with renal (kidney) disease, active substance users and those on methadone, and patients with more advanced liver damage. Of particular importance: This regimen looks to be especially effective in patients with kidney disease, including those on hemodialysis, with 99% achieving an SVR12. Finally, if you are HCV genotype 1a, you will need to take an HCV drug resistance test before starting Zepatier. If your hepatitis C virus is resistant, you have to add ribavirin and take the combination for an additional four weeks, for a total of 16 weeks. This improves its effectiveness and allows the medication to overcome resistance and dramatically improve your chances for cure.

Recommended adult and pediatric treatment regimens and durations

GENOTYPE AND PATIENT POPULATION	TREATMENT REGIMEN
1 A: Treatment-naïve, or pegylated interferon/ribavirin experienced without NS5A resistance	Zepatier only **for 12 weeks**
1 A: Treatment-naïve, or pegylated interferon/ribavirin experienced with NS5A resistance	Zepatier + ribavirin **for 16 weeks**
1 B: Treatment-naïve, or pegylated interferon/ribavirin experienced	Zepatier for **12 weeks**
1 A or 1 B: Pegylated interferon/ribavirin experienced	Zepatier + ribavirin **for 12 weeks**
4: Treatment-naive	Zepatier **for 12 weeks**
4: Pegylated interferon/ribavirin experienced	Zepatier + ribavirin **for 16 weeks**

Daklinza daclatasvir, or DCV

DRUG CLASS
NS5A replication complex inhibitor

GENOTYPE
1 3

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Bristol-Myers Squibb

AWP
$25,200 / month for 30 mg, 60 mg, and 90 mg tablets

DOSAGE

Take one 60 mg tablet once daily with or without food; 30 mg and 90 mg tablets are also available. Must be taken in combination with Sovaldi (sofosbuvir); ribavirin may be included for some genotypes, treatment-experienced patients, or with cirrhosis. Check package insert for complete dosing details.

BLACK BOX WARNING

Before starting treatment with any DAA, including Daklinza, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment; some may need to take HBV treatment. See box on page 45 for more information and consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Side effect data reported here come from the package insert, clinical trials, and from post-marketing experience. When used in combination with sofosbuvir, commonly reported side effects are headache, nausea and fatigue; less common side effects include loss of appetite, insomnia, dizziness, cough and nasal congestion, arthralgia, myalgia, pruritis, dry skin, alopecia (hair loss), rash, depression and anxiety. Not all people experience all side effects, and most are considered mild to moderate: No one discontinued therapy because of them. If used with ribavirin, pregnant women or women who are trying to become pregnant cannot take Daklinza; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit. See page 25 for drug interactions with Sovaldi.

Do not take with the anti-seizure medications phenytoin, carbamazepine, oxcarbazepine or phenobarbital; anti-tuberculosis medications rifampicin, rifabutin, or rifapentine; the steroid dexamethasone; or St. John's wort. All of these medications weaken Daklinza's effectiveness, and the treatment will not work. Daklinza is safe to use with darunavir/ritonavir, darunavir/cobistat, lopinavir/ritonavir, rilpivirine, dolutegravir, raltegravir, and tenofovir. Dose adjustments of daclatasvir may be required when used with atazanavir/ritonavir, atazanavir/cobistat, efavirenz, or cobicistat. Talk to your medical provider for dosage adjustment questions. Daklinza is safe to take with immunosuppressants cyclosporine, tacrolimus, sirolimus, and mycophenolate mofetil. No interactions with methadone, buprenorphine, or naloxone.

MORE INFORMATION

Daklinza plus Sovaldi is an excellent option for patients with genotype 3 without cirrhosis, and is very effective in HIV/HCV co-infected persons. If you're taking HIV antivirals, you may have to increase or decrease your Daklinza. Your medical provider will review this with you, but it's important to ask: "Will my HIV medication affect my Daklinza?" It's worth noting that in Europe, it was also approved for use in people with HCV GT 4, but not in the U.S. Additionally, there has been research showing Daklinza to be effective against GT 2 and may be an option for off-label use (that is, although not FDA approved, there's enough evidence to support its effectiveness). In fact the AASLD/IDSA guidelines do list Daklinza as a potential option for treating HCV GT 2. Talk with your medical provider about which treatment is right for your genotype, and check if your insurance will cover off-label treatments.

Recommended dosage for HCV and HIV/HCV co-infected persons (TREATMENT DURATION: 12 WEEKS)

PATIENT POPULATION	GENOTYPE 1 REGIMEN	GENOTYPE 3 REGIMEN
No cirrhosis	Daklinza + Sovaldi	Daklinza + Sovaldi
Compensated cirrhosis (Child-Pugh A)	Daklinza + Sovaldi	Daklinza + Sovaldi + ribavirin
Decompensated cirrhosis (Child-Pugh B or C)	Daklinza + Sovaldi + ribavirin	Daklinza + Sovaldi + ribavirin
Post-transplant	Daklinza + Sovaldi + ribavirin	Daklinza + Sovaldi + ribavirin

This information comes from the package insert. The AASLD/IDSA HCV Guidance recommends considering 24 weeks of treatment with the above regimens for patients with cirrhosis. Talk with your medical provider about the length that is best for you.

Viekira XR ombitasvir/paritaprevir/ritonavir plus dasabuvir, or OMB/PTV/r + DAS

DRUG CLASS
ombitasvir: **NS5A inhibitor;** paritaprevir: **NS3/4A protease inhibitor, boosted with ritonavir;** dasabuvir: **non-nucleoside NS5B polymerase inhibitor**

GENOTYPE
1

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
AbbVie

AWP
$33,327.60 / month

DOSAGE

Take three dasabuvir/ombitasvir/paritaprevir/ritonavir 200 mg/8.33 mg/50 mg/33.33 mg tablets once daily with food. If ribavirin is prescribed, take a weight-based dose, two times daily with food. Take your missed dose as soon as possible, unless it's too close to your next dose. Never double dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including Viekira XR, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 45 for more information; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. The most commonly experienced side effects were headaches, fatigue, nausea, pruritus (itching), skin reactions, insomnia, and asthenia (loss of strength); all side effects were considered mild. Monitor for elevated ALTs, particularly in the first four weeks of treatment. This was a rare issue in clinical trials, but occurred more frequently in women who were using ethinyl estradiol-containing contraceptives and other estrogens. Women using estrogens while on Viekira XR should monitor hepatic labs during treatment as needed, and consult with their medical provider should they experience fatigue, weakness, lack of appetite, nausea, vomiting, jaundice, or discolored feces. When taken with ribavirin, there is an increased risk of fatigue, nausea, headaches, and pruritus. For more information on the side effects of ribavirin, refer to its drug page on page 33. When this regimen is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions are recommended.

POTENTIAL DRUG INTERACTIONS

Viekira XR may interact with other drugs; for a complete listing, refer to the package insert. Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit. Do not take with St. John's wort. Do not take with the HIV medications efavirenz, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or atazanavir/ritonavir. Do not take with anticonvulsants carbamazepine, phenytoin or phenobarbital. Do not take with rifampin. Do not take with PDE5 inhibitors Viagra, Cialis, or Levitra. Do not take with the sedatives triazolam or midazolam. Do not take with lovastatin. Women taking ethinyl estradiol-containing medications should monitor for ALT elevations (see above). Methadone, buprenorphine, and naloxone are safe to take with Viekira XR, but monitor for sedation and cognitive effects.

MORE INFORMATION

This is a reformulated version of Viekira Pak: While the older version needed twice-daily dosing for one of the medications, Viekira XR is taken once daily. Viekira XR is able to be used in patients who are treatment-naïve and -experienced, HIV/HCV co-infected, have renal disease, or are post-transplant, but is not recommended for people with decompensated cirrhosis. People with moderate to severe cirrhosis—Child-Pugh B and C—should not take Viekira XR. Viekira XR can also be used in liver transplant recipients with normal functioning and mild fibrosis (F2 or less) with ribavirin for 24 weeks.

Treatment duration by patient population, including HIV/HCV co-infection

PATIENT POPULATION	TREATMENT AND DURATION
1 A, **no cirrhosis**	Viekira XR + ribavirin for 12 weeks
1 A, **with compensated cirrhosis**	Viekira XR + ribavirin 24 weeks
1 B, **no cirrhosis or with compensated cirrhosis**	Viekira XR for 12 weeks

Technivie ombitasvir/paritaprevir/ritonavir, or OMB/PTV-r

DRUG CLASS
ombitasvir: **NS5A inhibitor;** paritaprevir: **NS3/4A protease inhibitor, boosted with ritonavir**

GENOTYPE
4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
AbbVie

AWP
$30,661.20 / month

DOSAGE

Take two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily with food. Daily dosing comes co-packaged to facilitate proper adherence. Must be taken with ribavirin at a weight-based dose, twice daily with food. Take your missed dose as soon as possible, unless it's too close to your next dose. Never double dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including Technivie, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 45; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. The most commonly experienced side effects were headaches, fatigue, nausea, pruritus (itching), skin reactions, insomnia, and asthenia (loss of strength); all side effects were considered mild, and none of the participants in the clinical trials discontinued Technivie because of them. Monitor for elevated ALTs, particularly in the first four weeks of treatment. This was a rare issue in clinical trials, but did occur more frequently in women who were using ethinyl estradiol-containing contraceptives and other estrogens. Women using estrogens while on Technivie should monitor hepatic labs during treatment as needed, and consult with their medical provider should they experience fatigue, weakness, lack of appetite, nausea, vomiting, jaundice, or discolored feces. As Technivie is taken with ribavirin, there is an increased risk of fatigue, nausea, headaches, and pruritus. For more information on the side effects of ribavirin, refer to its drug page on page 33. Pregnant women or women who are trying to become pregnant cannot take ribavirin; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions are recommended.

POTENTIAL DRUG INTERACTIONS

Technivie may interact with other drugs; for a complete listing, refer to the package insert. Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit. Do not take with St. John's wort. Do not take with the HIV medications efavirenz, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or atazanavir/ritonavir. Do not take with anticonvulsants carbamazepine, phenytoin, or phenobarbital. Do not take with rifampin. Do not take with PDE5 inhibitors Viagra, Cialis, or Levitra. Do not take with the sedatives triazolam or midazolam. Do not take with lovastatin or simvastatin. Women taking ethinyl estradiol-containing medications should monitor for ALT elevations (see above). Do not take with the benzodiazepines triazolam or midazolam as Technivie can increase their concentrations and lead to possible overdose and death. Methadone, buprenorphine, and naloxone are safe to take with Technivie, but monitor for sedation and cognitive effects.

MORE INFORMATION

Technivie was approved in July 2015 as a new option for people with HCV genotype 4. It contains the same medications found in Viekira XR, minus the dasabuvir. It is a once a day medication, but it still needs ribavirin that needs to be taken twice a day, making it a less ideal choice for those with adherence issues or who can't take ribavirin. Technivie can be used in patients who are treatment-naïve and experienced, HIV/HCV co-infected, have renal disease, are post-transplant, but is not recommended for people post-liver transplant or with decompensated cirrhosis. People with moderate to severe cirrhosis—Child-Pugh B and C—should not take Technivie.

Treatment duration, including HIV/HCV co-infection

4, No cirrhosis or with compensated cirrhosis (Child-Pugh A) Technivie + ribavirin* **for 12 weeks**

*Technivie without ribavirin can be considered for treatment-naïve patients without cirrhosis.

Olysio simeprevir, SMV

DRUG CLASS
NS3/4A protease inhibitor

GENOTYPE
1 4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Janssen Therapeutics

AWP
$26,544 / month

DOSAGE

Take one 150 mg capsule once daily with food; must be taken in combination in combination with Sovaldi or pegylated interferon/ribavirin (see below for details). Do not crush or dissolve the capsule. Olysio should never be taken by itself. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. The chart on this page summarizes the various treatment regimens and durations.

