

# PA

POSITIVELY AWARE

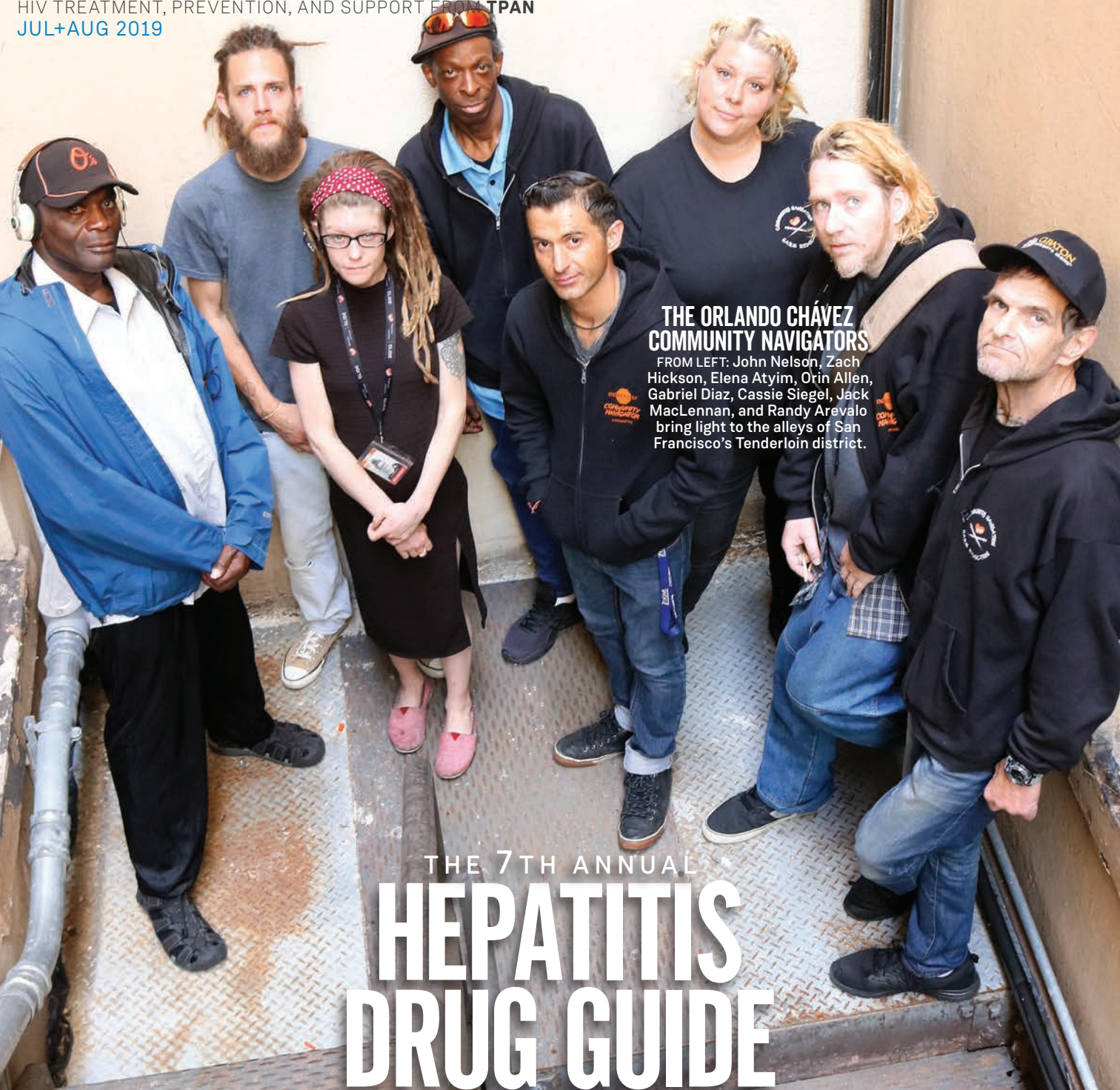
HIV TREATMENT, PREVENTION, AND SUPPORT FROM TPAN  
JUL+Aug 2019

FINDING THE RIGHT  
HCV TREATMENT  
FOR YOU

10 WAYS  
TO LOVE  
YOUR LIVER

HEPATITIS B—  
A FORGOTTEN  
RISK

WHAT YOU NEED  
TO KNOW ABOUT  
HEPATITIS A



## THE ORLANDO CHÁVEZ COMMUNITY NAVIGATORS

FROM LEFT: John Nelson, Zach Hickson, Elena Atyim, Orin Allen, Gabriel Díaz, Cassie Siegel, Jack MacLennan, and Randy Arevalo bring light to the alleys of San Francisco's Tenderloin district.

THE 7TH ANNUAL

# HEPATITIS DRUG GUIDE

## IMPORTANT FACTS FOR BIKTARVY®

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

(bik-TAR-vee)

### MOST IMPORTANT INFORMATION ABOUT BIKTARVY

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

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

### ABOUT BIKTARVY

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

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

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

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

### BEFORE TAKING BIKTARVY

**Tell your healthcare provider if you:**

- ▶ Have or have had any kidney or liver problems, including hepatitis infection.
- ▶ Have any other health problems.
- ▶ Are pregnant or plan to become pregnant. It is not known if BIKTARVY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking BIKTARVY.
- ▶ Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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

- ▶ Keep a list that includes all prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- ▶ BIKTARVY and other medicines may affect each other. Ask your healthcare provider and pharmacist about medicines that interact with BIKTARVY, and ask if it is safe to take BIKTARVY with all your other medicines.

### POSSIBLE SIDE EFFECTS OF BIKTARVY

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

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

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch), or call 1-800-FDA-1088.

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

### HOW TO TAKE BIKTARVY

Take BIKTARVY 1 time each day with or without food.

### GET MORE INFORMATION

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



Get HIV support by downloading a free app at  
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**LOVE  
WHAT'S  
INSIDE®**

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Because HIV doesn't change who you are.

BIKTARVY® is a complete, 1-pill, once-a-day prescription medicine used to treat HIV-1 in certain adults. **BIKTARVY does not cure HIV-1 or AIDS.**

**Ask your healthcare provider if BIKTARVY is right for you.  
To learn more, visit [BIKTARVY.com](https://www.biktarvy.com).**

Please see Important Facts about BIKTARVY, including important warnings, on the previous page and visit [BIKTARVY.com](https://www.biktarvy.com).

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**LIVE LIFE POSITIVELY AWARE.**

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

FROM LEFT: Cassie Siegel, Randy Arevalo, Elena Atyim, Orin Allen, Gabriel Diaz, John Belson, Jack MacLennan, and Zach Hickson carry on the work of community advocate Orlando Chávez.





**PHOTOGRAPHING THIS ISSUE'S COVER** had added meaning for the staff of San Francisco's Glide Foundation who took part in the shoot. The day marked the first anniversary since the death of Orlando Chávez, a colleague and leading activist who fought for wider access to hepatitis C (HCV) medications in the Bay Area.

When Glide created its community (or peer) navigation program in August 2018, it was named in honor of Chávez. The program trains people who are vulnerable to or who have been treated for HCV to use their life experiences to connect to others in their community. Located in San Francisco's Tenderloin district, Glide is at ground zero where HCV, drug use, and poverty converge. The community navigators have overcome, or are still dealing with, many of the challenges that they are now helping others face.

"People with lived experience have the potential to be highly effective navigators because of their connection to the community—shared life experience may build the foundation of trust, rapport, and connection, and it is understood that connection lays the groundwork for positive, healthy changes," said Harm Reduction Programs Director Paul Harkin, who photographed the cover. For Harkin, having community peers in the mix of program activities has always been crucial.

The photo shoot participants all came from Glide's second cohort of community navigators, who began their training in April 2019. The group was trained by outreach coordinator William Buehlman and community health outreach worker Amber Sheldon. Navigators Elena Atyim and Zack Hickson graduated with the original cohort, but returned to help Buehlman and Sheldon teach the class.

Orlando Chávez's work continues in his name. A few of the newly minted community navigators who took part in the photo shoot talked about why their work is important to them:

**John Nelson:** "After my treatment and eventual cure of hep C in just eight weeks, and with no side effects, I was encouraged to seek out those who were not aware of the new treatments. I committed myself to educate them in the same way I was, and to get them into HCV treatment."

**Elena Atyim:** "I've been fighting for the lives of people living with hepatitis C because I lived with the disease. No one should have to live with hep C, because today we can treat everyone."

**Zach Hickson:** "I cured my hep C, and I want to help others to do the same—no matter where they are in their life."

**Orin Allen:** "This cohort has been educational as well as enjoyable—getting to work with harm reduction staff; getting people tested, linked to care, and being trained in overdose prevention is meaningful."

**Jack MacLennan:** "Harm reduction has been improving my life for years. Hep C has affected my family and friends, and is a big part of why I do this work. It's inspired me to want to help end hep C."

—RICK GUASCO

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Photo: © Todd Rosenberg Photography. Dancers: Greig Matthews & Joanna Wozniak.  
Attire: Chiari Boni La Petite Robe Dress provided by Neiman Marcus.



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## AIDS IN 1982

### JOIN US



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I loved reading your special issue on aging and HIV [Spring 2019] since I am now a senior citizen, at 65. So that puts me in a category that could be called “original” long-term survivor, at more than 36 years. The MACS [Multicenter AIDS Cohort Study] took a sample of my blood in 1983 when the study started. In ’85, when the first test for HIV came out, they froze my blood and lo and behold, I was positive. But I knew before ’83 that I was positive, because of the large swollen lymph nodes seen in so many men with HTLV-III (isn’t that what it was called it back then?).

In 1982 I received a referral to a highly recommended surgeon to do a biopsy of my big lymph nodes. In presenting his findings, he told me in a rude manner that I had AIDS and needed to go home and get my things in order for the end. Because I was working in a hospital and was not afraid of doctors, I asked him what he found in the tissue he recovered that indicated AIDS, and he had no answer. I said then that there was nothing he could point to that specifically pointed to AIDS. I was then essentially ushered out of the exam room.

I was furious. I sent a letter to the president of the hospital where this doctor practiced. The president answered my letter personally and we actually talked on the phone. We agreed that the doctor would be brought up before the Chief Medical Officer. I agreed that would suffice. Some of my friends at my job wanted me to go further, but I said no more.

So without any clinical proof, I knew I was positive then. And I was really mad to have been treated like trash. Really pissed.

That’s a long story leading to a question: What percentage of all people living with HIV (I still call them “PWA” [people with AIDS]) are 65 years and older?

I’m really on a roll today, after reading “Changing how we age” with HIV [the Guest Editor’s Note by Theo Smart, Spring 2019]. The HIV organization here does a great job for the size of this town, but they have nothing specific for us old farts.