BLACK BOX WARNING

Before starting treatment with any DAA, including Olysio, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 45 for more information; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. Olysio is associated with a rash and photosensitivity (allergic-like reaction to the sun). The rash was generally mild, with very few people experiencing a severe rash. The photosensitivity is considered mild to moderate; anyone taking Olysio should wear sunscreen and take other protective measures. There have been reports of liver decompensation and liver failure in patients with advanced liver disease: monitor liver chemistry tests before and during treatment with Olysio. Other side effects include pruritus (itching), nausea, myalgia (muscle pain), and shortness of breath. If taken with pegylated interferon (drug page is online only) and ribavirin, additional side effects related to those medications include fatigue, headaches, nausea, fever, chills, and joint pain. For more information, see their respective drug pages. Pegylated interferon has been associated with depression, anxiety, and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting it. If used with ribavirin, cannot be taken by pregnant women or women who are trying to become pregnant; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Talk to your medical provider and/or pharmacist about any and all medications you are taking whether they're prescribed, over-the-counter, or illicit. Olysio interacts with many other medications, and this is not a complete list. For more interactions, see the package insert.

Risk of serious symptomatic bradycardia when taken with Sovaldi (sofosbuvir) and amiodarone; see Sovaldi drug page for more details. Olysio + Sovaldi should not be taken with amiodarone.

Do not take with any HIV protease inhibitors (PIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs) Sustiva (efavirenz, also in Atripla) or Viramune (nevirapine) or Intelence (etravarine), or with cobicistat-boosted regimens (Genvoya, Stribild). Olysio can be taken with Edurant (rilpivirine), Isentress (raltegravir), Tivicay (dolutegravir), and the nucleoside reverse transcriptase inhibitors including Truvada, Ziagen (abacavir), Emtriva (emtricitabine), Epivir (lamivudine), Epzicom, and Viread (tenofovir). Olysio boosts the levels of erectile dysfunction drugs (Viagra, Cialis, and Levitra). Start with the lowest dose possible and increase as needed. Do not use with the herbs milk thistle (silymarin) or St. John's wort. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the concentrations of Olysio, thus reducing its effectiveness. Rifampin, rifabutin, and rifapentine should not be taken. Antibiotics erythromycin, clarithromycin, and telithromycin increase levels of Olysio so they should be avoided, as should the antifungals fluconazole, voriconazole, itraconazole, ketoconazole, and posaconazole. Antiarrhythmics such as Tambocor and Cordarone should not be taken; no interactions with methadone and buprenorphine.

MORE INFORMATION

Although it is approved for the treatment of GT 1 o 4 with the combination of Olysio + pegylated interferon + ribavirin, this regimen is not recommended for use: The SVR rates don't stand up to the interferon-free regimens, to say nothing of the severity of side effects and length of treatment. There is an FDA approved interferon-free version: The combination of Olysio plus Sovaldi with or without ribavirin. This combination is listed as an option as a recommended regimen for use in people with GT 1.

TWO IMPORTANT COMPONENTS OF OLYSIO TREATMENT

1. People with genotype 1a need a blood test called a "Q80K polymorphism," for a resistant strain of HCV. This polymorphism reduces treatment effectiveness and other medications should be considered. When used with sofosbuvir, this blood test is not recommended as the Q80K polymorphism does not impact treatment outcomes with this combination. 2. When not used with sofosbuvir, Olysio is "response-guided therapy": Treatment should be stopped if one has a detectable HCV viral load of any level at weeks 4, 12, or 24.

Approved treatment durations for Olysio with sofosbuvir

PATIENT TREATMENT HISTORY	TREATMENT AND DURATION
Treatment-naïve without cirrhosis	Olysio + Sovaldi for 12 weeks
Treatment-experienced without cirrhosis	Olysio + Sovaldi for 12 weeks
Treatment-naïve with cirrhosis	Olysio + Sovaldi for 24 weeks
Treatment-experienced with cirrhosis	Olysio + Sovaldi for 24 weeks

name TBD

glecaprevir/pibrentasvir, or G/P (formerly ABT-493/ABT-530)

DRUG CLASS	GENOTYPE	HIV/HCV CO-INFECTION	MANUFACTURER	AWP	FDA STATUS
glecaprevir: **NS3/4A protease inhibitor;** pibrentacvir: **NS5A inhibitor**	1 2 3 4 5 6	**TO BE DETERMINED**	**AbbVie**	**TO BE DETERMINED**	**Approval expected summer 2017**

DOSAGE

Take three glecaprevir/pibrentacvir 100 mg/40 mg tablets once daily for a total of 300 mg/120 mg. Food restrictions to be determined. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including G/P, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 45; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. As this fixed-dose combination is not yet FDA approved, side effect data come from conference presentations and peer-reviewed scientific journal articles. A complete listing of side effects will be included in the package insert. All side effects are considered very mild and the regimen was very well tolerated in all clinical trials. The most commonly reported side effects were fatigue, headaches, and pruritus (itchy skin). There were no serious lab abnormalities, and very few people stopped treatment because of side effects: Only four in the Expedition-4 study stopped treatment.

POTENTIAL DRUG INTERACTIONS

As this medication is not yet FDA approved, there are limited data on drug interactions. For more comprehensive information, refer to the package insert upon approval. Some information available from conferences and other sources. There are no dose adjustments needed for G/P when taken with the HIV antivirals elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide, abacavir, dolutegravir, or lamivudine.

MORE INFORMATION

AbbVie's next regimen, G/P, marks an exciting development in HCV treatment: It's the first pangenotypic regimen that cures people with 8 weeks of treatment without ribavirin. It has very high cure rates: The overall cure rate (sustained virologic response, or SVR) across all genotypes was 97.5%, but when you remove genotype 3, that number improves to 99% (GT 3 still achieves a 95% SVR). It also appears to be an excellent regimen for people with kidney disease, curing 98% of patients with severe kidney disease with 12 weeks of treatment. This regimen also appears to be an excellent choice for patients post-liver or kidney transplant, having cured 99% of people in one study. See below for a summary of clinical trial results.

Glecaprevir/pibrentacvir: Summary of clinical trial results

STUDY	PATIENT POPULATION	DURATION	TREATMENT REGIMEN	SVR12 (CURE) RATE
Endurance-1	1: No cirrhosis, treatment-naïve or cured with prior interferon-based treatments; HIV/HCV co-infected patients	8 weeks	G/P	**99%** (348 of 351 patients)
Endurance-3	3: No cirrhosis and treatment-naive	8 weeks	G/P	**95%** (149 of 157)
Surveyor-2	2 4 5 6: No cirrhosis, treatment-naïve or cured with prior interferon-based treatments	8 weeks	G/P	**97%** (196 of 203)
Expedition-4	1 2 3 4 5 6 with chronic kidney disease, including those on dialysis	12 weeks	G/P	**98%** (102 of 104)
Magellan-1	1: No cirrhosis and history of treatment failure with a DAA medication	12 weeks	G/P (There was an arm that included ribavirin, but it did not improve SVR rates.)	**96%** (48 of 50)
Magellan-2	1 2 3 4 5 6 with one liver or kidney transplant	12 weeks	G/P	**99%** (98 of 99)

name TBD sofosbuvir/velpatasvir/voxilaprevir, or SOF/VEL/VOX

DRUG CLASS
sofosbuvir: **Nucleotide NS5B polymerase inhibitor;** velpatasvir: **NS5A inhibitor;** voxilaprevir: **NS3/4A protease inhibitor**

GENOTYPE 1 2 3 4 5 6

HIV/HCV CO-INFECTION
TO BE DETERMINED

MANUFACTURER
Gilead Sciences

AWP
TO BE DETERMINED

FDA STATUS
Approval expected summer 2017

DOSAGE

Take one FDV SOF/VEL/VOX 400 mg/100 mg/100 mg tablet once per day. Food restrictions to be determined. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING

Before starting treatment with any DAA, including SOF/VEL/VOX, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 45; consult your medical provider.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

See black box warning. As this fixed-dose combination is not yet FDA approved, side effect data come from conference presentations and peer-reviewed scientific journal articles. A complete listing of side effects will be included in the package insert. Not everyone will experience side effects. For those who do, all side effects are considered mild, and the regimen was very well tolerated in all clinical trials. The most commonly reported side effects are headache, fatigue, diarrhea, and nausea. There were no significant lab abnormalities of concern. Only 1 out of 1,056 patients who received this medication in clinical trials stopped taking it because of side effects. In a study that looked at treatment of patients with decompensated cirrhosis, there were more side effects experienced: In addition to those listed above, this patient group had anemia, insomnia, pruritus (itchy skin), muscle spasms, dyspnea (shortness of breath), and cough. Some of these were likely related to the ribavirin taken, but this is also a group that has many medical issues due to advanced liver disease. Even here, the side effects were tolerable, and there were few discontinuations. If used with ribavirin, cannot be taken by pregnant women or women who are trying to become pregnant; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit. We don't have much published information on drug interactions with SOF/VEL/VOX, but we do know the interactions with SOF/VEL, as those are the drugs that make up Epclusa. Refer to the package insert when this medication is FDA approved for more details. SOF/VEL should not be taken within 4 hours of antacids. Take at the same time with H2-receptor antagonists, otherwise wait 12 hours to take at a dose that does not exceed doses comparable to famotidine 40 mg twice daily. May use proton pump inhibitors comparable to omeprazole 20 mg or lower, but on an empty stomach. Do not take with the HIV antiretrovirals efavirenz or tipranavir/ritonavir. Do not take with the antimycobacterials rifabutin, rifampin, or rifapentine; the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine; the anti-cancer drug topotecan; or the herb St. John's wort.

Sofosbuvir should not be used with amiodarone. Cases of symptomatic bradycardia and fatal heart attack, and cases requiring a pacemaker, have occurred. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. See your doctor.

MORE INFORMATION

The summer of 2017 will likely see AbbVie and Gilead get their respective drugs approved by the FDA, and we will now have the ability to treat just about everyone with HCV in 8 to 12 weeks, with few side effects at extremely high rates of cure (95% and higher). SOF/VEL/VOX marks the next generation of Gilead drugs, and will provide people who have been considered difficult to treat with a new option to get cured. Of particular importance is this medication's effectiveness in people with cirrhosis and/or HIV drug resistance: This is a wonderful achievement and offers hope to people living with HCV-associated cirrhosis.

SOF/VEL/VOX: Summary of clinical trial results

STUDY	POPULATION	GENOTYPE	TREATMENT	DURATION	SVR12
Polaris-1	NS5A-experienced; 41% with cirrhosis	1 2 3 4 5 6	SOF/VEL/VOX	12 weeks	**96%** (253 of 263)
Polaris-2	DAA treatment-naïve; 18% had cirrhosis	1 2 3 4 5 6	SOF/VEL/VOX	8 weeks	**95%** (476 of 501)
Polaris-3	DAA treatment-naïve; 100% with cirrhosis	3	SOF/VEL/VOX	8 weeks	**96%** (106 of 110)
Polaris-4	DAA treatment-experienced (no NS5A); 46% with cirrhosis	1 2 3 4	SOF/VEL/VOX	12 weeks	**97%** (177 of 182)

Copegus, Moderiba, Ribasphere ribavirin, RBV

DRUG CLASS
Nucleoside analog

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Copegus: **Genentech**;
Moderiba: **AbbVie**;
Ribasphere: **Kadmon**

AWP
$1,390 / month for generic, based on 1,200 mg/day

DOSAGE

Ribavirin dosage depends upon the brand, and is given in either fixed doses or in doses related to weight (weight-based). The dose range is 800 mg to 1,400 mg per day taken in two divided doses. Depending upon the manufacturer, tablets are available in 200 mg, 400 mg, 500 mg, and 600 mg. A liquid dose is also available. Must be taken with food. Ribavirin should never be taken by itself. Take your missed dose as soon as possible, unless it's too close to your next dose. Never double dose.

Generic available.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

There are two very serious potential side effects associated with ribavirin: Anemia, and birth defects or fetal death. The anemia can be very severe and can happen very quickly, usually within the first 1–2 weeks of starting treatment. The anemia can cause severe fatigue, dizziness, headaches, and shortness of breath; routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended. The anemia may also cause or worsen cardiac conditions. The other major side effect is birth defects or fetal death in pregnant women. Pregnant women or women who are trying to become pregnant cannot take ribavirin; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. It is unknown if ribavirin passes through breast milk or the impact it could have on breastfeeding babies. Other side effects that have been reported with ribavirin include rash and itching, and there is a small risk of pancreatitis. If you experience any symptoms related to pancreatitis (severe stomach pain that radiates to your back, nausea, vomiting, and/or diarrhea) you should call your advice nurse (when applicable) or go to an emergency department for evaluation. If you have renal (kidney) disease, talk with your medical provider about potential dosage adjustments as the levels of ribavirin can be increased dramatically. Some people who are taking ribavirin experience what is commonly called "riba-rage," that is they get easily irritated and get angry easier.

POTENTIAL DRUG INTERACTIONS

Ribavirin cannot be used with didanosine (Videx-EC, Videx, ddI) as this combination can lead to potentially fatal levels of ddI; similarly, azathioprine (an immunosuppressive) cannot be used. Ribavirin is okay to take with other HIV antivirals, but check closely for anemia.

MORE INFORMATION

It's not entirely understood how ribavirin works against HCV, but along with interferon, it's been a major part of HCV treatment for years, and while interferon is no longer used, ribavirin continues to play an important role in many treatments and patient populations. That said, we are in the ribavirin-free era with many of the current HCV DAAs and all of the soon-to-be-approved ones able to be used without it.

If you need to take it, the side effects can be difficult. If you become anemic while on ribavirin, your medical provider may be able to adjust the dose accordingly. The anemia often happens quickly, so get blood tests to monitor it early in your treatment. "Riba-rage" is not a common occurrence, but it's good to be aware and (if disclosing HCV status is not an issue) telling the people around you about it so you can get the support you need to minimize its impact.

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OR THE LATEST NEWS. GO TO THE NEW POSITIVELYAWARE.COM.

HEPATITIS C PATIENT ASSISTANCE PROGRAMS

Treatment for HCV can be expensive, but the good news is that help is out there. All of the pharmaceutical companies have a patient assistance program (PAP) to help uninsured people, and some also provide help for underinsured people to cover all or part of the costs of their drug. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. Check with each program for details.

FINANCIAL ASSISTANCE AND ACCESS ADVOCACY PROGRAMS

Harbor Path
Provides a single site for all patient assistance program applications for both HIV and HCV medications.
harborpath.org

HealthWell Foundation
Their newly formed hepatitis C co-pay assistance program can provide up to $15,000 to eligible patients who are insured and have an annual household income of up to 500% of the federal poverty level.
(800) 675-8416
HealthWellFoundation.org

Link2Labs
A discount lab service for uninsured, low income and high deductible insured persons. They have lab services in all states except: CT, MA, NJ, NY and RI. Their easy-to-use website allows you to enter the labs you need, pay for them, find a lab near your ZIP code, and receive your results securely online.
Link2labs.com

Needy Meds
Provides a one-stop site for patient assistance programs and other discount opportunities for a variety of pharmaceuticals; also has a very useful database to find free and low-cost medical clinics that can be searched by ZIP code.
needymeds.com

Partnership for Prescription Assistance
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop shopping site for over 475 public and private patient assistance programs, including around 200 offered by the drug companies themselves. They also have a directory of over 10,000 free or low-cost clinics that can be searched by ZIP code.
pparx.org

Patient Access Network Foundation
Has an HCV-specific program, and can offer up to $7,200 in financial assistance for eligible individuals.
(866) 316-7263
panfoundation.org

Patient Advocate Foundation
Has an HCV-specific program, and a "Co-Pay Relief" program that can offer up to $24,000 in co-pay assistance for eligible individuals. They also have case managers who can assist patients with insurance denials and access to care issues.
(800) 532-5274
copays.org/diseases/hepatitis-c

PHARMACEUTICAL CO-PAY AND PATIENT ASSISTANCE PROGRAMS

DRUG NAME	MANUFACTURER	PHONE NUMBER	WEBSITE
Daklinza	Bristol-Myers Squibb	(844) 44-CONNECT (844) 442-6663)	daklinza.bmscustomerconnect.com/patient-support
Epclusa	Gilead Sciences	(855) 7-MYPATH (855) 769-7284	mysupportpath.com
Harvoni	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284)	mysupportpath.com
Moderiba	AbbVie	(844) MODERIBA (844) 663-3742	moderiba.com/patient-support/financial
Olysio	Janssen Therapeutics	(855) 5-OLYSIO (855) 565-9746	olysio.com/support
Ribasphere	Kadmon	(888) 668-3393	ribapak.com/hcp/resources.html
Sovaldi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284	mysupportpath.com
Technivie	AbbVie	(844)-2PROCEED (844) 277-6233)	viekira.com/patient-support/financial-resources
Viekira XR	AbbVie	(844)-2PROCEED (844) 277-6233	viekira.com/patient-support/financial-resources
Zepatier	Merck	(866) 251-6013	merckhelps.com/ZEPATIER

ISTOCKPHOTO

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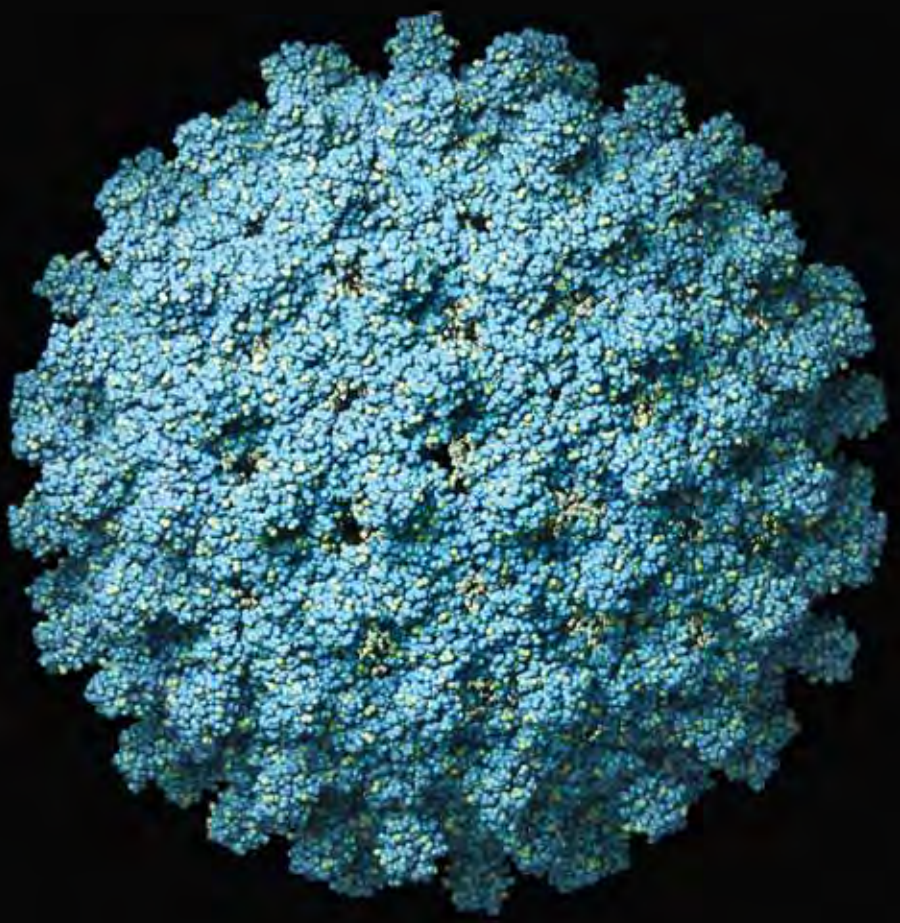
WHAT YOU SHOULD KNOW ABOUT HEPATITIS B

Another important virus to keep in mind

BY ANDREW REYNOLDS



This year's hepatitis drug guide takes on hepatitis B virus (HBV) in addition to hepatitis C. Both viruses commonly affect people living with HIV. Testing and treatment for both is important for the HIV-positive population and others vulnerable to HBV.

This is not an exhaustive review of all things related to HBV, but this article will cover four basic topics: transmission, testing, vaccination, and treatment. We're not going to cover pregnancy in detail: That is a complicated subject that deserves an article of its own. Check out the Hepatitis B Foundation listed in the HBV resource section on page 57 for more information related to HBV and pregnancy. >>

An overview

HBV is a virus that infects the liver. It is the most common infectious disease in the world, with over 2 billion people worldwide having been infected with it in their life, and approximately 240 million of those are chronically infected (living with HBV). Worldwide, it leads to over 780,000 deaths per year. In the United States there are between 850,000 and 2.2 million people living with HBV, and about 10% of people living with HIV are co-infected with it.

Transmission

Hepatitis B is transmitted in much the same way as HIV: It's spread when the blood, semen, vaginal fluids, or other body fluids of an HBV-infected person gets into a person who is not infected or protected by immunity (through vaccination or cleared infection). It is also commonly transmitted from mother to child during birth.

Only about 5 to 10% of adults exposed to HBV will be chronically infected. That said, HBV is highly infectious through blood or sexual fluids, so if you think you've been exposed to it and have not been vaccinated, you should go see a medical provider ASAP: There are ways to prevent infection after exposure (called post-exposure prophylaxis, or PEP). And of course, if you have not yet been vaccinated, see your medical provider or head to an STD clinic to start an HBV vaccination schedule. See below for more details about testing and vaccination. >>

WHO SHOULD GET TESTED FOR HBV?

THERE ARE THREE BROAD CATEGORIES for determining who should be tested for HBV: People from countries with high rates of HBV ("endemic" is the term used to describe this), people in certain medical situations or conditions, and people with certain risk factors. If someone was born in certain regions of the world, including but not limited to Asia, Southeast Asia, sub-Saharan Africa, and certain parts of the Mediterranean and South America, they should be screened. This is especially important for immigrants, refugees, asylum seekers, and children adopted from abroad. Similarly, if a child is born to a mother from one of these regions, they should be tested, too. In addition to screening based on country of origin, there are certain medical conditions or situations (such as hemodialysis patients or all pregnant women), as well as groups with certain risk factors.

Who should get screened

Anyone from endemic regions of the world

- Anyone born in a country with HBV rates greater than 2%
- Anyone born in the U.S. who did not receive a vaccination and whose parents were born in a country with HBV rates greater than 8%

Anyone with certain medical situations or conditions

- All pregnant women
- Babies born to HBV-infected mothers
- Hemodialysis patients
- Anyone needing immunosuppressive therapy (such as chemotherapy or those receiving organ transplants)
- Anyone with HCV before undergoing DAA therapy
- Donors of blood, plasma, organs, tissues, or semen (before donation)
- Anyone with an unexplained elevated ALT/AST liver test

Risk-based

- Anyone who injects drugs
- Men who have sex with men
- Anyone living with HIV
- Household members, needle-sharing (including injection equipment), or sex partners of anyone who has HBV
- Anyone who is the source of blood or body fluids resulting in a potential HBV exposure (such as an occupational needlestick, or blood splash, or sexual assault) where post-exposure prophylaxis may be necessary

SOURCE: CENTERS FOR DISEASE CONTROL (CDC.GOV/HEPATITIS)

These activities have been associated with the risk of transmission:

Mother-to-child transmission during pregnancy and labor

Condomless sex with an infected partner

Sharing syringes and other drug-injection equipment (cookers, cotton, water, etc)

Sharing household items such as razors or toothbrushes with an infected person

Other blood-to-blood contact

Occupational exposure from needlesticks or other risks of blood-to-blood contact

Other than transmission via blood, sex, or mother-to-child, HBV is very hard to get. It is not transmitted from casual contact, including the following:

Sharing eating utensils

Sharing drinking glasses

Hugging or kissing

Exposure to other body fluids such as sweat or tears

Hepatitis B is not transmitted through food (that's hep A), but can be transmitted from an HBV-infected mother to baby through pre-chewed food.

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Testing

Hepatitis C is often called the "silent epidemic," as most people who have it don't know it due to a lack of noticeable symptoms. The same can be said of HBV: Most people who get HBV don't know it because it rarely leads to signs or symptoms in the acute or chronic stages of infection. Over time, as the liver gets damaged, noticeable symptoms may arise, but screening for the virus is the only way to be sure you're infected or not.

Testing for HBV can be intimidating, especially when compared to some of the other testing you may have done for other diseases. When you take an HIV test, your results are either negative or positive for HIV antibodies. Hepatitis C testing is a little more involved: You test either negative or positive for HCV antibodies, and then do a confirmatory viral load test to confirm a positive result.

Hepatitis B testing is more complex. It is a blood test that looks for a marker or a series of markers to determine where a person is at on the spectrum of HBV infection (acute or chronic), if immune to it (through vaccine or natural immunity from prior infection), or vulnerable to infection and in need of vaccination.