NAME WITHHELD

### DRUG CHARTS IN PRISON

I was diagnosed with HIV in October 2016, four months before being arrested and going to prison. I wasn’t taking it very well. We all know it’s not an easy thing to take in. I’m open about having HIV here in prison, which is not an easy place to be open about it.

Everything that I have learned about HIV was in jail and prison, more so in prison. They had a magazine at my facility called *Plus*, all about HIV. I found that to be helpful. It showed me that there are things in here that can help me. I now also get *POZ* and *POSITIVELY AWARE* magazines.

I took a peer facilitator class about HIV and STDs, which was pretty good. We had to do a presentation at the end of the class. One of the topics we could pick to talk about that stood out brighter than the North Star to me was a *personal story*. I told the teacher I’ll do treatment because I self carry my medication [some inmates must stand in line to get their therapy]. We had an 8–10 minute window to speak.

As I was speaking I had charts about the medication, what each drug class does. I circled the pills

on the chart that I was currently on and showed them my pillbox. Through my presentation I got really into it. I got choked up a bit. I wound up speaking for over 20 minutes, but what got me the most was this one guy who said, “I would like to shake your hand” and he gave me a hug. I just try to show people what HIV is today and what it isn’t. I’m just so happy to have people I can actually talk to about this and get the most current information out there. I’ve come a long way in this short time. I went to jail with a viral load in the millions and a CD4 count at 35. My last lab results showed my viral load is undetectable—U=U—my CD4 count went up from 598 to 774. I’m glad things are going the way they’re going. My medication recently got changed. I’m on a new pill—well, new to me—Symtuza, but my specialist still has me on Tivicay [plus Symtuza] for now. Our plan is to get down to just the Symtuza.

As I’ve told my family and friends, I’m all in on this HIV stuff. I’m from NYC, but there are so many places I can go not only for myself but to help others. HIV has been a big bully for long enough. I, like many others, am here to stand up against it. *Silence spreads stigma, speaking silences stigma*. That’s what I’m living by, that’s my motto.

ANTHONY D.

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**GUEST EDITOR'S NOTE**  
ANDREW REYNOLDS

# HEPATITIS ELIMINATION: Back to basics

**T**HIS IS MY SIXTH YEAR WRITING THE HEPATITIS DRUG GUIDE, and through the years I've been able to write other HCV- and harm reduction-related articles in other issues of POSITIVELY AWARE. Taken together, it is my hope that we address many of the issues that are important to people living with or at risk for viral hepatitis. In this year's guide, we're going back to basics. With pages devoted to a basic overview of hepatitis A, B, and C, as well as other related topics like HIV/HCV co-infection, and an overview of the liver to go along with the individual drug pages, we hope to provide you with a useful resource.

Looking back, it is remarkable to think how far we've come in HCV drug development and how fast it has happened. In fact, the World Health Organization has set the year 2030 as a goal to eliminate viral hepatitis! Imagine a world without hepatitis C and B. We can get there!

There are many hurdles to overcome, but the tools to get us there exist and we need to build the political commitment to put them in action. Here are just three things we can do to push the agenda to make hepatitis C and B a thing of the past.

**Remove all restrictions on HCV treatment access.** This is a no-brainer: We can't eliminate HCV if we don't treat everyone. In the United States, access is getting better, but some private insurance plans and state Medicaid programs continue to put up barriers to HCV cure and treatment. Denying HCV treatment because a person's liver damage is not advanced enough or because of substance use is bad policy for individual health, leading to greater suffering. It's also bad public health since the more people we cure, the less likely hepatitis will be transmitted to others. And it is just morally and ethically wrong to deny a person a cure. Check out [stateofhepc.org](http://stateofhepc.org) for an overview of state Medicaid restrictions and see what grade your state gets!

**Support and expand syringe access and other harm reduction services, including MAT.** In addition to treating everyone for HCV, we also need to expand access to sterile syringes and other injecting equipment, as well as other harm reduction services such as overdose prevention and access to medication assisted therapy (MAT). In an ideal world, we'd have a network of syringe service programs always within reach; in an even dreamier world, we'd have them with safe consumption spaces. Additionally, improving access to MAT—medications like methadone, buprenorphine, and naltrexone—is a proven intervention to treat and manage opioid addiction. Research has also shown us that MAT can also reduce new

HCV infections, and is even more effective when combined with syringe service programs and HCV treatment for people who inject drugs. Check out amfAR's Opioids and Health Indicator Database for more information: [opioid.amfar.org](http://opioid.amfar.org).

**Push for an HBV cure.** We can treat hepatitis B virus—and we cover the treatments in this issue—but to date, there is still no cure for it. There is lots of research and development going on right now, with approximately 50 HBV potential cures under investigation, but we need to make sure there is enough funding and support to do this essential work. Follow the work of HBV organizations such as The Hepatitis B Foundation for advocacy alerts and policy sign-on letters, and cure research news: [hepb.org](http://hepb.org).

And most importantly: **Listen to people living with HCV and HBV.** This is another no-brainer, and it is one that we must do if we want to adequately address viral hepatitis and effectively meet the needs of people living with HCV and/or HBV. Indeed, most of the best advocates for these two diseases are people who have been cured of the disease or those who are still living with it. Their lived experience makes them the experts! It is challenging to build a movement of health advocates and activists. We've long had great organizations doing the work, but bringing in the patient voice has been difficult for a variety of reasons. In July 2019, the National Viral Hepatitis Roundtable (NVHR) is organizing the first of its kind NVHR Patient Summit—100 people living with (or cured from) HCV will come together in Atlanta for two days to learn more about HCV, advocacy tools and strategies, and to build a network of advocates. Check out [nvhr.org](http://nvhr.org) for more information.

There's work to do, but we can see a world without viral hepatitis on the horizon.

*Andrew*

There are many hurdles to overcome, but the tools to get us there exist, and we need to build the political commitment to put them into action.



ENID VÁZQUEZ @ENIDVAZQUEZPA

# BRIEFLY

## Monthly injectable HIV med on the way

ViiV Healthcare submitted a New Drug Application (NDA) to the FDA for a monthly injectable HIV medication. **Two shots in the butt muscles**—one injection of cabotegravir and one of rilpivirine. That’s it.

Rilpivirine is already available in tablet form (under the brand name Edurant). The new injectables are long-acting versions, so it’s called long-acting cabotegravir and rilpivirine (CAB LA/RPV LA).

The NDA was submitted April 29. Learn more at [positivelyaware.com/drug-guides/long-acting-cabotegravirrilpivirine](http://positivelyaware.com/drug-guides/long-acting-cabotegravirrilpivirine).

## Activists sue AIDS pharma

Declaring that pharmaceutical companies work together to keep the cost of HIV medications high, lawyers filed an antitrust lawsuit against them in federal court in San Francisco on behalf of AIDS activists. *Peter Staley et al. vs. Gilead Sciences et al.* states that **“the manufacturers used anticompetitive tactics to keep prices high** on some of the most important and widely used medicines for the treatment and prevention of the HIV virus, including Truvada, Descovy, Atripla, Genvoya, and Odefsey,” among other antiviral drugs. The lawsuit also declares that the companies agreed among themselves not to use cheaper generic versions of their medications in combining them for fixed-dose combinations.

Lead plaintiff and

renowned AIDS activist Peter Staley said, “ACT UP successfully fought for a dramatically lower price on AZT, the first AIDS drug, resulting in far lower prices on the next 10 drugs that came to market. Now Gilead and its co-conspirators have turned back the clock to monopolistic practices and pricing. We will not let this stand.”

## PARTNER2 and undetectable virus

The PARTNER2 study showing that undetectable viral load in gay men means that they are unable to transmit HIV to their sex partners was published May 2 in the leading medical journal *The Lancet*.

“Our results provide a similar level of evidence on viral suppression and HIV transmission risk for gay men to that previously generated for heterosexual couples and suggest that the risk of HIV transmission in gay couples through condomless sex when HIV viral load is suppressed is effectively zero,” the research team reported. **“Our findings support the message of the U=U (undetectable equals untransmittable) campaign,** and the benefits of early testing and treatment for HIV.”

Results were based on 972 gay male couples.

Although the findings were first reported several years ago, publication in a medical journal is given greater weight because of the vigorous review process undergone before publication.

Read the study free online at [thelancet.com/journals/lancet/article/](http://thelancet.com/journals/lancet/article/)

[PIIS0140-6736\(19\)30418-0/fulltext](https://news.trust.org/item/20190508111736-cdfe3).

Ian Green, CEO of the Terrence Higgins Trust, the largest non-profit HIV organization in the UK, wrote an opinion piece on the effect that these findings have on stigma, “Stop doubting the evidence—people living with HIV and on effective treatment cannot pass it on.” Read it at [news.trust.org/item/20190508111736-cdfe3](https://news.trust.org/item/20190508111736-cdfe3).

## Gilead donates Truvada for PrEP

Gilead Sciences, maker of Truvada for PrEP (HIV prevention), announced that it would donate the medication to the Centers for Disease Control and Prevention (CDC) to support the agency’s national efforts to protect people against the virus. The company said it would provide the CDC with up to **2.4 million bottles a year up to 2030,** destined for uninsured individuals. Gilead reported that “This medication donation is among the largest ever in the United States and is part of Gilead’s broader ongoing initiatives to help ensure that everyone who can benefit from PrEP is able to access it.”

As usual, it was good news/bad news for activists. On the one hand there was gratitude for help in fighting the epidemic. On the other hand, there was pointing to the problems that continue. Among other things, Gilead reached an agreement to make generic Truvada available next year. (Go to [breakthepatent.org](http://breakthepatent.org) for more on that.) Descovy, on the other hand, is far

from becoming available as a generic. It’s also set to be FDA approved for HIV prevention this year.

Editorials in *The New York Times* discussed several problems with the donations, stating that Truvada was created with taxpayer dollars and that the donation—a tax writeoff—will probably benefit the company’s stockholders more than the people receiving the donations. One editorial was titled “Gilead’s Gift Horse.”

## Australian man talks about his HIV while on PrEP

After years of being a public face for PrEP, Australian Steve Spencer recently acquired HIV. He was then **open about his new status,** starting at the 41st Sydney Gay and Lesbian Mardi Gras Parade in March. “This has turned a process of grief and anguish into an event of celebration—a celebration of my health, a celebration of my community, and a celebration of remaining true to myself,” Spencer told writer Nic Holas in an interview. Read “I am Prepared”: Steve Spencer on Becoming HIV Positive in the Era of PrEP and U=U” at [starobserver.com.au/news/national-news/i-am-prepared-steve-spencer-on-becoming-hiv-positive-in-the-era-of-prep-and-uu/179646](http://starobserver.com.au/news/national-news/i-am-prepared-steve-spencer-on-becoming-hiv-positive-in-the-era-of-prep-and-uu/179646).