Your medical provider will help you make sense of the results, but it is still important for you to understand them, too. **The chart below** provides you with the various results and explains what they mean.

Again, this looks intimidating: If you get a lab result without any explanation of the results, you can compare to the results listed above. Your medical provider can also explain the results. Check out the HBV resources section on page 57 for more

SEROLOGIC MARKERS FOR HBV—

What do they mean?

SEROLOGIC MARKER	RESULT	INTERPRETATION / MEANING
HBsAg **anti-HBc** **anti-HBs**	NEGATIVE NEGATIVE NEGATIVE	**Susceptible; get vaccinated**
HBsAg **anti-HBc** **anti-HBs**	NEGATIVE POSITIVE POSITIVE	**Immune due to natural infection;** no vaccination necessary
HBsAg **anti-HBc** **anti-HBs**	NEGATIVE NEGATIVE POSITIVE	**Immune due to hepatitis B vaccination**
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	POSITIVE POSITIVE POSITIVE NEGATIVE	**Acutely (recently) infected**
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	POSITIVE POSITIVE NEGATIVE NEGATIVE	**Chronically infected;** monitor disease, prevent transmission to others, and if necessary, treat the infection
HBsAg **anti-HBc** **anti-HBs**	NEGATIVE POSITIVE NEGATIVE	**Interpretation is unclear, with four potential outcomes:** **1.** Resolved infection **2.** False-positive anti-HBc (and vulnerable to infection) **3.** "Low level" chronic infection **4.** Resolving acute infection Follow-up visits with a medical provider for further tests to monitor what is happening and ultimate result.

SEROLOGIC DEFINITIONS

HBsAg: Hepatitis B surface antigen. **Anti-HBs:** Hepatitis B surface antibody. **Anti-HBc:** Total hepatitis B core antibody. **IgM anti-HBc:** Immunoglobin M antibody to hepatitis B core antigen.

SOURCE: CENTERS FOR DISEASE CONTROL (CDC.GOV/HEPATITIS)

WHO SHOULD GET VACCINATED?

THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDS THAT THE FOLLOWING PERSONS BE VACCINATED AGAINST HEPATITIS B:

All infants, beginning at birth

All children under 19 years of age who have not been vaccinated previously

Susceptible sex partners of hepatitis B surface antigen (HBsAg)-positive persons

Sexually active persons who are not in a long-term, mutually monogamous relationship (for example, had more than one sex partner during the previous six months)

Anyone seeking evaluation or treatment for a sexually transmitted disease

Men who have sex with men

Injection drug users

Susceptible household contacts of HBsAg-positive persons

Health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids

Anyone with end-stage renal disease, including pre-dialysis, hemodialysis, peritoneal dialysis, and home dialysis patients

Residents and staff of facilities for developmentally disabled persons

Travelers to regions with intermediate or high rates of endemic HBV infection

Anyone with chronic liver disease

Anyone with HIV infection

Unvaccinated adults with diabetes mellitus ages 19 through 59 years (discretion of clinicians for unvaccinated adults with diabetes mellitus who are age 60 and over)

All other persons seeking protection from HBV infection—acknowledgment of a specific risk factor is not a requirement for vaccination

information and HBV phone lines to help you make sense of the results.

Vaccination

Hepatitis B is vaccine preventable. The vaccine is safe and highly effective in preventing HBV, working in over 95% of people who get it. The vaccine is administered at 0, 1, and 6 months. This vaccine is effective for the rest of your life with no need for a booster shot in your future.

If a person already has HBV, the vaccination will offer no protection against disease progression and risk of liver disease. Sometimes, people get vaccinated without getting checked for chronic infection: Ask your medical provider if you have been checked for chronic HBV infection (or, if you are someone who was exposed to the virus and then cleared it, and are thus naturally immune) before starting a vaccination schedule.

Treatments

While HBV is preventable with a vaccine, to date there is no cure for it. There are treatments, however, that can help control and slow the virus from reproducing. These treatments can slow down the damage done to the liver and reduce the risk of long-term problems like cirrhosis or liver cancer.

While HBV is treatable, not everyone needs to be treated. HBV treatment is not recommended for someone in the acute stage of infection: Most people will clear it naturally and treatment doesn't look to improve the chances of clearing it. If someone is chronically infected, but has normal liver function tests called ALT or elevated ALT with low or undetectable HBV viral loads, then they do not need >>

A FORGOTTEN RISK

Hep B prevention in people who inject drugs

The risk of HIV and hepatitis C infection from the sharing of syringes and related injection equipment gets the most attention; it is important to keep HBV at the forefront of our prevention efforts, too. Indeed, one of the first needle exchange programs was started in Amsterdam by a group of people who inject drugs (PWID) and their allies in response to an HBV outbreak.

As the opioid crisis rages throughout the United States, we are seeing increases in HBV rates among PWID, and in pregnant women infected due to injection drug use that can lead to mother-to-child transmission if gone unchecked. See below for some prevention and harm reduction tips to reduce the risk of infection among PWID.

HBV PREVENTION TIPS FOR PWID:

HBV vaccination. This is easily the most important recommendation: Get vaccinated and you don't have to worry about getting infected later. All PWID should be vaccinated against HBV. Test to make sure you don't already have it or are already immune to it (see page 42). If you're still at risk of infection, get vaccinated.

Safe injection practices. New, unused injecting equipment—syringes, cookers, cotton, water, etc.—for each injection is the best way to prevent HBV (as well as HCV and HIV). Check to see where you can get these in your local area: Syringe access sites may be available, or you may be able to purchase syringes from a pharmacy.

Other harm reduction practices. New, unused injection equipment is the gold standard for prevention, but if you have no access to them and have to share or reuse them, rinsing them with bleach is the next best thing. In lab settings, bleach has been shown to be effective in disinfecting and killing HIV, HCV, and HBV. You should rinse with cold water, draw up the bleach (ideally keep the bleach in there for 2 minutes, then rinse it out with cold water again. For more information on how to use bleach to disinfect a syringe, check out this video: harmreductionworks.org.uk/2_films/does_cleaning_syringes_work.html.

Reducing or stopping injection drug use. If you are ready for drug treatment or can get into opioid replacement therapy, you won't be injecting drugs any longer and thus not at risk. This is easier said than done, so if you're not ready, you may consider different, non-injecting ways of taking your drug of choice. If you snort drugs, don't share straws. If you smoke them, don't share pipes or try to cover the mouthpiece to avoid any potential blood contact. If you choose to stop (or are forced to stop due to incarceration or other reasons), be mindful of the risk of opioid overdose should you use again. Be safe: If possible, don't use alone (each person using their own injecting equipment) and carry naloxone to reverse an overdose should one occur. Naloxone is available at many syringe access sites.

Practice safer sex and other prevention strategies. While preventing infection from injection drug use, don't forget about other ways to get it. Minimize your risk of sexual transmission through the use of condoms or other barriers.

HARM REDUCTION AND SAFER DRUG USE RESOURCES

The Harm Reduction Coalition
harmreduction.org
An advocacy and education organization that offers a safer injecting booklet, "Getting Off Right," found at harmreduction.org/wp-content/uploads/2011/12/getting-off-right.pdf.

The Chicago Recovery Alliance
anypositivechange.org
A racially and ethnically diverse group comprised of people living with HIV, hepatitis, and substance use who work to improve the health of people impacted by drug-related harm. They have an excellent safer injection guide, "Better Vein Care—Safer Injection Guide," along with educational videos, found at anypositivechange.org/bvcsiALL.pdf.

treatment. While they do not need treatment, they should be monitored routinely and engage in healthy liver behaviors and activities.

Treatment for HBV is called for in anyone with cirrhosis, regardless of ALT or HBV viral load. Similarly, anyone living with chronic HBV who is undergoing immunosuppressive therapy should be treated to prevent an HBV flare-up. There are other varied scenarios where a person should be treated for HBV, but those conversations are best to be had with a medical provider. If you're living with HBV and are concerned about whether or not you should take HBV treatment, talk with your medical provider.

Currently there is no cure for HBV. There are several drugs under investigation to determine their effectiveness and safety for treating and curing HBV. Stay tuned to POSITIVELY AWARE and other resources for updates on research on new therapies and cures.

For more information on HBV treatments, check out the pages 46–51.

Conclusions

Hepatitis B is very common and a potentially deadly infection that leads to much suffering worldwide. The burden in the U.S. is also high, with new outbreaks and infections spreading due to injection drug use and mother-to-child transmission as a result of the opioid crisis. To date, we have no cure, but with increased vaccinations and screening we can eliminate HBV in the U.S. and beyond. PA

TEN WAYS TO LOVE YOUR LIVER

Health and wellness tips for living well with HBV

1. Learn about HBV. Hepatitis B can be complicated, from understanding the test results to managing chronic infection to making treatment decisions. There are excellent resources available to help you. Start here with this guide, and then check out the "Hepatitis B Resources" on page 57 to learn more.

2. Get the hepatitis A vaccine. Hepatitis A is a viral infection of the liver. It's a short-term (also called "acute") infection that, while it will make you miserable, is rarely serious. However, if you live with HIV, HCV, or HBV, you should get vaccinated as it could make your liver disease worse. It's a two shot sequence: After your first shot, you get the second one 6 months later.

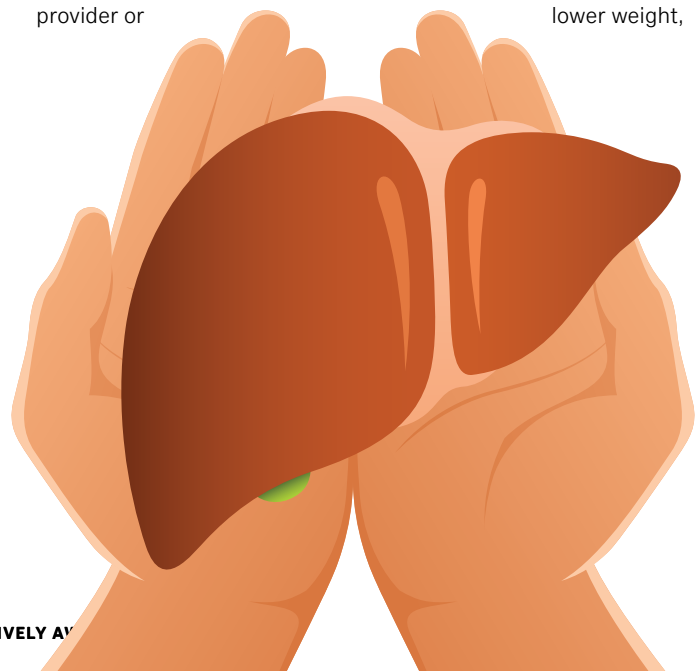
3. Test for hepatitis C (HCV) and HIV. Co-infection with either disease can increase the risk of liver damage in a shorter amount of time. Knowing your status for HCV and HIV is also important for treatment decisions for all three viruses.

4. Avoid alcohol. Ideally, people with HBV should not drink alcohol. Too much alcohol alone can be very hard on the liver, and alcohol and viral hepatitis are not a good mix: It speeds up *and* worsens HBV-related liver damage. Changing a drinking habit is hard, so get the help and support you need to reduce or quit safely.

5. Eat well. People with liver disease should minimize their fat intake, as well as watch their sugar and sodium. The more fresh fruits and vegetables you can eat the better. Do not eat raw or undercooked shellfish. Talk with your medical provider or pharmacist before starting any vitamins, minerals, or herbal supplements.

6. Drink coffee. Coffee has been shown to both slow down liver disease and reduce the risk of cirrhosis and liver cancer. It's not entirely clear why it works, but it does. Drinking 2–3 cups per day may improve your liver health.

7. Exercise. Check with your medical provider first to make sure it's safe to exercise. Exercise will burn calories and fat, maintain or lower weight, and lower stress. Exercise also helps against feeling tired and may even improve your mood. You don't have to do anything super difficult: Something as simple as a 30-minute-a-day walk can help.



AALTAZAR /ISTOCKPHOTO

8. Tell your sexual partners to test and see if they need to get vaccinated for HBV. As HBV can be transmitted sexually, talking to your sexual partners about HBV and preventing transmission is important. Sexual partners who have not been vaccinated against HBV should be.

9. Practice safe injection and safe sex practices to avoid infecting others. As HBV can be transmitted through the sharing of injection equipment, talking to your drug-using partners about HBV and preventing transmission is important. Drug-sharing partners who have not been vaccinated against HBV should be.

10. See your provider regularly and check for liver damage. You may not need HBV treatment; indeed, most people don't need it. It is still important to monitor your liver and get regular checkups.

HEPATITIS B MEDICATIONS BY CLASS

CLASS	BRAND NAME	GENERIC/COMMON NAME	STATUS	MANUFACTURER	SEE PAGE
Nucleoside reverse transcriptase inhibitor; NRTI	Epivir-HBV	lamivudine, 3TC	APPROVED	GlaxoSmithKline	46
	Baraclude	entecavir, ETV	APPROVED	Bristol-Myers Squibb	48
	Hepsera	adefovir, ADV	APPROVED	Gilead Sciences	47
	Viread	tenofovir disoproxil fumarate, TDF	APPROVED	Gilead Sciences	50
	Vemlidy	tenofovir alafenamide, TAF	APPROVED	Gilead Sciences	49
Interferon-alfa	Pegasys	peginterferon alfa-2a, PEG-IFN	APPROVED	Genentech	51
	Intron A	interferon alfa-2b	APPROVED	Merck	51

REACTIVATING HEPATITIS B

Hepatitis B reactivation in people co-infected with HCV and HBV undergoing HCV Direct-Acting Antiviral therapy

HBV reactivation has occurred in people co-infected with HCV/HBV while they were either on or shortly after HCV DAA treatment, resulting in hepatic flares, and in some cases a liver transplant or death. This reactivation does not happen to everyone—there were 24 cases reported to the FDA over approximately two and a half years—but it's a serious enough risk that **several precautions should be taken:**

PATIENTS SHOULD BE SCREENED for HBV with both an HBsAg and an anti-HBc test before starting any HCV DAA (for more details on testing, see page 45).

PATIENTS WHO TEST NEGATIVE for HBV should be vaccinated against it.

PATIENTS WHO TEST POSITIVE for HBV should be assessed to see if they need HBV treatment prior to starting HCV treatment.

PATIENTS WITH HBV should be monitored with blood tests and clinically for signs of a hepatic flare-up or HBV-reactivation.

PATIENTS MAY NEED to take anti-HBV medications to treat active infection or reactivation.

In addition to these clinical measures taken by a medical provider, patients should watch for any signs or symptoms of HBV reactivation, including the following: Yellowing of the eyes or skin (jaundice), loss of appetite, nausea or vomiting, lighter-colored stools, pain in the liver (right side of the belly, below the ribs), weakness, and fatigue.

It's important to note that while this is a potentially serious adverse event that can be very frightening for someone living with HCV/HBV, it does not mean that she or he cannot be treated for HCV with DAAs. With proper monitoring and appropriate prevention measures, patients can be safely and successfully cured of HCV with no reactivation of HBV.

RIZVAN3D /ISTOCKPHOTO

Epivir-HBV lamivudine, or 3TC

DRUG CLASS
Nucleoside reverse transcriptase inhibitor; NRTI, "nuke"

MANUFACTURER
GlaxoSmithKline

AWP
$1,1760.76 / month; generic: $966.66 / month

DOSAGE

ADULT: **One 100 mg tablet once daily, with or without food.**

PEDIATRIC (AGE 2-17): **3 mg per kg of weight, for no more than 100 mg per day. Oral solution (liquid) for dosages less than 100 mg.**

Dose adjustments needed for individuals with kidney disease. See below and consult a medical provider for more detail. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

Generic available.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Overall, Epivir-HBV is a very well tolerated medication with minimal side effects. When side effects do occur, they include headache, nausea, fatigue, and diarrhea. Nasal symptoms and cough can occur, too. Insomnia, dizziness, and muscular pain may also occur. There are two potentially serious side effects when taking Hepsera. Lactic acidosis: The build-up of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued; difficulty breathing; stomach pain with nausea and vomiting; feeling cold and chills, especially in arms and legs; dizziness and light-headedness; fast or irregular heartbeat; or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, pain, and achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Epivir-HBV has no significant drug interactions. Epivir-HBV should not be taken with full strength Epivir for HIV treatment. It should not be taken with the following HIV combination medications, as they already contain Epivir or other related medications: Atripla, Combivir, Complera, Descovy, Emtriva, Epzicom, Genvoya, Hepsera, Odefsey, Stribild, Triumeq, Trizivir or Truvada.

MORE INFORMATION

Don't confuse Epivir-HBV with Epivir for the treatment of HIV: Epivir-HBV is 100mg while the Epivir for the treatment of HIV is 300mg. If you are co-infected with HBV/HIV, you should take the 300mg dose. If you are co-infected, you should not treat HBV without also treating HIV: Resistance can develop if that occurs. Another HIV medicine—Viread—also works against both HIV and HBV, and is another option for treatment. Taken together, they can help decrease the risk of HBV drug resistance. If your HIV becomes resistant to Epivir, it does not mean your HBV did (and vice versa). If you have HBV, and need to switch from any Epivir-containing regimens, there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those at risk of HBV reactivation while undergoing HCV DAA treatment, Epivir-HBV is one of the medications you could be prescribed to prevent it from happening.

Dosage of Epivir-HBV in adult patients with renal impairment

CREATININE CLEARANCE (mL/min)	RECOMMENDED DOSAGE
50 or less	100 mg once daily
30–49	100 mg first dose, then 50 mg once daily
15–29	100 mg first dose, then 25 mg once daily
5–14	35 mg first dose, then 15 mg once daily
less than 5	35 mg first dose, then 10 mg once daily

Hepsera adefovir dipivoxil, adefovir, or ADV

DRUG CLASS
Nucleoside reverse transcriptase inhibitor; NRTI, "nuke"

MANUFACTURER
Gilead Sciences

AWP
$1,588.42 / month

DOSAGE

One 10 mg tablet once daily, with or without food. Dose adjustments needed for individuals with kidney disease. Not recommended for use in children under age 12.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Hepsera is a well tolerated medication, with the following potential side effects: asthenia (weakness), headaches, abdominal pain, nausea, excessive gas, diarrhea, and dyspepsia (indigestion). These tend to be mild and manageable. As Hepsera is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine and serum phosphorus should be standard of care, too. There are two potentially serious side effects when taking Hepsera. Lactic acidosis: The build-up of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued; difficulty breathing; stomach pain with nausea and vomiting; feeling cold and chills, especially in arms and legs; dizziness and light-headedness; fast or irregular heartbeat; or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, pain, and achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Do not take Hepsera with the HIV/HBV treatment Viread or Vemlidy, including any combination medications that include either of them: Atripla, Complera, Descovy, Odefey, Stribild, Genvoya, or Truvada. Hepsera is eliminated by the kidneys, so it should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin).

MORE INFORMATION

Hepsera was the second medication approved for treating HBV. Hepsera will not cure you of HBV (no HBV medication will cure you), but it can decrease your risk of long-term complications like cirrhosis or liver cancer. Although Hepsera is not an HIV medication, it does have some activity against HIV and should not be taken by itself if you are HIV-positive. If your HBV is resistant to Epivir-HBV (lamivudine), use Hepsera with Epivir-HBV. If your HBV viral load does not fall below 1,000 copies/ml with this combination, you and your medical provider should consider alternative treatments. Hepsera is not to be used in people with decompensated cirrhosis.

If you have kidney disease and/or are on hemodialysis,
Hepsera can be taken safely, but with the following dose adjustments:

CREATININE CLEARANCE (mL/min)	RECOMMENDED DOSAGE AND SCHEDULE
50 or greater	10 mg every 24 hours
30-49	10 mg every 48 hours
10-29	10 mg every 72 hours
Hemodialysis patients	10 mg every 7 days following dialysis

Baraclude entecavir, or ETV

DRUG CLASS
Nucleoside reverse transcriptase inhibitor; NRTI, "nuke"

MANUFACTURER
Bristol-Myers Squibb

AWP
$1,646.98 / month for both .05 mg and 1 mg tablets

DOSAGE

ADULT (AGE 16 AND OLDER): **If treatment-naïve with no resistance, one 0.5 mg tablet once daily on an empty stomach (no food 2 hours before or 2 hours after taking pill). If resistant to lamivudine or telbivudine (brand name Tyzeka, discontinued for use since December 2016), 1 mg once daily on an empty stomach.**

ADULT WITH DECOMPENSATED LIVER DISEASE: **1 mg once per day. Dose adjustments needed for individuals with kidney disease. See drug page and consult a medical provider for more detail.**

PEDIATRIC (AGE 2-15): **Weight-based dosing required. See package insert and consult your medical provider. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.**

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Baraclude is a very well tolerated medication with minimal side effects. When side effects do occur, they include headache, fatigue, dizziness, and nausea. There are two potential serious side effects when taking Baraclude. Lactic acidosis: The build-up of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills, especially in arms and legs, dizziness and lightheadedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, pain, and achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Baraclude is safe to take with all HIV medications, with no drug interactions. Baraclude is eliminated by the kidneys, so it should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin).

MORE INFORMATION

Baraclude will not cure you of HBV (no HBV medication will cure you), but it can decrease your risk of long-term complications like cirrhosis or liver cancer. Baraclude is one of three preferred medications (including Viread and pegylated interferon) for the treatment of HBV in both mono- and HBV/HIV co-infected persons. Although Baraclude is not an HIV medication, it does have some activity against HIV. It should not be taken by itself if you are HIV-positive. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV. You should be checked for resistance to Epivir (lamivudine) before starting Baraclude: Epivir resistance decreases the effectiveness of Baraclude at the 0.5 mg dose, and must be increased to 1 mg.

For patients with kidney disease, the following chart reviews the dosage requirements:

CREATININE CLEARANCE (mL/min)	PRESCRIBED DOSE: 0.5 MG	DOSE FOR LAMIVUDINE-REFRACTORY OR PATIENTS WITH DECOMPENSATED CIRRHOSIS: 1.0 MG
50 or greater	0.5 mg once per day	1 mg once per day
30 to 49	0.25 mg once per day or 0.5 mg every 48 hours	0.5 once per day or 1 mg every 48 hours
10 to 29	0.15 mg once per day or 0.5 mg every 72 hours	0.3 mg once per day or 1 mg every 72 hours
Less than 10 or on dialysis	0.05 mg once per day or 0.5 mg every 7 days	0.1 mg once per day or 1 mg every 7 days

Vemlidy tenofovir alafenamide, or TAF

DRUG CLASS
Nucleoside reverse transcriptase inhibitor; NRTI, "nuke"

MANUFACTURER
Gilead Sciences

AWP
$1,197.32 / month

DOSAGE

One 25 mg tablet once per day, with food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Vemlidy is a very well tolerated medication with minimal side-effects. The most commonly reported side effects were headache, abdominal pain, fatigue, cough, nausea and back pain. Not everyone experiences side effects, but among those who did, approximately 1% had to stop taking Vemlidy. As Vemlidy is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine and of serum phosphorus should be standard of care, too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain or fractures with or without muscular pain, consult your medical provider immediately. There are two potentially serious side effects when taking Hepsera. Lactic acidosis: The build-up of lactic acid in the blood that could be fatal.Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills, especially in arms and legs, dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, pain, and achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. As Vemlidy is related to Viread (tenofovir DF), the two medications cannot be taken together. Similarly, it cannot be taken with any of the following HIV combination medications, as they contain Tenofovir DF: Atripla, Complera, Descovy, Odefsey, Stribild, Genvoya, or Truvada. If taken with the anticonvulsant carbamazepine, Vemlidy dosage should be increased to two tablets once per day. Vemlidy should not be taken with oxcarbazepine, phenobarbital, or phenytoin. Vemlidy should not be taken with the antimycobacterial medications rifabutin, rifampin and rifapentine. Vemlidy should not be taken with St. John's wort.

MORE INFORMATION

Vemlidy was approved for HIV in 2015 and then for HBV in 2016. It's related to Viread (see page 50), using a smaller dose that is more efficiently delivered so the risks of kidney disease and loss of bone density appear to be less. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV. If you have HBV/HIV and need to switch from any Viread-containing regimens, there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those at risk of HBV reactivation while undergoing HCV DAA treatment, Vemlidy is one of the medications you could be prescribed to prevent it from happening. Vemlidy should not be used in patients with severe kidney disease who have a creatinine clearance below 15 mL per minute. Vemlidy should not be used in patients with decompensated cirrhosis (Child-Pugh B or C).