Dr. Demetre Daskalakis, Deputy Commissioner for the Division of Disease Control in New York City’s Department of Health and Mental Hygiene, discusses the 2-1-1 method of PrEP Spencer used, at [out.com/health/2019/3/22/](http://out.com/health/2019/3/22/)

what-you-need-know  
-about-prep-demand. “This is an effective strategy, Dr. Daskalakis explains.

## Ban ends UCSF's fetal tissue HIV cure research

The White House announced that the U.S. Department of Health and Human Services would ban the use of fetal tissue in any federally funded medical research. The June 5 announcement immediately halted HIV cure research that used fetal tissue at the University of California-San Francisco.

“Today’s action ends a 30-year partnership with the [National Institutes of Health] to use specially designed models that could be developed only through the use of fetal tissue to find a cure for HIV,” said the university’s chancellor, Sam Hawgood, MBBS. “We believe this decision to be politically motivated, shortsighted and not based on sound science.”

**Fetal tissue collected from elective abortions has been instrumental in work on such diseases as HIV, cancer, and Zika.**

According to a *Washington Post* report, an anonymous White House official said that Vice President Mike Pence, who strongly opposes abortion, worked closely with HHS to develop the policy.

Read the HHS statement: [hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html](https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html).

—RICK GUASCO, from reports in the *Washington Post* and the *San Francisco Chronicle*

## Tenofovir class action lawsuits

Law firms have been advertising a class action lawsuit against the makers of the HIV medication tenofovir DF (brand name Viread, also found in Atripla, Complera, Stribild, and Truvada). What should you know about joining such a suit as a plaintiff?

I reached out to Eric K. Farmer, PharmD, who worked on the 2019 POSITIVELY AWARE HIV Drug Guide. He checked with Katherine Wood, MLP Attorney for Indiana University Health Methodist and University Hospitals, where Dr. Farmer practices.

“Class action lawsuits aren’t likely to get individual class members much money, unless they suffered serious injuries and become named plaintiffs in the case,” Wood said. “Class actions generally are not about making individual class members rich, and getting compensation is often much harder than getting judgments that force people to stop engaging in an illegal activity. Patients who have had serious injuries may get compensated more fairly (kidney failure or severe bone density loss), but it’s not guaranteed or even more likely than not. But really, the lawyers are the ones who will get compensated fairly for their time working on the case, and the class members will get compensated partially (and possibly insignificantly) for their actual injuries.”

I also reached out to the Legal Council for Health Justice in Chicago. The council provided the following:

**Are my injuries serious enough to have a good case?** Each law firm is going to have their own opinion on how severe injuries must be to have a strong case.

**A case can take a long time to settle.** Even if a claim is settled before trial, it could still take years before plaintiffs see any award. Going to trial or additional appeals can further delay resolution.

**If you want to file your own claim, you will need to find a law firm willing to represent you as an individual.** You will need to have a strong claim, serious injuries, and be willing to participate in litigation.

By contrast, in a class action a group of people with the same or similar injuries

caused by the same product or action sue the defendant as a group. Your participation in a class action may be very minimal unless you are a named plaintiff. Named plaintiffs are representatives of the class and are named in the lawsuit. They participate more in the case and can get a larger portion of any award.

Law firms representing consumers usually get paid by taking a percentage of the final award. If their clients lose the case, they do not get paid. If their clients win, it is common for a law firm to take around 40%.

It can be exciting to hear about cases with multi-million dollar settlements. However, even if a class action is settled for a large amount of money, class members may only end up with a small portion. How much each person gets depends on many things, but a big factor is how many people are in the class.

Imagine a class action is settled for \$5 million and there are 5,000 class members. First, the law firm will take their fee and additional funds to cover court costs. If the law firm takes 40%, that leaves less than \$2 million to be divided among the plaintiffs. Even if named plaintiffs and class members receive an equal amount of the settlement, they would each get only \$400.

This is not to discourage participation in class actions, but it is important to manage your expectations.

Here are a few things to think about when searching for a lawyer to represent you:

**Consider talking to more than one law firm before you sign any agreement.** It’s better to understand your options.

**How well will the law firm communicate with you?** Do they clearly explain the process and how long it may take? Will you have a point person you can contact? Will they provide you regular updates?

**What will it cost you?** What will they charge you for their services? Can they provide a clear list of costs? For example, will you have to pay for experts, medical consultation, and court costs?

**SPECIAL THANKS** to Jessica Rhoades, staff attorney at the Legal Council for Health Justice, for putting together this information.

## PrEP and the pharmacist

More than seven years after its FDA approval, it seems that in many ways, Truvada for PrEP (HIV prevention) is still getting off the ground. Although it is nearly 100% effective in stopping HIV, **Truvada for PrEP continues to struggle with issues of access, adherence, and stigma.** Moreover, other PrEP strategies are in the works, such as a monthly injection, and they will undoubtedly bring their own issues.

Among the medical professionals looking to help resolve the distractions associated with PrEP is Eric K. Farmer, PharmD, BCPS, AAHIVP, a clinician at the LifeCare Clinic at Indiana University Health Methodist Hospital in Indianapolis. Dr. Farmer has also updated POSITIVELY AWARE's Annual HIV Drug Guide for the past two years.

He led a team of pharmacists from Temple University Hospital in Philadelphia, The Brooklyn Hospital Center, Tufts Medical Center in Boston, and the Emory University Hospital Midtown Outpatient Infectious Disease Clinic in Atlanta to see how the profession can improve on the benefits of PrEP. The team published their report, "The Pharmacist's Expanding Role in HIV Pre-Exposure Prophylaxis [PrEP]" in the May 2 issue of *AIDS Patient Care and STDs*.

Ironically, one of the first points they make is how accessible pharmacists are to patients. Ironic because that was a point made by the first pharmacist to work on the HIV Drug Guide, back in 1997, Glen Pietrandoni, of Walgreens Specialty Pharmacy (he created the network of stores around the country specifically to help patients living with HIV). "Ask your doctor" sounds like good advice, but your pharmacist is probably easier to reach. (Besides, with their Doctor of Pharmacy degrees, many pharmacists are doctors.)

"As one of the most widely accessible health care resources, pharmacists are well positioned to improve patient understanding, promote medication adherence, provide key risk reduction counseling, and enhance PrEP efficacy," Dr. Farmer and his colleagues write. "Pharmacists' knowledge and accessibility in nearly every urban and rural community can be leveraged as part of a comprehensive HIV prevention strategy to expand access to care and improve population health. As trusted health care professionals, pharmacists develop a strong rapport with

patients and may be the key to address current disparities in PrEP prescribing patterns as well as serve as an essential liaison between patients and other members of the multi-disciplinary care team."

Nevertheless, they report on one survey of pharmacists in which nearly half of them said they were uncomfortable counseling people on PrEP. In fact, 71% indicated that they didn't feel they had enough knowledge to counsel their patients. Other surveys showed similar problems.

Significant progress was reported, however, such as the One-Step PrEP clinic in the Kelley-Ross Pharmacy in Seattle. The pharmacists there evaluate people for PrEP, have lab tests run, provide education, and dispense the PrEP medication. Other pharmacies with a PrEP practice are the Gateway Apothecary in St. Louis, the Scales Pharmacy in Denver, the Kansas City CARE Clinic, and the Brooklyn Hospital Center.

For people living outside a metropolitan area, telemedicine for PrEP services has been used. For example, the Signal Center for Health Innovation started a TelePrEP program in collaboration with the Iowa Department of Public Health and the University of Iowa Health Care System.

"These community, pharmacist-run PrEP-based services may improve access to PrEP by offering a convenient (and potentially less stigmatizing) location for those seeking PrEP, offering extended hours for services (weekends/evenings), and increasing access to specialty trained drug therapy experts able to counsel on medications, support adherence, mitigate financial barriers, and serve as a strong community ally to support HIV prevention efforts," the team writes.

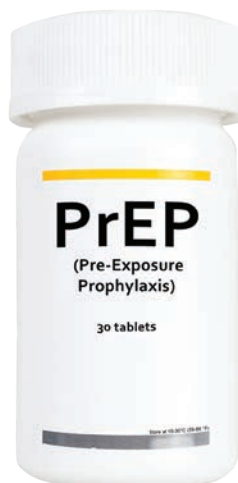
They also point out that in most states, pharmacists can manage medication (initiate and discontinue, monitor safety) with a collaborative drug therapy agreement (CDTA) with other medical providers.

Other points made:  
 ■ "With nonadherence

being a limiting factor to PrEP efficacy, repeated risk reduction education and adherence assessments must coincide with PrEP delivery."

- "Pharmacists identify patients at risk of HIV, target personalized barriers to medication uptake/adherence, link patients to other providers if necessary, initiate PrEP if allowed under the laws and statutes of the respective state, and monitor for side effects directly related to PrEP or indirectly from drug interactions."
- "Pharmacists remove barriers to medication uptake and access with knowledge of medication reimbursement and alternative mechanism of payment (e.g., manufacturer copayment assistance.)"
- "Team-based approaches for consistent risk reduction counseling may be more likely to affect a significant behavioral change in the patient with one or more risk factors for HIV. Individuals obtaining outpatient prescription medications for treatment of sexually related conditions, including but not limited to erectile dysfunction, vaginal dryness, sexually transmitted infection treatment, HIV PEP [post-exposure prophylaxis], oral contraceptives, or over-the-counter (OTC) items related to sexual activity such as condoms, lubrication, or OTC testing products, indicate opportunities for sexual health counseling, including PrEP education. Pharmacists in the community setting have the unique opportunity to engage and counsel patients who purchase or exchange syringes for injection substance use (as allowed by state law), advocate for immunizations, and provide additional risk reduction counseling regarding communicable diseases."

Lastly, Dr. Farmer and his colleagues note that in order to achieve the National HIV/AIDS Strategy for 2020 goals of increasing access to and uptake of PrEP, community pharmacists and ambulatory clinic-based pharmacists should be a part of curbing the epidemic.





## IN THE CLINIC

For the medical community, we cannot say cure. But for the community—they need to hear about this [another patient, in London, who was possibly cured of HIV].

Cure [however] is in the eye of the beholder. It means different things to different people. One of my patients said, “I feel cured. One pill once a day—that’s a cure.”

—PABLO TEBAS, MD, of the University of Pennsylvania, and principal investigator of the ACTG (AIDS Clinical Trials Group) unit there, at the 2019 CROI conference in Seattle in March. He reported on a potential cure strategy in his own research, where viral loads were kept low in a small group of patients after receiving an intervention and then stopping their antiviral therapy. Read the summary and view the webcast for “Delayed Viral Rebound During ATI after Infusion of CCR5 ZFN-Treated CD4 T Cells” (Abstract 25), at [croiconference.org](http://croiconference.org).

SHARE your clinical and medical insights with POSITIVELY AWARE for our In the Clinic feature. Send to [e.vazquez@tpan.com](mailto:e.vazquez@tpan.com).

**PA**  
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TEBAS: IFARA

QUOTE FROM READER SURVEY; MODEL PORTRAYAL

## A next step for adults with HIV who have been undetectable\* for at least six months.

\*Undetectable means keeping the amount of HIV in the blood at very low levels (less than 50 copies per mL).

### Important Facts about JULUCA

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

#### What is JULUCA?

- JULUCA is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults to replace their current anti-HIV-1 medicines when their healthcare provider determines that they meet certain requirements.
- HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
- It is not known if JULUCA is safe and effective in children.

#### How do I take JULUCA?

- **Take JULUCA 1 time a day exactly as your healthcare provider tells you.**
- **Always take JULUCA with a meal.** A protein drink alone does not replace a meal.

#### Do not take JULUCA if you

- have ever had an allergic reaction to a medicine that contains dolutegravir or rilpivirine.
- are taking any of the following medicines: dofetilide; carbamazepine; oxcarbazepine; phenobarbital; phenytoin; rifampin; rifapentine; proton pump inhibitors (including esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole); St. John's wort (*Hypericum perforatum*); or more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate.

#### Before taking JULUCA

##### Tell your healthcare provider if you:

- have ever had a severe skin rash or an allergic reaction to medicines that contain dolutegravir or rilpivirine.
- have or have had liver problems, including hepatitis B or C infection.
- have ever had a mental health problem.
- are pregnant or plan to become pregnant. One of the medicines in JULUCA, called dolutegravir, may harm your unborn baby.
  - **You should not take JULUCA at the time of becoming pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may change your medicine during this time in your pregnancy.
  - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with JULUCA, and you should consistently use effective birth control (contraception) during treatment with JULUCA.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with JULUCA.

#### Before taking JULUCA (cont'd)

##### Tell your healthcare provider if you (cont'd):

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take JULUCA.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. It is not known if JULUCA can pass to your baby in your breast milk. Talk with your healthcare provider about the best way to feed 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 JULUCA.
- Do not start taking a new medicine without telling your healthcare provider.

#### What are the possible side effects of JULUCA?

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

- **Severe skin rash and allergic reactions.** Call your healthcare provider right away if you develop a rash with JULUCA. **Stop taking JULUCA and get medical help right away if you develop a rash with any of the following signs or symptoms:** fever; generally ill feeling; tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of the skin; redness or swelling of the eyes; swelling of the mouth, face, lips, or tongue; problems breathing.
- **Liver problems.** People with a history of hepatitis B or C virus who have certain liver function test changes may have an increased risk of developing new or worsening changes in certain liver tests during treatment with JULUCA. Liver problems, including liver failure, have also happened in people without history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver function. **Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:** your skin or the white part of your eyes turns yellow (jaundice); dark or "tea-colored" urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of your stomach area.
- **Depression or mood changes.** Tell your healthcare provider right away or get medical help if you have any of the following symptoms: feeling sad or hopeless; feeling anxious or restless; have thoughts of hurting yourself (suicide) or have tried to hurt yourself.
- **The most common side effects of JULUCA include:** diarrhea and headache.

These are not all the possible side effects of JULUCA. Tell your healthcare provider right away if you have any new symptoms while taking JULUCA. You may report side effects to FDA at 1-800-FDA-1088.



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Scan this code to hear stories from people living with HIV.

My doctor and I are proud  
of how far I've come.  
Now, I want to ask about  
**staying undetectable with  
fewer medicines in my HIV pill.**

**Rodney†**  
Undetectable  
since 2008

I started treating my HIV and reached an undetectable viral load.

And whenever I become aware of other treatment options, I talk to  
my doctor. Here's what I learned about JULUCA:

dolutegravir  rilpivirine

JULUCA is a once-daily complete HIV-1  
regimen that combines 2 medicines in just 1 pill.

**Ask your doctor about JULUCA.**

Learn more at [JULUCA.com](https://www.juluca.com)

†Rodney is a real patient with HIV paid by ViiV Healthcare.

**Important Facts about JULUCA (cont'd)**  
**Get more information**

- This is only a brief summary of important information about JULUCA. Talk to your healthcare provider or pharmacist to learn more.
- Go to [JULUCA.com](https://www.juluca.com) or call 1-877-844-8872, where you can also get FDA-approved labeling.



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 **Juluca**  
dolutegravir 50 mg/  
rilpivirine 25 mg tablets



# Losing your disability payments

An advocate at the Legal Council for Health Justice, **Marina Kurakin, MSW, MFA** outlines how you can protect yourself in a Social Security review

**I**n 2017, Social Security changed the way it reviews disability cases for individuals approved for SSI/SSDI based on their HIV/AIDS status. (SSI stands for “Supplemental Security Income” and SSDI stands for “Social Security Disability Income”.) As a result of this change, every person determined to be “disabled” by the Social Security Administration (SSA) needs to undergo a review of their medical and behavioral health. Before then, people living with HIV/AIDS had been exempt from these reviews.

The reviews come at different cycles, depending on SSA’s opinion of your chances for medical improvement. When it’s time for Social Security to look at your case, you receive a Continuing Disability Review (CDR) form in the mail. It’s your responsibility to complete this form and include information about current conditions, medications, tests, and medical providers.



You also have to answer questions about how you manage daily activities and state whether your condition has gotten worse, remained the same, or improved.

Before 2017, individuals approved for disability based on HIV status were protected from medical CDRs. Even if their conditions improved, as long as they had no reported work earnings, SSA did not investigate the medical progress of folks living with HIV.

CDRs are different from work-related reviews, which deal with an individual's working and earning while also receiving SSI/SSDI. Positive individuals have always been subject to work-related evaluation, as every disability recipient must follow work reporting guidelines.

Because treatment has improved the quality and length of life for many people living with HIV, Social Security no longer views HIV as a terminal illness. This gives Social Security

the power to look for improvements through CDRs.

**Individuals living with HIV who meet the following criteria continue to be exempt from a CDR:**

- Are diagnosed with Multicentric Castleman disease; primary central nervous system or primary effusion lymphoma; progressive multifocal leukoencephalopathy; or pulmonary Kaposi sarcoma

- Have functional limitations due to HIV (which limit your ability to complete activities of daily living like walking, sitting, standing, or lifting)

- Have a low CD4 count (50 or less)

- Have a CD4 count of 200 or less (or CD4 percentage of less than 14) plus a low BMI (body mass index) or hemoglobin count

- Experience HIV complications requiring at least three hospitalizations within a calendar year.

## CDR REVIEWS

When **POSITIVELY AWARE** first wrote about this rule change ([positivelyaware.com/articles/briefly-mayjun-2017](https://positivelyaware.com/articles/briefly-mayjun-2017)), we weren't

## LEGAL BRIEFS

Current cases from our files

- **A 30-year-old, born with HIV and now with undetectable viral load.** Social Security did not find evidence of disability from his CDR or medical records. He is now navigating his first work attempts as a 30-year-old and was connected to employment assistance.

- **A 45-year-old, originally approved for SSI based on HIV and depression.** He was deemed no longer disabled after submitting a CDR. With our help, he appealed the decision and we argued disability based on his low IQ. He now has his benefits back.

- **A 41-year-old originally approved for benefits based on HIV and bipolar disorder,** who stopped getting behavioral health treatment and was found no longer disabled. There were no recent medical records pointing to a disabling condition or current medical treatment.

- **A 27-year-old, approved based on AIDS and neurosyphilis,** just received a denial after completing a CDR. He is now undetectable, but not receiving regular care.

- **A 58-year-old, originally approved based on an AIDS diagnosis 25 years ago,** was found newly disabled due to behavioral health. He is getting weekly therapy and under the care of a psychiatrist.

sure how quickly it would go into effect.

After a year, AIDS Legal Council, a program of Legal Council for Health Justice in Chicago, has seen a huge rise in CDRs among our HIV-positive clients. Unfortunately, we often hear from individuals after they are found no longer disabled and lose their only source of income and insurance. One of my clients who came to us to appeal his CDR ruling had lost his disability income after more than 20 years of receiving benefits.

When we get calls about CDRs, one of the first questions we ask is about current treatment. Where are you going to a doctor, therapist, or specialist? How often do you go? What symptoms do you experience? Any side effects from medications? Would you be able to maintain a full-time job? Why or why not? Have you worked or attended any classes or trainings? Dealing with Social Security is often a frustrating and frightening process. Knowing the rules and talking with an attorney is usually a good idea.

In Chicago, you can contact the AIDS Legal Council by calling our intake line at (312) 427-8990. We've been providing free legal services to people living with HIV for 31 years. In 2018, we served 1,100 HIV-positive clients. If you live in Cook County, we would love to answer your questions.

Lots of other cities and states have their own Ryan White legal services, which can help walk you through the disability review minefield.

The most important bits of advice we can give is to continue getting regular care, reach out for help, and respond to any mail you receive from Social Security. **PA**

.....  
**MARINA KURAKIN, MSW, MFA,** is a legal advocate at the Legal Council for Health Justice, where she leads legal clinics focused on health insurance and public benefits, including one at TPAN every Thursday. She has extensive experience in working with refugees, people living with HIV, and other vulnerable populations. Because health is linked to social determinants, she concentrates on increasing resource access for all.

Because treatment has improved the quality and length of life for many people living with HIV, **Social Security no longer views HIV as a terminal illness.**



## HOW TO USE THIS GUIDE

**T**he POSITIVELY AWARE Hepatitis Drug Guide includes FDA-approved medications for the treatment of hepatitis B (HBV) and those that cure hepatitis C (HCV). Currently, there are no new HBV treatments that are close enough for FDA approval to be included this year, and there are no new HCV drugs at the development stage either. The guide lists FDA-recommended treatment regimens, as well as “off-label” recommendations (that is, treatment options that may not yet be FDA approved, but which are acceptable, safe, and effective to use according to medical providers and other experts). The information provided about these drugs comes from the package labels and 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.

Hepatitis C treatment comprises two or more medications—all of which are pills—taken together. Some treatments are a fixed-dose combination (FDC) pill

which contains medications from two (or more) different classes—for example, Eplclusa, which is one pill containing velpatasvir and sofosbuvir—or they may be

two (or more) separate pills. Some regimens may include weight-based ribavirin. Pegylated interferon is no longer used for the treatment of HCV.

Hepatitis B is treated with one medication at a time—either an antiviral such as Viread (tenofovir) or Baraclude (entecavir), or with pegylated interferon.

### What's new in 2019?

There is really nothing new in the hepatitis C treatment field: No new drugs are in development, because the ones we have available can treat and cure nearly everyone. If anything, we are removing drugs from this year's guide that have been discontinued. This year, Daklinza (daclatasvir, made by Bristol-Myers Squibb) was discontinued as of June, 2019.

In the area of hepatitis B, we have no new drugs—while there are a number of

potential new treatments in the pipeline, none are readily available. The field of drug development in HBV is exciting; while we don't have a cure yet, there is optimism that we are getting closer and closer to that goal. The World Health Organization reports that there are about 50 HBV (and hepatitis D) drugs in development, with about 17 of those in the phase 2 clinical trial stage. As new drugs are developed and get closer to FDA approval, Positively Aware will report on them and include them in future editions of the Drug Guide.