Viread tenofovir disoproxil fumarate, or TDF

DRUG CLASS
Nucleoside reverse transcriptase inhibitor; NRTI, "nuke"

MANUFACTURER
Gilead Sciences

AWP
$1, 279.94 / month

DOSAGE

ADULT (AGE 12 AND OLDER): **One 300 mg tablet once daily, with or without food. Dose adjustment needed for individuals with kidney disease. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose. Also available as 200 mg and 250 mg tablets. Not recommended for use in children under age 12.**

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Viread is a very well tolerated medication with minimal side effects. The most commonly reported side effects are diarrhea, nausea, asthenia (muscle weakness), headache, depression, and abdominal pain. Other, more rarely reported side effects include rash, excessive gas, and generalized pain and achiness, including back pain. Nervous system side effects include depression, insomnia, peripheral neuropathy, and dizziness. Viread may lead to decreases in bone mineral density (BMD), and patients should be monitored for osteoporosis or osteopenia. As Viread is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine and of serum phosphorus should be standard of care, too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain or fractures with or without muscular pain, consult your medical provider immediately. There are two potential serious side effects when taking Viread. Lactic acidosis: The build-up of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued; difficulty breathing; stomach pain with nausea and vomiting; feeling cold and chills, especially in arms and legs; dizziness and light-headedness; fast or irregular heartbeat; or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, pain, and achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Do not take Viread with the HBV treatment Hepsera. Viread cannot be taken with any of the following HIV combination medications, as they contain tenofovir DF: Atripla, Complera, Descovy, Odefsey, Stribild, Genvoya, or Truvada. Viread reduces the levels of Reyataz meaning that Reyataz 300 mg must be boosted with Norvir 100 mg or Tybost 150 mg (taken together with food) when used together. Kaletra, Prezista/Norvir, and Reyataz/Norvir increase Viread levels, but do not require dose adjustments. This interaction may increase Viread-related side effects, and patients should be monitored for them (including kidney disorders). Viread should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin). Viread is safe to take with HCV DAAs, but monitor for side effects if used with Epclusa.

MORE INFORMATION

Viread (and its related drug Vemlidy) are also HIV medications. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV. Another HIV medication—Epivir—also works against both HIV and HBV, and is another option for treatment. If you have HBV/HIV, and need to switch from any Viread-containing regimens, there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those at risk of HBV reactivation while undergoing HCV DAA treatment, Viread is one of the medications you could be prescribed to prevent it from happening.

Intron A; Pegasys

DRUG CLASS
Interferon-alpha

MANUFACTURER
Pegasys: **Genentech (Roche);**
Intron A: **Merck**

AWP
Pegasys: **$4,760.35 / month**
Intron A: **$2,158 / month**

DOSAGE

Pegasys
ADULT: **180 mcg injected intramuscularly once per week, no food restrictions.** PEDIATRIC: **Not recommended, but off-label use is possible. Consult with a medical provider for more information. Treatment length is 48 weeks.**

Intron A
ADULTS AND PEDIATRICS (AGE 1 AND OLDER): **3 million IU/m² three times a week (TIW) for the first week of therapy followed by dose escalation to 6 million IU/m² TIW (maximum of 10 million IU TIW) injections. Treatment length is 16 weeks for adults and 16–24 weeks for pediatrics.**

Take your missed dose as soon as possible on the same day or the next day and then continue on your regular dosing schedule; if multiple days are missed, check with your medical provider about what to do; never double dose or take doses too close together.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Interferon is associated with a large number of side effects: fatigue, headaches, nausea, chills, insomnia, anemia, pyrexia (fever), injection site reactions, loss of appetite, rash, myalgia (muscle pain), neutropenia, irritability, depression, alopecia (hair loss), dyspnea (shortness of breath), arthralgia (joint pain), pruritis (itching), flu-like feelings, dizziness, diarrhea, cough, weight loss, vomiting, unspecified pain, dry skin, anxiety, abdominal pain, leukopenia, and thrombocytopenia. In the case of the psychiatric/emotional side effects, interferon has been associated with depression, anxiety, and, in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HBV treatment (it does not mean you can't take HBV treatment, you just want to watch for signs and be able to take preventative actions ahead of time). As an injectable, injection site reactions (redness, swelling, and/or itching) and inflammation are common. If you have autoimmune hepatitis, or are allergic to any of the ingredients in interferon, you should not take it.

POTENTIAL DRUG INTERACTIONS

There are few drug interactions with interferon: Be sure to tell you medical provider or pharmacist about all the medications and herbs you take, whether prescribed, over-the-counter, or illicit, before starting this drug. Caution is advised when taken with warfarin, phenytoin, or methadone. Methadone levels may increase due to interferon, so methadone levels and signs and symptoms of a stronger narcotic effect should be monitored.

MORE INFORMATION

While interferon is no longer used in HCV treatment, there is still a potential role for it in HBV. That said, it is rarely used for HBV treatment. The World Health Organization does not include it in their HBV guidelines. It has some clinical advantages over the oral antivirals, as it's a finite therapy and it doesn't lead to HBV resistance, but it's a hard medication to take. Other medications are easier to take with fewer side effects. The AASLD Guidelines for the Treatment of Hepatitis B does include pegylated interferon alfa (PEG-IFN-a), along with Baraclude (entecavir or ETV) and Viread (tenofovir disoproxil fumarate or TDF) as first-line agents in the treatment of HBV. If you need HBV treatment, talk to your medical provider about which option is best for you.

WHAT IS GENVOYA®?

GENVOYA is a 1-pill, once-a-day prescription medicine used to treat HIV-1 in people 12 years and older who weigh at least 77 pounds. It can either be used in people who are starting HIV-1 treatment and have never taken HIV-1 medicines before, or people who are replacing their current HIV-1 medicines and whose healthcare provider determines they meet certain requirements. These include having an undetectable viral load (less than 50 copies/mL) for 6 months or more on their current HIV-1 treatment. GENVOYA combines 4 medicines into 1 pill taken once a day with food. GENVOYA is a complete HIV-1 treatment and should not be used with other HIV-1 medicines.

GENVOYA does not cure HIV-1 infection or AIDS.

To control HIV-1 infection and decrease HIV-related illnesses, you must keep taking GENVOYA. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

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

GENVOYA may cause serious side effects:

- **Worsening of hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking GENVOYA, your HBV may suddenly get worse. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to monitor your health.

Who should not take GENVOYA?

Do not take GENVOYA if you take:

- **Certain prescription medicines for other conditions.** It is important to ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA. Do not start a new medicine without telling your healthcare provider.
- **The herbal supplement** St. John's wort.
- **Any other medicines to treat HIV-1 infection.**

What are the other possible side effects of GENVOYA?

Serious side effects of GENVOYA may also include:

- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking GENVOYA.
- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. If you develop new or worse kidney problems, they may tell you to stop taking GENVOYA.
- **Too much lactic acid in your blood (lactic acidosis),** which is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Severe liver problems,** which in rare cases can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

The most common side effect of GENVOYA is nausea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

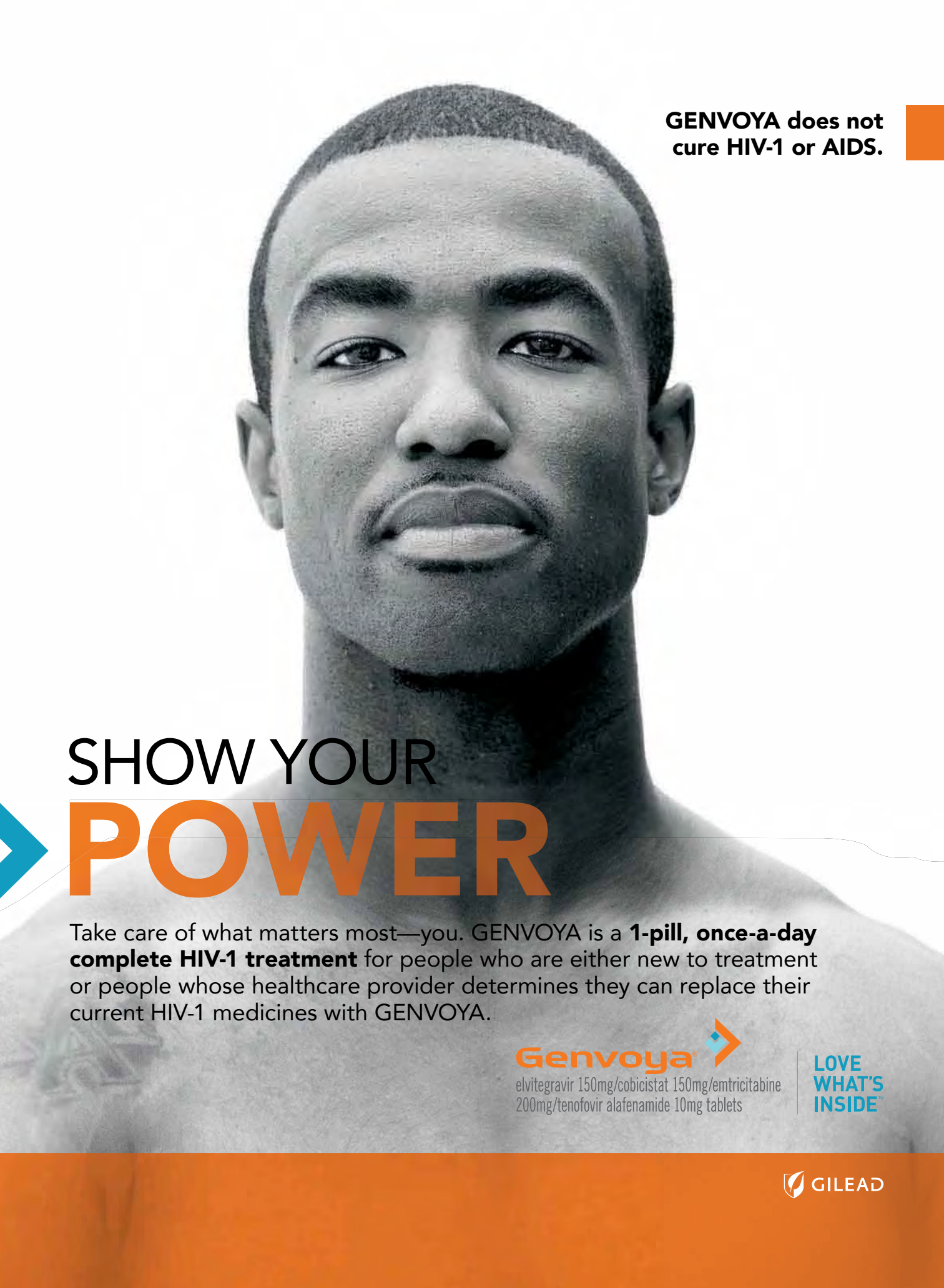
What should I tell my healthcare provider before taking GENVOYA?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how GENVOYA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Ask your healthcare provider if it is safe to take GENVOYA with all of your other medicines.
- **If you take antacids.** Take antacids at least 2 hours before or after you take GENVOYA.
- **If you are pregnant** or plan to become pregnant. It is not known if GENVOYA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking GENVOYA.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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.

Please see Important Facts about GENVOYA, including important warnings, on the following page.

Ask your healthcare provider if GENVOYA is right for you.


GENVOYA does not cure HIV-1 or AIDS.
SHOW YOUR
POWER
Take care of what matters most—you. GENVOYA is a **1-pill, once-a-day complete HIV-1 treatment** for people who are either new to treatment or people whose healthcare provider determines they can replace their current HIV-1 medicines with GENVOYA.
Genvoya®
elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets
LOVE WHAT'S INSIDE™
GILEAD

Genvoya®
elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets

(jen-VOY-uh)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT GENVOYA

GENVOYA may cause serious side effects, including:

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

ABOUT GENVOYA

- GENVOYA is a prescription medicine used to treat HIV-1 in people 12 years of age and older who weigh at least 77 pounds and have never taken HIV-1 medicines before. GENVOYA can also be used to replace current HIV-1 medicines for some people who have an undetectable viral load (less than 50 copies/mL of virus in their blood), and have been on the same HIV-1 medicines for at least 6 months and have never failed HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **GENVOYA does not cure HIV-1 or AIDS**. Ask your healthcare provider about how to prevent passing HIV-1 to others.