**Where applicable, each drug page will include:**

### 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, and sofosbuvir is abbreviated as SOF. For FDA-approved drugs, the brand name will appear first, at the top of the page, followed by the common name(s).

### FDA status

The medications this year are all FDA approved. There are no new hepatitis C or B drugs in development at a stage where we can report on them.

### 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, and six multi-class fixed-dose combinations:

- 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; however, for this guide will only refer to GT 1–6. In the United States, 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 a person's genotype to determine the correct treatment. Each drug page will list the genotype(s) that the drug is effective against, both those that are FDA approved as well as those that have enough evidence to be used "off-label."

### Dosage

HBV drugs are either oral tablets or an injectable. HCV drugs are all oral, 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 like 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 can be expensive, and there is much concern over the burden these high costs will 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 28.

### Potential side effects and adverse events

This section offers information about side effects and adverse events associated with the HCV 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 real world data from

patients who have taken them. 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 hepatitis C DAAs. 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 among people who were cured of HCV using DAAs, leading to hepatic flares, liver failure (requiring transplant), or, in some cases, death. See page 34 for more information on this warning.

### Potential drug interactions

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 with 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.

### More information

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

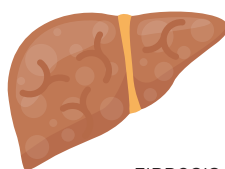
# Your liver and hepatitis



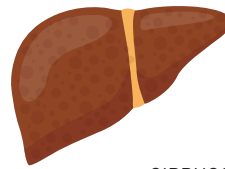
HEALTHY LIVER



HEPATIC



FIBROSIS



CIRRHOSIS

**THE LIVER IS THE BODY'S LARGEST INTERNAL ORGAN, and is responsible for over 500 vital functions. It's a remarkable organ that even has the ability to re-grow itself. The easiest way to think about the liver is as your body's filtering system and warehouse. The liver filters everything we eat, drink, breathe, or absorb through our skin. It also stores nutrients like vitamins, minerals, and iron.**

## OTHER FUNCTIONS OF THE LIVER INCLUDE:

- Clears out alcohol and drugs (both legal and illicit)
- Makes bile and helps digest food
- Manages fats and cholesterol
- Manages sugars
- Makes platelets that help blood to clot

A healthy liver is essential for a healthy life. Getting cured of hepatitis C (HCV) will stop the damage done to the liver, and may even lead to a reversal back to a healthy one, including minimizing the risk of liver cancer. Beyond cure, there are many things you can do to help your liver stay healthy.

## FIBROSIS AND CIRRHOSIS

**OVER TIME**, HCV can cause damage to the liver, leading to fibrosis and cirrhosis. For people living with HCV alone, the scarring process is relatively slow: Without treatment, it takes an average of 20–30 years for fibrosis to develop into cirrhosis. HIV/HCV co-infection can speed up liver damage dramatically.

## FIBROSIS

### CHRONIC INFLAMMATION OF

the liver leads to the production of substances (collagen and other proteins) that can damage the liver's cells. Over time, this damage can lead to scarring. Fibrosis refers to the development of scar tissue in the liver. In the early stages of fibrosis, the liver is able to perform its functions with relative ease. Over time, the fibrosis grows and the scar tissue spreads, stressing the liver and its ability to do its job. As the fibrosis and scar tissue expand, it can eventually lead to cirrhosis. The speed with which fibrosis develops is different from person to person, with several other factors that can speed it up.

## FACTORS THAT INFLUENCE THE RATE OF FIBROSIS PROGRESSION:

- Alcohol consumption
- Age at time of infection
- Co-infection with hepatitis B
- Co-infection with HIV
- Presence of other comorbid diseases (such as diabetes)

There are different ways your medical provider can measure fibrosis and cirrhosis, ranging from a liver biopsy (not done as frequently as in the past, but still the gold standard of measurement) to blood tests. Increasingly,

there is a non-invasive (that is, no blood needed) means of measuring liver scarring called "transient elastography" (aka FibroScan), which is painless, fast and easy. While each of these tests are different, they all report their results in a similar way (see chart below):

## FIBROSIS SCORING SYSTEM

SCORE	AMOUNT OF FIBROSIS
F0–F1	No to minimal fibrosis
F2	Significant fibrosis
F3	Severe fibrosis
F4	Cirrhosis

## CIRRHOSIS

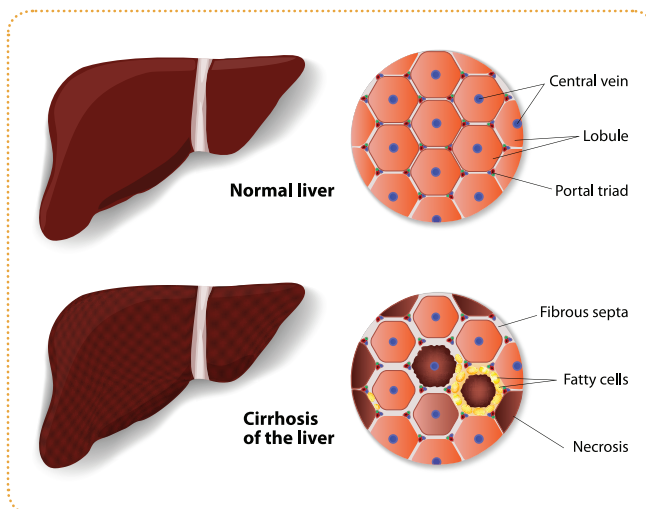
**AS THE FIBROSIS PROGRESSES** and the scarring covers more and more of the liver, it literally changes shape. This is called cirrhosis. Early cirrhosis, called compensated cirrhosis, can also be asymptomatic while the liver is still able to perform its functions.

As the scarring becomes more severe, the shape of the liver changes and it gets increasingly stiffer, reducing the blood flow and leading to a series of symptoms and complications. This is called decompensated cirrhosis, and it can become life-threatening without access to specialist health care.

Signs and symptoms of decompensated cirrhosis:

- Severe fatigue
- Loss of appetite
- Nausea
- Jaundice
- Weight loss
- Stomach pain
- Fluid retention
- Mental confusion

A person with decompensated cirrhosis should be in care with a liver specialist, routinely monitored for liver cancer and other serious problems, and be considered for a liver transplant.



# The FAQs of hepatitis C

Six things you should know about hepatitis C

## 1. What is hepatitis C?

“Hepatitis” means “inflammation of the liver.” There are lots of things that can cause hepatitis, or liver inflammation, including certain medications, excessive amounts of alcohol, other diseases, and viruses. Hepatitis can be both short-lived (called “acute”) or ongoing (called “chronic”). In addition to hepatitis C (HCV), there are other hepatitis viruses—A, B, D, and E. Hepatitis A and B are preventable by vaccine; D and E are very rare in the United States. There is no vaccine for HCV.

Hepatitis C is a virus that is transmitted by blood-to-blood contact that leads to either acute or chronic infection, and can lead to long-term liver damage. In chronic infection, HCV begins reproducing in the cells of the liver. Over time, this can lead to scarring and, as more and more scarring occurs, it can lead to cirrhosis and serious liver problems. However, HCV can be cured, preventing further liver damage and reducing the risk of developing liver cancer and other problems.

## 2. How is hepatitis C transmitted?

Hepatitis C is mainly spread by blood—when HCV-infected blood gets inside you. It is mostly transmitted these days through the sharing of drug injection equipment: syringes, cookers, cotton, and water. If HCV-infected blood gets in/on any of these injection items (“works”), they can transmit HCV to the next person who uses them.

Among HIV-negative heterosexuals, hepatitis C is not commonly transmitted through sex. However, among people living with HIV, especially men who have sex with men (MSM), the risk for sexual transmission of HCV is high. HCV has been

### ACUTE HEPATITIS C

- Flu-like symptoms
- Fatigue
- Fever
- Joint or muscle pain
- Dark urine
- Clay colored stools (poop)
- Diarrhea
- Nausea/vomiting
- Loss of appetite
- Jaundice (yellowing of skin or eyes)

### CHRONIC HEPATITIS C

- Fatigue (mild to severe)
- Fever
- Depression
- Joint or muscle pain
- Nausea
- Loss of appetite
- Skin problems
- Cryoglobulinemia (blood disorder)
- Peripheral neuropathy

### END-STAGE LIVER DISEASE

- Fatigue (often severe)
- Nausea/vomiting
- Fluid retention (especially in abdomen and legs)
- Jaundice
- Chronic pain
- Cognitive dysfunction/mental confusion
- Depression
- Loss of appetite
- Skin problems
- Cryoglobulinemia (blood disorder)
- Peripheral neuropathy
- Severe itching

found in the semen and rectal fluids of HIV-positive MSM; sex practices that can cause bleeding (such as fisting, rough sex, or toy play) can transmit hepatitis C.

## 3. What are the symptoms of hepatitis C infection?

The most common symptom is actually no symptom! Hepatitis C is called “The Silent Epidemic” for a reason: Most people who become infected never know they have it. People often want to know what symptoms to look out for to see if they have HCV, but the only way to know for sure is to test for it. That said, there are some symptoms to look for so that you can decide what to do. There are different symptoms for each stage of HCV infection—the acute stage (early infection), chronic stage (living with the virus until cured), and end-stage with cirrhosis (living with HCV for 20–30 years or more, for most people). This list is not complete, but indicates the most commonly experienced symptoms:

Again, this is not a complete list, so you should talk to your provider if you experience any of these symptoms, or if you aren't sure if something you're currently feeling is related to HCV. It's better to be safe than sorry! Many of these symptoms can be managed and/or treated, and once a person is cured, many of the symptoms may go away or become much less problematic.

## 4. How do I test for hepatitis C?

Testing for HCV is not a simple matter of getting tested and receiving a positive or negative result. It can be a little complicated. It's also different from HIV, so that can be confusing as well. Hepatitis C testing is a two-step process: first, you take an HCV antibody test; then, you confirm the result with a viral load (HCV RNA) test.

### THE HCV ANTIBODY TEST

The HCV antibody test will come up either negative or positive. If negative, you probably don't have HCV at this time. However, there's a “window period” with HCV antibodies similar to HIV. It may take up to six months to develop HCV antibodies. Therefore, if your most recent exposure for HCV occurred within the past six months, you will need to retest when you reach that six-month point.

If your antibody test comes back positive, you may have HCV—and “may” is the important word here. That's because about 25% (about 1 in 4 people) will clear hepatitis C on their own within six months of infection, but their result will still always indicate “positive” on an antibody test. Therefore, you'll need to get a viral load test, too (see below).

However, if you clear HCV during early infection, these antibodies cannot protect you from future hepatitis C

infection. People have been and can get re-infected! So it's important to protect yourself from re-infection.

### THE HCV VIRAL LOAD TEST

If you get a positive HCV antibody test, the next step is to get a viral load test to confirm it. If your last possible HCV exposure was at least six months ago and your test comes back negative, then you've cleared the virus. If it comes back positive, then you have chronic HCV infection, meaning that you will have it for the rest of your life until you get cured.

The other possibility is to have a negative HCV antibody test result with a positive viral load test. This means one of two things: (1) you were very recently infected with HCV, and your body hasn't yet produced enough antibodies to come back antibody-positive; or (2) you have a weakened immune system (low CD4 cells) and your body may not be able to produce enough antibodies in response to HCV. In either situation, it's important to talk with your medical provider about what these results mean and what next steps you should take.

## 5. Who should get tested for hepatitis C?

At some point in the near future, HCV testing will likely be routinely done for everybody, but for now it's not a test that everyone gets. For now, whether or not you get an HCV test will depend upon the following factors: what year you were born, high-risk practices, potential exposures from a past medical procedure, and certain medical conditions. The list below describes who should get tested for HCV:

### YEAR YOU WERE BORN

If you were born between 1945 and 1965—a baby-boomer—you should get tested for HCV at least once in your life. If you have any on-going risk factors (see below), you will need to test more frequently.

### RISK FACTORS

Anyone with risk factors for HCV should be tested at least once, or on an on-going basis if the risks continued. In this case, testing should be at least once per year, but you may want to do it more frequently if you are injecting drugs or are living with HIV and are sexually active.

The following risk behaviors or potential exposures call for HCV testing:

## Test results and their meaning

(remaining mindful of the 6-month HCV window period)

HCV ANTIBODY RESULT	HCV VIRAL LOAD RESULT	WHAT IT MEANS
Negative	Negative	You do not have HCV.
Positive	Negative	You do not have HCV: You have cleared the virus either through treatment or as one who naturally clears the virus.
Positive	Positive	You have chronic HCV.
Negative	Positive	You have early HCV infection and have yet to produce HCV antibodies OR your immune system is weakened enough that it cannot produce HCV antibodies.

- Injection drug use, even if just once in your life;
- Intranasal drug use (sniffing from a straw);
- Any incarceration;
- Getting a tattoo in an unregulated setting;
- Long-term hemodialysis;
- Child born to an HCV-infected mother
- Blood exposure on the job, including needle sticks and/or blood splashes to the eyes.

### PAST MEDICAL PROCEDURES

Today's blood supply and blood products are very safe, as are organs for transplant. That said, HCV is a relatively recent discovery; we did not screen for it prior to July, 1992. If you received any of the following, you should test for HCV:

- Blood transfusion before July 1992;
- Organ transplant before July 1992;
- Clotting factors before 1987

Other conditions and circumstances:

- HIV infection
- People starting PrEP (Pre-exposure prophylaxis)
- People on PrEP (not officially recommended yet, but should be. See box below)
- Organ donors
- People with unexplained chronic liver disease.

## 6. Can hepatitis C be cured?

Yes, and it's pretty easy to cure these days! The old days of HCV treatment, when you had to take pills and get injections for a year, and maybe you were lucky to be cured are long gone. Today, people living with HCV take medications called "direct-acting antivirals, or DAAs. These medications are all oral (pills only), and are taken once a day for as little as

8–12 weeks (24 weeks in rare cases). They are usually very well tolerated with few side effects, all of which are often very mild. There really isn't anyone who can't be treated and cured with these medications, and even if your first course of treatment doesn't work, there are options for re-treatment. Once cured, your risk of ongoing HCV-related liver disease will stop and you'll likely reap a host of additional health benefits.

### BENEFITS OF HCV CURE

- ✓ Negative HCV viral load for life
- ✓ Disappearance of HCV virus from the liver
- ✓ Normalization of AST, ALT, and GGT (liver function enzymes)
- ✓ Platelet increase in patients with thrombocytopenia
- ✓ Reduced risk of developing cirrhosis
- ✓ Reversal of fibrosis and, in some cases, cirrhosis
- ✓ Disappearance of varices (dilated blood vessels in the esophagus)
- ✓ Reduced risk of progression to liver cancer
- ✓ Reduced risk of decompensated liver disease
- ✓ Reduced risk of progression to liver failure and liver transplant
- ✓ Eliminated risk of transmission to drug using or sexual partners
- ✓ Eliminated risk of mother-to-child transmission
- ✓ Improved quality of life
- ✓ Reduction of psychological distress (anxiety, depression, etc.)
- ✓ Elimination of HCV-related stigma
- ✓ Lessened healthcare utilization and costs
- ✓ Return to the work-force and/or improved productivity

SOURCE: RUI MARINHO, 2014

# Hepatitis C

## Direct-Acting Antivirals (DAAs)

Preferred regimens based on AASLD treatment guidelines located at [hcvguidelines.org](http://hcvguidelines.org)  
Medications listed in alphabetical order

BRAND NAME	GENERIC (COMMON) NAME	MANUFACTURER	GENOTYPE	COPAY CARD	PATIENT ASSISTANCE PROGRAM	GENERIC AVAILABLE
<b>Epclusa</b>	sofosbuvir/velpatasvir (SOF/VEL)	Gilead	1 2 3 4 5 6	✓	✓	✓*
<b>Harvoni</b>	sofosbuvir/ledipasvir (SOF/LDV)	Gilead	1 4 5 6	✓	✓	✓*
<b>Mavyret</b>	glecaprevir/ pibrentasvir (GLE/PIB)	AbbVie	1 2 3 4 5 6	✓	✓	✗
<b>Vosevi</b>	sofosbuvir/velpatasvir/ voxilaprevir (SOF/VEL/VOX)	Gilead	1 2 3 4 5 6	✓	✓	✗
<b>Zepatier</b>	grazoprevir/elbasvir (GZR/EBR)	Merck	1 4	✓	✓	✗

\* Authorized generic available



# Epclusa

sofosbuvir/velpatasvir (SOF/VEL)

## DRUG CLASS

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

## GENOTYPE



## MANUFACTURER

**BRAND:** Gilead Sciences; **AUTHORIZED GENERIC:** Asegua Therapeutics LLC

## AWP

**BRAND:** \$29,904 / month; **AUTHORIZED GENERIC:** \$9,600 / month

## DOSE

**One tablet once daily, usually for 12 weeks, with or without food. See treatment table for this page online. Each tablet contains 400 mg of sofosbuvir and 100 mg of velpatasvir. Ribavirin may be added in patients with decompensated cirrhosis. The brand name is dispensed in a bottle, and the authorized generic is dispensed in a blister pack. The authorized generic was created to help lower cost and has identical ingredients as the brand name.**

Sofosbuvir-based regimens are not recommended in people with creatinine clearance (CrCl) less than 30 mL/min.

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

## ■ 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, and the real world experience has been very similar. 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). The majority of these side effects are considered to be mild and occurred at similar rates to placebo in clinical trials. Similar side effects can occur in

patients with decompensated cirrhosis, with the addition of diarrhea. Again, these are all considered mild to moderate in severity, and very few people have to discontinue treatment because of them. Epclusa has not been studied in pregnant women or nursing mothers, so the impact it may have on fetal development or nursing babies is unknown. Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

## ■ Potential drug interactions

Before starting Epclusa, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes as they happen during treatment. Epclusa should not be taken within 4 hours of antacids. If taking H2-receptor antagonists, take Epclusa at the same time or separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of proton pump inhibitors (PPI) is not recommended, but if medically necessary, Epclusa should be taken with food and 4 hours before taking a PPI comparable to omeprazole 20 mg or lower. Epclusa should not be taken with the following

HIV medications: efavirenz or tipranavir/ritonavir. Use caution and monitor renal function when taking Epclusa with tenofovir disoproxil fumarate (TDF). Avoid use if taking TDF with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine, as they reduce the concentrations of sofosbuvir and may reduce its effectiveness. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Epclusa. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia. 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 symptoms occur.

## ■ More information

Epclusa marked an exciting development for treating HCV: a pangenotypic (active against all 6 genotypes) once-per-day regimen taken for 12 weeks without ribavirin (in most situations) that has minimal side effects and high cure rates.

It is an effective and highly tolerable treatment option for people with GT3, with SVR12 rates as high as 98% for treatment-naïve patients without cirrhosis. Treatment experience and the presence of cirrhosis appear to lower the SVR12 rates (94 and 93%, respectively), but this is still a good, interferon- and ribavirin-free, option for this hard-to-treat patient group. It's also an excellent treatment for people with more advanced cirrhosis: The ASTRAL-4 study, which looked at patients with decompensated liver disease, resulted in an SVR12 of 83% for people taking Epclusa for 12 weeks and 86% for people taking Epclusa for 24 weeks. The rate of SVR12 increased to 94% when ribavirin was added to Epclusa for 12 weeks, which is why this is the recommendation in patients with decompensated cirrhosis. Finally, it's also an excellent choice for HIV/HCV co-infected persons. The ASTRAL-5 study, which looked at treating HIV/HCV co-infected persons with Epclusa, had an overall 95% SVR12 and included treatment-experienced patients and those with compensated cirrhosis.

Epclusa is taken for 12 weeks by people without cirrhosis or who have compensated cirrhosis, with ribavirin added for people who have decompensated cirrhosis (or extended for 24 weeks if not eligible for ribavirin). Treatment is for all genotypes and whether treatment-experienced or not (although this depends on what previous medicines were taken). See [hcvguidelines.org](http://hcvguidelines.org) for additional information on clinical studies and treatment recommendations.

## BLACK BOX WARNING

**Before starting treatment with any direct-acting antiviral (DAA), including Epclusa, 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 current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 34 for more information and consult your medical provider.**





# Harvoni

ledipasvir/sofosbuvir (LDV/SOF)

## DRUG CLASS

ledipasvir: NS5A inhibitor; sofosbuvir: Nucleotide analog NS5B polymerase inhibitor

## GENOTYPE

1 4  
5 6

## MANUFACTURER

BRAND: Gilead Sciences; AUTHORIZED  
GENERIC: Asegua Therapeutics LLC

## AWP

BRAND: \$37,800/ month;  
AUTHORIZED GENERIC: \$14,400 / month

## DOSE

One tablet once daily without regard to food. Tablet contains 90 mg of ledipasvir and 400 mg of sofosbuvir. Duration of therapy is 12 or 24 weeks, depending upon treatment experience and level of cirrhosis. In some cases, an 8-week treatment duration is possible. See treatment table for this page online. Ribavirin may be added in patients with decompensated cirrhosis or liver transplant patients without cirrhosis. See treatment duration table for this page online. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. Harvoni is FDA-approved for use in children age 12 and older or weighing at least 77 pounds (35 kg).

Sofosbuvir-based regimens are not recommended in people with creatinine clearance (CrCl) less than 30 mL/min.