Do NOT take GENVOYA if you:

- Take a medicine that contains: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®), cisapride (Propulsid®, Propulsid Quicksolv®), dihydroergotamine (D.H.E. 45®, Migranal®), ergotamine (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), lovastatin (Advicor®, Altoprev®, Mevacor®), lurasidone (Latuda®), methylergonovine (Ergotrate®, Methergine®), midazolam (when taken by mouth), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pimozide (Orap®), rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®), sildenafil when used for lung problems (Revatio®), simvastatin (Simcor®, Vytorin®, Zocor®), or triazolam (Halcion®).
- Take the herbal supplement St. John's wort.
- Take any other HIV-1 medicines at the same time.

GET MORE INFORMATION

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

POSSIBLE SIDE EFFECTS OF GENVOYA

GENVOYA can cause serious side effects, including:

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

The most common side effect of GENVOYA is nausea.

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

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

BEFORE TAKING GENVOYA

Tell your healthcare provider if you:

- Have or have had any kidney or liver problems, including hepatitis infection.
- Have any other medical condition.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA.

HOW TO TAKE GENVOYA

- GENVOYA is a complete one pill, once a day HIV-1 medicine.
- Take GENVOYA with food.

GILEAD

HEPATITIS B PATIENT ASSISTANCE PROGRAMS

You may have challenges accessing HBV treatments, but help is out there. All of the pharmaceutical companies that sell HBV medications have a patient assistance program (PAP) to help uninsured or underinsured people cover all or part of the costs of their drug. If you are insured, but have a high co-pay, there are co-pay assistance services, too. Additionally, there are non-profit organizations that can help with some additional support for co-pays. Check with each program for details.

The organizations listed below can help you find low-cost medical care, navigate the health care access and insurance field, or get financial assistance to help with HBV costs and related healthcare expenses. These programs have different eligibility requirements, and some have limited funds each year.

FINANCIAL ASSISTANCE AND ACCESS ADVOCACY PROGRAMS

HealthWell Foundation
Offers a co-pay assistance program that can provide up to $10,000 to eligible patients who are insured and have an annual household income of up to 400% of the federal poverty level.
(800) 675-8416
HealthWellFoundation.org

Needy Meds
Provides a one-stop site for patient assistance programs and other discount opportunities for a variety of pharmaceuticals; also has a very useful database to find free and low-cost medical clinics that can be searched by ZIP code.
needymeds.com

Partnership for Prescription Assistance
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop shopping site for over 475 public and private patient assistance programs, including around 200 offered by the drug companies themselves. They also have a directory of over 10,000 free or low-cost clinics that can be searched by ZIP code.
pparx.org

Patient Access Network Foundation
Has an HBV-specific program, and can offer up to $4,500 in financial assistance for eligible individuals.
(866) 316-7263
panfoundation.org

Patient Advocate Foundation
Has an HBV-specific program, and can offer up to $4000 in co-pay assistance for eligible individuals. They also assist patients with insurance denials and access to care issues.
800-532-5274
copays.org/diseases/hepatitis-c

ISTOCKPHOTO

PHARMACEUTICAL CO-PAY AND PATIENT ASSISTANCE PROGRAMS

MEDICATION	MANUFACTURER	WEBSITE	PHONE NUMBER
Epivir-HBV lamivudine	Glaxo Smith Kline	gskforyou.com/unisured-patient-assistance/prescription-medicines/	888-825-5249
Baraclude entecavir	Bristol-Myers Squibb	bms.com/patient-and-caregiver/get-help-paying-for-your-medications.html	855-898-0267
Hepsera adefovir	Gilead	gileadadvancingaccess.com	800-226-2056
Viread tenofovir disoproxil	Gilead	gileadadvancingaccess.com	800-226-2056
Vemlidy tenofovir alafenamide	Gilead	gileadadvancingaccess.com	800-226-2056
Intron A interferon alfa-2b	Merck	merckaccessprogram.com/hcp/intron-a/	855-257-3932
Pegasys pegylated interferon	Genentech	genentech-access.com/patient/brands/pegasys/how-we-help-you.html	888-422-2377

THE 14TH
RIDE FOR AIDS CHICAGO

YOU CAN STILL DONATE:
rideforaids.org

Thanks to you, we've raised over $4.8 million for HIV/AIDS and LGBTQ services in Chicago. The Ride for AIDS Chicago is produced by TPAN, the non-profit publisher of POSITIVELY AWARE.

WITH SPECIAL THANKS TO OUR SPONSORS

EMD SERONO · janssen · MERCK INVENTING FOR LIFE · Thera technologies · Hill-Rom · mb financial bank · B BRIDGEVIEW BANK GROUP · BRADFORD ALLEN · TCN · STEAM WORKS BATHS

RESOURCES, SERVICES, AND INFORMATION

To read the online version of the POSITIVELY AWARE HEPATITIS B & C DRUG GUIDE, go to positivelyaware.com. Here are additional sources

HEPATITIS B

Hepatitis B Foundation
Provides a wealth of information on HBV in all areas from awareness to prevention to treatment. They offer educational resources via fact sheets, videos, podcasts, and blog posts. They also have an excellent section on liver cancer via their Liver Cancer Connect program, and information on HBV and pregnancy. Information is offered in a variety of languages.
hepB.org

Asian Liver Center, Stanford University
A world-renowned program that works to eliminate the stigma of HBV, as well as prevent transmission and reduce deaths from liver disease in Asian Americans in the US and Asians throughout the world. It is an excellent resource for patients and providers.
Stanford.edu/liver.html

American Liver Foundation
Provides information and fact sheets on a wide range of liver diseases, including HBV and HCV. They also have an excellent program for caregivers of people with liver disease: CaringBridge. They have local chapters throughout the U.S. and often have educational and awareness events. Check their website for activities and events in your area.
liverfoundation.org

HBV Advocate
The hepatitis B page of the HCV Advocate has fact sheets and a blog on a wide array of HBV topics and information. An excellent source of scientific and conference data, too.
hcvadvocate.org/hbv

Know Hepatitis B
This education and social campaign has a variety of material, including fact sheets, posters, videos, and more on HBV in a wide variety of languages. There is also an excellent resource section for medical providers.
cdc.gov/knowhepatitisB/index.htm

HEPATITIS C

HELP-4-HEP
National hepatitis C support line staffed by peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9 am–7pm ET.
877-435-7443 toll-free

The HCV Advocate
Offers a wealth of HCV informational fact sheets and booklets. Monthly newsletter, *The HCV Advocate*.
hcvadvocate.org

Hepatitis Foundation International
An advocacy and education organization that offers an array of services and information related to viral hepatitis and other liver conditions.
hepatitisfoundation.org

The Hepatitis C Mentor and Support Group, Inc.
An excellent resource for HCV support groups throughout New York, with links to many other resources for people living with HCV.
hepatitiscmsg.org

Hep C Association
An excellent source for HCV news and information.
hepcassoc.org

Liver Health Connection
Array of services for people in Colorado. Excellent site for news and information.
liverhealthconnection.org

Project Inform
Advocates for issues related to HIV, HCV and health care access. Up-to-date information on HIV and HCV care and health care reform.
projectinform.org

Treatment Action Group
National advocacy, research, and policy think tank on HIV, hepatitis C, and tuberculosis. They produce fact sheets, policy papers, and annual *Pipeline Report*.
treatmentactiongroup.org

National AIDS Treatment Advocacy Project
Excellent website for scientific results from HIV and HCV conferences and academic articles.
natap.org

HIVandHepatitis.com
Presents high quality and accurate news coverage on the prevention and treatment of HIV, HCV, and HIV/HCV co-infection.
HIVandHepatitis.com

HepatitisC.net
Provides education, tools and resources to help you manage your disease. Articles are written by people living with HCV (including some who have been cured), patient advocates, and medical providers.
hepatitisc.net

Caring Ambassadors
An education and advocacy organization whose website offers a wealth of information for people living with HCV. Their *Hepatitis C Choices* book offers a comprehensive overview of all aspects of the disease.
hepcchallenge.org

NEW SITE OFFERS A VIEW OF HEPATITIS IN THE U.S.

AIDSVu.org, whose interactive website offers a visualization of HIV statistics from national to local levels, has launched a similar site for a state-by-state view of hepatitis across the U.S. HepVu.org provides basic information about hepatitis A, B, and C, along with a list of resources. Public health tracking for hepatitis C, in particular, is not as extensive as it has been with HIV, but the hope is that the new site will raise awareness among advocates, public health departments, policymakers, and citizens.

TPAN

30 YEARS OF HOPE

TPAN transforms lives through the power of hope. For three decades, TPAN has been a safe haven for those seeking a pathway that embraces self-empowerment and a non-judgmental philosophy of holistic care.

THURSDAY, SEPTEMBER 28, 2017

JOIN US, along with a group of TPAN's surviving founders, and special guest Peter Staley, HIV activist and an early member of ACT UP—for a special evening commemorating the 30th anniversary of TPAN.

Moonlight Studios 1446 W. KINZIE STREET CHICAGO
VIP RECEPTION AT 6 P.M. DOORS OPEN AT 7 P.M.
LIGHT HORS D'OEUVRES OPEN BAR
VIP $175 **GENERAL ADMISSION** $125

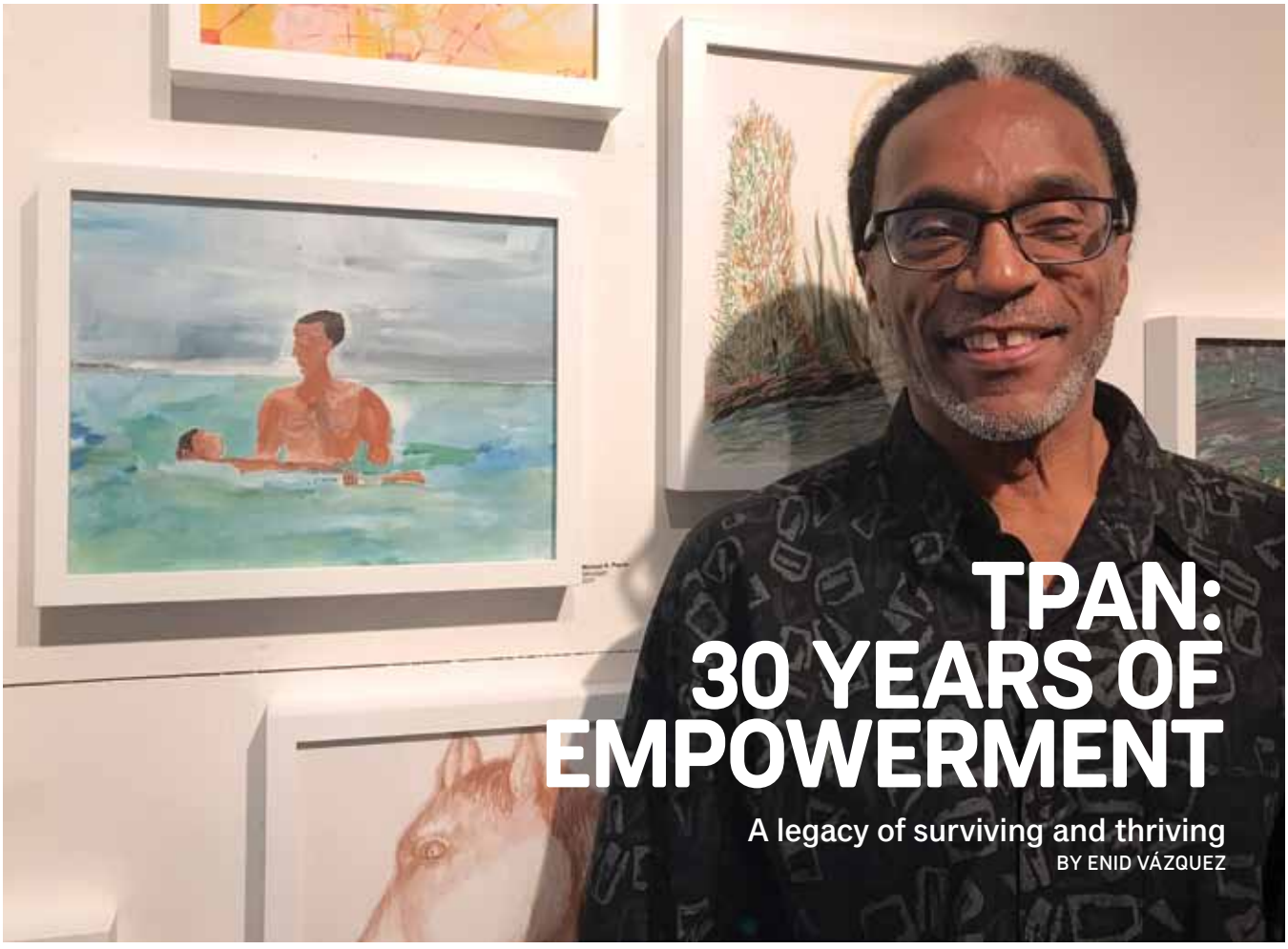
For details, contact James Craig, **j.craig@tpan.com**.