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

## ■ Potential side effects and adverse events

Harvoni is generally well tolerated, and very few people in clinical trials discontinued treatment due to side effects (1% or less). The most commonly reported side effects are fatigue, headache, nausea, diarrhea, and insomnia, and are all considered to be mild in severity. Additional side effects observed in patients with decompensated cirrhosis or after liver transplant were thought to be due to their medical condition rather than the medication. Harvoni has not been studied in pregnant or nursing women, so the

impact it may have on fetal development or nursing babies is unknown.

Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

## ■ Potential drug interactions

Before starting Harvoni, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes as they happen during treatment. Harvoni should not be taken within 4 hours of antacids. If taking H2-receptor antagonists, take Harvoni at the same time or

separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of proton pump inhibitors (PPI) is not recommended, but if medically necessary, Harvoni should be taken at the same time as a PPI comparable to omeprazole 20 mg or lower under fasted conditions (on an empty stomach). Use caution and monitor renal function when taking Harvoni with tenofovir disoproxil fumarate (TDF). Avoid use if patient is taking TDF with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions. Do not take Harvoni with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine, as they reduce the concentrations of sofosbuvir and may reduce its effectiveness. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain

(myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Harvoni. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia. 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 symptoms occur.

## ■ More information

Harvoni was an exciting development for treating HCV in 2014 as it was the first one-pill, once-daily regimen with minimal side effects and high rates of SVR12 with treatment durations ranging from 8 to 24 weeks. Although there are now many treatment options available, Harvoni is still commonly used. Harvoni was the first of two combination DAAs that have been FDA-approved for use in children (age 12 or older or at least 77 pounds) with HCV genotypes 1, 4, 5, and 6 with either no cirrhosis or compensated cirrhosis.

See [hcvguidelines.org](http://hcvguidelines.org) for additional information on clinical studies and treatment recommendations.

## BLACK BOX WARNING

**Before starting treatment** with any direct-acting antiviral (DAA), including Harvoni, 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 current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 34 for more information and consult your medical provider.



# Zepatier

grazoprevir/elbasvir (GZR/EBR)

## DRUG CLASS

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

## GENOTYPE

**1 4**

## MANUFACTURER

Merck

## AWP

\$8,736 / month

## DOSE

**One tablet once daily with or without food. Each tablet contains 100 mg of grazoprevir and 50 mg of elbasvir. Ribavirin may be added in patients with certain baseline NS5A polymorphisms (mutations that may make the Zepatier less effective).**

Zepatier can be used in severe renal impairment, including in patients on hemodialysis. NS3/4A protease inhibitors, such as grazoprevir, are contraindicated in patients with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis. Using Zepatier in decompensated cirrhosis may cause significantly higher amounts of grazoprevir in the blood and may increase ALT (liver enzyme).

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

### ■ Potential side effects and adverse events

Zepatier is very well tolerated with minimal side effects. In clinical trials, very few people—around 1%—discontinued treatment due to side effects. The most commonly reported side effects are fatigue and headaches. These side effects are considered mild and are comparable in patients with and without cirrhosis. Nausea, insomnia, and diarrhea have also been reported. Zepatier has not been studied in pregnant women or nursing mothers, so the impact it may have on fetal development or nursing babies is unknown.

Pregnant women or women

who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

### ■ Potential drug interactions

Before starting Zepatier, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes as they happen during treatment. Zepatier should not be taken with HIV medications that require a booster (meaning they require another medication such as ritonavir or cobicistat to increase the drug levels in the body), such as atazanavir, darunavir, or elvitegravir. Zepatier should also not be taken with the HIV medications efavirenz or etravirine. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Zepatier. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Unlike several of the other HCV medications, Zepatier does not interact with acid reducing

agents. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction.

### ■ More information

Zepatier was an excellent medication upon its release, but it is not used much any longer as the other newer DAAs are preferred. Of particular importance: This regimen is especially effective in patients with kidney disease, including those on hemodialysis, with 99% achieving an SVR12. This regimen was studied in a number of unique patient populations including HIV/HCV co-infection and significant

renal impairment, including hemodialysis. The C-EDGE COINFECTION study showed minimal side effects in HIV/HCV co-infected patients who were given Zepatier and it did not negatively impact their HIV viral suppression. The C-SURFER study showed that Zepatier is well tolerated in Stage 4 and Stage 5 chronic kidney disease, and less than 1% discontinued treatment due to side effects. Both of these groups have high rates of SVR12 making it a good option in these patient populations. If you have HCV genotype 1a, you will need to take an HCV drug resistance test before starting Zepatier. If your hepatitis C virus is resistant, you will have to add ribavirin and take the combination for an additional four weeks (16 weeks total). This improves its effectiveness and allows the medication to overcome resistance, dramatically improving your chances for cure.

### Recommended treatment regimen and duration in persons with HCV genotype 1 or 4

Genotype 1a, treatment-naïve or PegIFN/RBV-experienced* without baseline mutations**	<b>Zepatier for 12 weeks</b>
Genotype 1a, treatment-naïve or PegIFN/RBV-experienced* with baseline mutations**	<b>Zepatier + ribavirin for 16 weeks</b>
Genotype 1b, treatment-naïve or PegIFN/RBV-experienced*	<b>Zepatier for 12 weeks</b>
Genotype 1a or 1b, PegIFN/RBV/PI-experienced***	<b>Zepatier + ribavirin for 12 weeks</b>
Genotype 4, treatment-naïve	<b>Zepatier for 12 weeks</b>
Genotype 4, PegIFN/RBV-experienced*	<b>Zepatier + ribavirin for 16 weeks</b>

\*Pegylated interferon + ribavirin

\*\*NS5A polymorphisms at amino acid positions 28, 30, 31, 93

\*\*\*Pegylated interferon + ribavirin + NS3/4A protease inhibitor (boceprevir, telaprevir, simeprevir)

### NOTES:

Testing for baseline NS5A polymorphisms is not required for genotype 1b or in patients on hemodialysis. Ribavirin dosing is weight-based: 1,000 mg daily if less than 165 pounds (75 kg); 1,200 mg daily if greater than or equal to 165 pounds (adjust for renal dysfunction or lab abnormalities). Administer in 2 divided doses daily with food.

### BLACK BOX WARNING

**Before starting treatment** with any direct-acting antiviral (DAA), including Zepatier, 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 current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 34 for more information and consult your medical provider.



# Mavyret

glecaprevir/pibrentasvir (GLE/PIB)

## DRUG CLASS

**glecaprevir:** NS3/4A protease inhibitor;

**pibrentasvir:** NS5A inhibitor

## GENOTYPE



## MANUFACTURER

AbbVie

## AWP

\$15,840 / month

## DOSE

Three tablets once daily with food. Each tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir for a total daily dose of 300 mg/120 mg. It is important to take all three tablets at the same time (do not separate throughout the day). See treatment duration table for this page online. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. Mavyret is FDA-approved for use in children age 12 and weighing at least 99 pounds (45 kilograms).

Mavyret can be used in severe renal impairment, including in patients on hemodialysis. NS3/4A protease inhibitors, such as glecaprevir, are contraindicated in patients with moderate or severe liver impairment (Child-Pugh B, C), which is also called decompensated cirrhosis. Using Mavyret in decompensated cirrhosis may cause significantly higher amounts of glecaprevir in the blood and may increase ALT (liver enzyme).

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

## ■ Potential side effects and adverse events

Mavyret is a very well-tolerated medication with minimal side effects. In clinical trials, very few people (about 0.1%) discontinued Mavyret due to side effects. Only headaches and fatigue were reported by clinical trial participants at rates higher than 10% (16 and 11%, respectively), with even fewer reporting nausea or diarrhea. Rates of side effects are not affected by treatment duration, presence of cirrhosis, HIV/HCV

co-infection, history of kidney transplant, and adolescence. There are no serious lab abnormalities expected. Mavyret has not been studied in pregnant women or nursing mothers, so the impact it may have on fetal development or nursing babies is unknown.

## ■ Potential drug interactions

Before starting Mavyret, be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes as they happen

during treatment. Mavyret should not be taken with HIV medications that require ritonavir as a booster to increase the drug levels in the body, such as atazanavir and darunavir. Mavyret should also not be taken with the HIV medications efavirenz or etravirine. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Mavyret. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use of ethinyl estradiol (estrogen)-containing birth control is not recommended due to potential increase in ALT (liver enzyme). Mavyret should not be used with cyclosporine doses higher than 100 mg daily. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction.

## ■ More information

Mavyret marks an exciting development in HCV treatment: it's the first pan-genotypic regimen that cures most people without ribavirin in as few as 8

weeks of treatment. Some people may need to take Mavyret for up to 16 weeks depending on previous treatment experience and presence of cirrhosis. 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 more than 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 (EXPEDITION-4) as well as for patients post-liver or kidney transplant, having cured 99% of people (MAGELLAN-2). In April 2019, Mavyret received FDA approval for use in liver and/or kidney transplants. Mavyret is the second combination DAA that has been FDA-approved for use in children age 12 and older or weighing at least 99 pounds (45 kg) for genotypes 1, 2, 3, 4, 5, and 6 with either no cirrhosis or compensated cirrhosis. For all of this great news, Mavyret is not recommended for people with moderate to severe liver damage, and alternative DAAs are better choices. For more information, see [hcvguidelines.org](http://hcvguidelines.org).

## BLACK BOX WARNING

**Before starting treatment** with any direct-acting antiviral (DAA), including Mavyret, 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 current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 34 for more information and consult your medical provider.



# Vosevi

sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX)

**DRUG CLASS**

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

**GENOTYPE**



**MANUFACTURER**

Gilead Sciences

**AWP**

\$29,904 / month

**DOSE**

**One tablet once daily with food. Each tablet contains 400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir.**

Sofosbuvir-based regimens are not recommended in people with creatinine clearance (CrCl) less than 30 mL/min. NS3/4A protease inhibitors, such as voxilaprevir, are not recommended in patients with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis. Using Vosevi in decompensated cirrhosis may cause significantly higher amounts of voxilaprevir in the blood and may increase ALT (liver enzyme).

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

**Not FDA approved for use in co-infection, but may be considered.**

**■ Potential side effects and adverse events**

Vosevi is very well-tolerated with minimal side effects. In fact, in the clinical trials for Vosevi, there were very few people—0.2%—who discontinued treatment due to side effects. The most commonly reported side effects are headache, fatigue, diarrhea, and nausea. Asthenia (weakness), insomnia, rash, and depression have also been reported, but in less than 10% of people. All adverse events are generally mild to moderate in severity and similar between people with and without compensated cirrhosis. There are no significant lab abnormalities of

concern. Vosevi has not been studied in pregnant women or nursing mothers, so the impact it may have on fetal development or nursing babies is unknown.