100% of this event's proceeds will support TPAN's mission. With your help, TPAN can continue to provide free HIV prevention, mental health, case management, and support services. TPAN is the proud publisher of the HIV treatment magazine POSITIVELY AWARE.

SOME OF TPAN'S FOUNDING MEMBERS GATHER AT BELMONT ROCKS, 1987. PHOTO BY BILLY HOWARD

TPAN 30 YEARS

Help TPAN in its mission to share information and support with those living with and vulnerable to HIV; go to **tpan.com/donate**.



TPAN: 30 YEARS OF EMPOWERMENT

A legacy of surviving and thriving

BY ENID VÁZQUEZ

PHOTO: JESSIE MOTT

As always, Michael Payne had some of his artwork bought at the annual exhibit of TPAN's art therapy group. Like the buyers and other attendees, I love Michael's work too. His art stands out for its beauty or its power, or both.

In 2008, I helped Michael write a story called "Saved By the Art." It remains one of my favorite stories of everything I've ever worked on for POSITIVELY AWARE. It talks about how Michael had set aside his prolific artwork for years, away in a closet, until an art class at TPAN brought back his artistic spirit and he hasn't stopped creating since. He went from suffering over his lipodystrophy—he was looking into surgery—to focusing on art, becoming a happy, creative spirit no longer dwelling on something he now saw as trivial and unimportant. That's what I loved most, because Michael was—and is—a beautiful man. As usual with this condition, the changes in his face were disturbing to him, but not others.

I told him how much I loved that story.

He said that while his sister was dying of cancer, he sent a copy to her. She never said anything about it, even though they talked every day on the phone.

At her funeral, his nephew said, "I saw the article." Michael feigned pulling back, showing me how he felt, as if his nephew might hit him. "I thought he might call me the 'f' word," (and Michael whispered *faggot*). Instead, his nephew said, "It was beautiful."

"I used the article to come out to them," he said, the first I knew about this, although I see Michael nearly every week. "It was my way of coming out as gay, and as HIV-positive."

In his family, men weren't supposed to be gay, he said. That probably didn't mean much to his sister as she struggled with her illness. At one point, she told Michael, "All of that fighting over who would get mom and dad's house when they died—that was a waste of time."

Michael went on to tell me that during a recent meeting of BUS (Brothers United in Support, for black men), the group was joined in a conference call with a member who was very ill and in the hospital. Every man in the meeting spoke to him, saying their goodbyes. He died a few hours later.

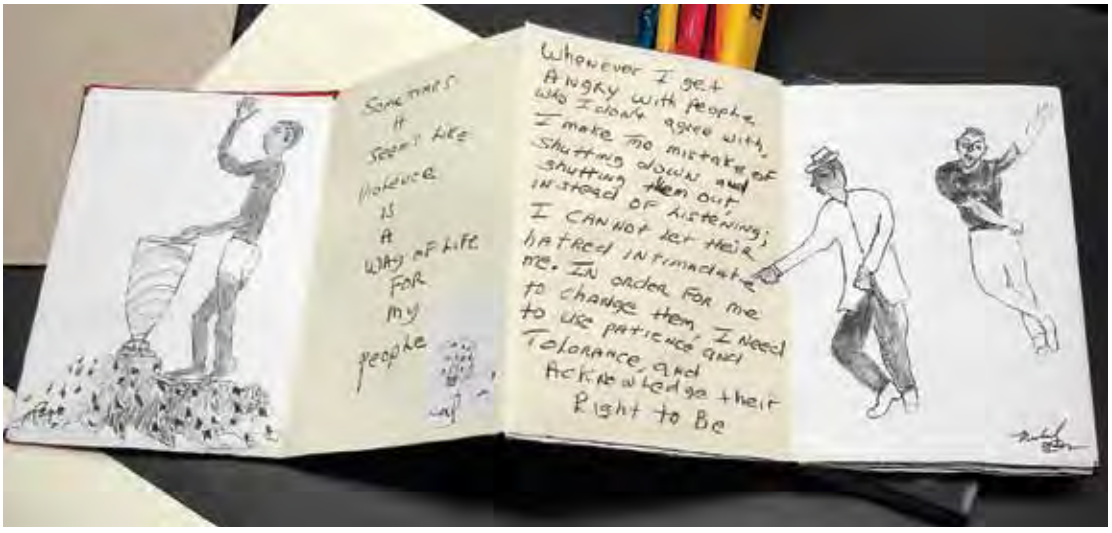
I didn't realize how strong their ties were. For a long time, BUS was the largest support group at TPAN. The group consistently had 20 members a week in attendance. Then for a few years, the group stopped meeting altogether. At TPAN's urging, they picked back up about a year or so ago and it was as if they had never stopped. The members had stayed in touch with one another all along.

Michael talked about the annual BUS retreat to a Wisconsin campsite, and how spiritual the retreats were, how uplifting.

I remembered those retreats, and how much BUS members loved them and looked forward to them. I remember how they returned full of energy and excitement, high in spirit. I had heard of the medical presentations and the social events involved. I had no idea that there were any spiritual-based practices whatsoever for the retreats.

"There's so much that TPAN's done that's been forgotten about," Michael said.

TPAN moved its offices in May and I



A TPAN BOOKMAKING WORKSHOP PROVIDED MICHAEL PAYNE WITH THE CREATIVE OUTLET TO EXPRESS HIS FEELINGS.

found a mounted cardboard exhibit of photos from a BUS retreat. What synchronicity. Stories and images continued to pop up.

A friend asked me over dinner how the buddy program was doing. I said we no longer had one. She said she recently saw *her* buddy. They get together once or twice a year since they were matched in the program 10 years ago. How astounding, I thought. We no longer even have the program—who knows how many people are still being served through services started long ago?

Someone told me about learning he was positive and thinking he was going to die and feeling desperate. He was given a copy of POSITIVELY AWARE and he called TPAN to join an HIV education series, but it was already full. "I'm going to die" he cried over and over, and space was made for him. He learned about the new medications and met with others living long-term with HIV. His despair lifted and never returned.

People often say, "TPAN saved my life." I know that sometimes that is literal, and sometimes that is an emotional response. The emotional perception is just as valid.

I'm constantly surprised at how much gets done through TPAN, and how the one hand doesn't know what the other hand is doing. Volunteers and staff members are constantly helping others with amazing results, stories that are rarely shared. We do our work, as staff or as volunteers, and keep going as if it was just another day in the office.

Two months ago, Lisa Congelton, a volunteer from the early days in the 1980s stopped by the office. She looked around our office with wonder. "What are you thinking?" I asked. She said, "Honestly … I can't believe that TPAN has a staff."

It reminded me all over again of how TPAN—and by extension, POSITIVELY AWARE—was born in the living room of founder Chris Clason, and of how much work was done by volunteers.

At the new office, I told this story to one of our last remaining founders who joined Clason in his living room to help create TPAN, Bernard (Bernie) J. Brommel. He was in town to, among other things, help us plan for our upcoming 30th anniversary. Bernie is now in his 80s, relies on a walker (and husband Carl Ratner) to help him get around, and receives dialysis. But his brain and his spirit are as strong as ever. As a psychologist, he continues to be published.

When I told him what Lisa had said, he told me simply, "Me too." He added one other point: "Hannah (Hedrick) and I took care of the rent." *That's* dedication.

***That* is survival.** … All of it. I came across this during the move: "Through the grant from Burroughs Wellcome, POSITIVELY AWARE moved from an all-volunteer operation working out of the editor's home to a staff of four in offices subsidized by a local business owner." Burroughs Wellcome, which eventually became GlaxoSmithKline and today has all of its HIV medications under the ViiV Healthcare enterprise, provided the half-million dollar grant that turned POSITIVELY AWARE into a national magazine.

This year, our 30th anniversary, I'm sure we've forgotten the majority of our stories about helping people living with HIV to survive and thrive.

Last spring, POSITIVELY AWARE editor Jeff Berry sent an e-mail message to the staff after he came across a reference to the magazine by chance while out of town and eating dinner at a restaurant while browsing on his phone. In a bulletin board called *Prison Talk* for friends or family members of incarcerated individuals, he read about an inmate whose copy of POSITIVELY AWARE had been held up by the prison staff for months, but when it finally arrived, he read about a drug effect he had been suffering from that had his medical providers stumped. As a result, an adjustment was made.

"I have to tell you I was suddenly overcome with emotion and had to fight back the tears as I read the thread, and as my food arrived (I probably looked kind of silly, people probably thought my dinner date was a no-show!). It really spoke to me about why we all are in this work, but how sometimes we have to be gently reminded that the sacrifices we all make, the long days, the hard work, the (sometimes) thankless jobs we all do, that without a doubt it touches people's lives, and it makes a difference. And many times we will never know how much of a difference we are making, or how many lives we touch. But I hope you are all aware that the work you do every day here at the organization does have a real impact on the lives of many, many individuals, so please take a moment and be proud of who we are and what we do, because I am proud of all of you."

Chris Clason's living room never quite went away. His spirit lives on. All those who joined him—those who are gone, those who are still here—their spirit lives on. PA

JOIN US Thursday, September 28, 2017 at Moonlight Studios in Chicago for *TPAN: 30 Years of Hope*, with special guest Peter Staley, HIV activist extraordinaire and early member of ACT UP. The struggle continues. Go to tpan.com for more information.

PHOTO: ENID VÁZQUEZ

REPRIEVE

There's a Link Between HIV & Heart Disease.

- Studies have shown that people living with HIV are 50–100% more likely to develop cardiovascular disease (including heart attack and stroke) than individuals without HIV.
- REPRIEVE is a clinical research trial exploring long-term prevention of heart disease among people living with HIV.

Preventing Heart Disease

REPRIEVE will evaluate if a daily dose of pitavastatin lowers the risk of heart-related disease among people living with HIV.

Pitavastatin, is a statin that is approved by the FDA. Statins are used to lower cholesterol and prevent heart disease.

Based on current information, pitavastatin is considered safe for use with all MD-prescribed antiretroviral therapy regimens.

Benefits of REPRIEVE to Minimize Risk

All participants will receive guidance on steps to improve heart health, including:

- Taking antiretroviral therapy
- Keeping cholesterol, blood pressure, and blood sugar in good range
- Not smoking
- Eating well
- Exercising

But long term research is needed for HIV-specific strategies for preventing heart attack and stroke.

Learning More About Heart Disease Prevention Among People with HIV

WHAT YOU NEED TO KNOW ABOUT REPRIEVE

LENGTH OF PARTICIPATION
48 months on average

SIMPLE TIME COMMITMENT
Visits about **3** times per year

THERE'S A SITE NEAR YOU

YOU MAY BE ELIGIBLE IF YOU ARE:

- ☑ HIV positive between the ages of 40 and 75
- ☑ On antiretroviral therapy (ART) for at least 6 months prior to study entry
- ☑ No history of cardiovascular disease (including heart attack or stroke)
- ☑ Not currently using a statin drug

Learn more about the REPRIEVE trial and how to sign-up: www.reprievetrial.org

Participating in the REPRIEVE trial is not about "adding just another pill", it's about paving the way to healthier hearts for the HIV community.

Help the community learn about the REPRIEVE clinical trial:

Call: 1-877-29-HEART

facebook.com/reprievetrial

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NIH