**■ Potential drug interactions**

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes as they happen during treatment. Vosevi should not be taken within 4 hours before or after you take antacids. If taking H2-receptor antagonists, take Vosevi at the same time or separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of

proton pump inhibitors (PPI) is not recommended, but if medically necessary, Vosevi can be taken with a PPI comparable to omeprazole 20 mg or lower. Vosevi should not be taken with the following HIV medications: efavirenz, atazanavir, lopinavir/ritonavir, or tipranavir/ritonavir. Use caution and monitor renal function when taking Vosevi with tenofovir disoproxil fumarate. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Vosevi. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia. 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 symptoms occur.

**■ More information**

Approved in 2017, Vosevi marks the next generation of Gilead drugs for treatment of hepatitis C 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 previous DAA treatment experience and HCV drug resistance. It is FDA approved for the re-treatment of HCV in people who are treatment-experienced, and although it can be used off-label for the initial treatment of HCV, it's best to use other options and save this one just in case it is needed later. In POLARIS-1, 97% of patients with GT1 achieved SVR12 (cure), and neither compensated cirrhosis nor presence of baseline resistance mutations appeared to affect outcomes. This is a wonderful achievement and offers hope to people living with HCV-associated cirrhosis. See the chart below for general treatment recommendations and [hcvguidelines.org](http://hcvguidelines.org) for additional information.

**BLACK BOX WARNING**

**Before starting treatment** with any direct-acting antiviral (DAA), including Vosevi, 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 current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 34 for more information and consult your medical provider.

GENOTYPE	PATIENTS PREVIOUSLY TREATED WITH AN HCV REGIMEN CONTAINING:	LENGTH OF TREATMENT
1 2 3 4 5 6	NS5A inhibitor*	12 weeks
1 a or 3	Sofosbuvir** without an NS5A inhibitor	12 weeks

\*In clinical studies, this included daclatasvir, elbasvir, ledipasvir, ombitasvir, and velpatasvir  
 \*\*In clinical studies, this included sofosbuvir alone or in combination with any of the following: peginterferon/ribavirin, ribavirin, boceprevir, simeprevir, or telaprevir



# Ribetol; ribavirin

ribavirin (RBV)

**DRUG CLASS**

Nucleoside analog

**GENOTYPE****MANUFACTURER**

REBETOL (SOLUTION): Merck

GENERIC CAPSULES/TABLETS: **Manufacturers vary**

**AWP (BASED ON 1,200 MG/DAY DOSING)**

REBETOL (SOLUTION): **\$1,960 / month;**

GENERIC 200 MG TABLET: **\$222-\$1,670 / month**

GENERIC 200 MG CAPSULE: **\$230-\$1,668 / month**

**DOSE**

Ribavirin dosage depends on several factors, including the brand used, indication for treatment, patient lab values, and patient tolerability. It is given in either fixed doses or in doses related to weight (weight-based). The dose range is 600 mg to 1,200 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. Ribavirin solution (liquid) and generic tablets are also available. The brand name is dispensed in a bottle, and the authorized generic is dispensed in a blister pack. The authorized generic was created to help lower cost and has identical ingredients as the brand name. It must be taken with food. Ribavirin may be added to direct-acting antiviral (DAA) therapy in people that have severe hepatic impairment (decompensated cirrhosis) or in people who have certain resistance mutations that make the DAA less effective. It should never be taken by itself.

Dose adjustment in patients with kidney dysfunction varies based on brand used. In general, use of ribavirin is contraindicated in people with creatinine clearance (CrCl) less than 50 mL/min.

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

**■ Potential side effects and adverse events**

There are two very serious potential side effects associated with ribavirin: anemia and birth defects/miscarriage/still-birth. The anemia caused by ribavirin can be very severe and can happen very quickly, usually within the first 1–2 weeks of starting treatment. Anemia can cause severe fatigue, dizziness, headaches, and shortness of breath; routine blood testing 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 breast-feeding 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 the HIV medication didanosine (Videx-EC, Videx, ddl) as this combination can lead to potentially fatal levels of ddl. Similarly, azathioprine (an immunosuppressive) cannot be used due to increased concentrations of azathioprine. Use caution if ribavirin given

with zidovudine, lamivudine, or stavudine (medications to treat HIV) due to potential for worsening side effects (anemia) and possible loss of HIV viral suppression (controversial if this actually occurs).

**■ More information**

It's not entirely understood how ribavirin works against HCV. It previously played a major part in HCV treatment for years when used in combination with interferon but is not generally reserved for certain patient populations with severe hepatic impairment. We are essentially in the ribavirin-free era with many of the current HCV DAAs.

If you need to take ribavirin, the side effects can be difficult. If you become anemic while on ribavirin, your medical provider may need 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.

# Hepatitis C co-pay and patient assistance programs

Treatment for HCV may 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.

## Harbor Path

[harborpath.org](http://harborpath.org)

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

## HealthWell Foundation

(800) 675-8416

[HealthWellFoundation.org](http://HealthWellFoundation.org)

Their newly formed hepatitis C co-pay assistance program can provide up to \$30,000 to eligible patients who are insured and have an annual household income of up to 500% of the federal poverty level.

## Needy Meds

[needy meds.com](http://needy meds.com)

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.

## Partnership for Prescription Assistance

[pparx.org](http://pparx.org)

A free, confidential program offered by the pharmaceutical industry; serves as a one-stop shopping site for over 475 public and private patient assistance programs, including about 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.

## Patient Access Network Foundation

(866) 316-7263

[panfoundation.org](http://panfoundation.org)

Has an HCV-specific program, and can offer up to \$7,000 in financial assistance for eligible individuals.

## Patient Advocate Foundation

(800) 532-5274

[copays.org/diseases/hepatitis-c](http://copays.org/diseases/hepatitis-c)

Has an HCV-specific program, and can offer up to \$15,000 in financial assistance for eligible individuals. They also assist patients with insurance denials and access to care issues.

## Additional financial assistance and access advocacy programs

DRUG NAME	MANUFACTURER	PHONE NUMBER	WEBSITE
<b>Harvoni</b>	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284	<a href="http://mysupportpath.com">mysupportpath.com</a>
<b>Sovaldi</b>	Gilead Sciences	(855) 7-MYPATH (855) 769-7284	<a href="http://mysupportpath.com">mysupportpath.com</a>
<b>Epclusa</b>	Gilead Sciences	(855) 7-MYPATH (855) 769-7284	<a href="http://mysupportpath.com">mysupportpath.com</a>
<b>Zepatier</b>	Merck	(866) 251-6013	<a href="http://merckhelps.com/ZEPATIER">merckhelps.com/ZEPATIER</a>
<b>Vosevi</b>	Gilead	(855-) 7-MYPATH (855) 769-7284	<a href="http://mysupportpath.com">mysupportpath.com</a>
<b>Mavyret</b>	Abbvie	1-877-628-9738	<a href="http://mavyret.com/hcp/patient-support">mavyret.com/hcp/patient-support</a>
<b>Rebetol</b>	Merck	-	No patient assistance available.

# Hepatitis C treatment for people with **HIV/HCV** co-infection

BY ANDREW REYNOLDS

**I**t wasn't that long ago when treating hepatitis C in people living with HIV was limited to two drugs: pegylated interferon and ribavirin. These medications were very challenging: People had to take them for a year, inject one of them, suffer severe side effects and worst of all, they were not very effective at curing people. Today, HCV treatment is easier than ever: For most people it can be completed in 8–12 weeks (some people may need 24 weeks), with few pills (and no injections!) and manageable side effects that are usually quite mild. Best of all, they cure people at very high rates, between 90 to 100% of the time. These new treatments also work very well in people living with HIV. HIV infection might complicate treatment, but it's nothing that can't be managed and you can still be cured of HCV.

The following are some key points for people living with HIV and HCV. This information comes from the recommendations in The Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents ([aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0](http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0)) and the "AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C" ([hcvguidelines.org](http://hcvguidelines.org)), the two leading professional guidelines for managing and treating HIV and HCV, respectively. They guide your medical providers in their practice, and offer valuable information to you, too.

## Managing HIV in co-infected persons

Managing and treating your HIV maintains your immune system and keeps your HIV viral load undetectable, but it is also good for your HCV. HIV treatment slows down liver damage and reduces the risk of liver-related problems for people who are co-infected.

There can be drug interactions between your HIV and HCV medications. In these cases, it may be necessary to switch your HIV regimen to accommodate the HCV treatment. If you can't (or don't want) to change meds, you may be able to try an HCV treatment that doesn't interact

with your HIV medications. Make sure your HIV and your HCV providers know about all the medications you're taking so they can help you manage any potential interactions.

The most important thing is that you should not stop taking your HIV therapy to take your HCV treatment. You can take treatment for both at the same time.

## HCV treatment in co-infected persons

Everyone with HCV should be treated for it regardless of the amount of liver damage one might have, and persons with HIV/HCV co-infection are no exception. In fact, the "AASLD/IDSA Guidance" states that people who are co-infected can be treated and re-treated with the same DAAs as those who are living with HCV alone. There may be some drug interactions between HIV and HCV meds, so make sure your all of your medical providers know what you're taking.

The cure rates for HIV/HCV co-infected people are extremely good, closely mirroring those of people who do not have HIV. Hepatitis C DAAs are easy to take and the medications have few side effects. There's never been a better time to treat HCV.

## When to begin HCV treatment for people with co-infection

As soon as possible. Co-infected persons who are

cured of HCV have lower risk of liver problems down the line. The sooner you get cured, the less likely the liver damage. Even if you find out that your liver has more advanced damage, getting cured reduces the risk of long-term problems. Additionally, depending upon how much damage there is, you might even be able to reverse it.

The only time you might consider holding off on HCV treatment is if your CD4 cells are below 200. If this is the case, it might make sense to wait a bit so the HIV medications can suppress the virus and give your immune system a chance to recover. Talk with your medical provider about the best course of action here.

## Maximizing treatment effectiveness

Adherence to your HIV medications is extremely important to keep your viral load suppressed and minimize the risk of developing drug resistance. The same is true of your HCV medications: The better you are at taking your HCV medications, the better your chance of being cured of hep C.

Adherence is more than just taking the pills every day. It includes taking them as prescribed to avoid drug interactions that might weaken the DAA's effectiveness. Check with your medical provider about everything you're taking—prescribed and over-the-counter—to make sure you can take them safely and to maximize your chance at a cure.

## Preventing re-infection after treatment

You can get hepatitis C more than once. After you've been cured, it will still be important to prevent reinfection with HCV. If you inject drugs, use new syringes and injecting equipment and avoid sharing

them. People living with HIV are more vulnerable to sexual transmission of HCV, so minimizing your risk of exposure to HCV through safer sex practices (condoms for anal sex, gloves for fisting, and so on) can offer you protection from re-infection.

After you've been cured, and if you have ongoing risk that could lead to re-infection, you'll want to get tested for the virus by doing a viral load test (you'll always have HCV antibodies) to check for HCV.

## Manage other potential liver conditions

People living with HIV are at great risk of having "non-alcoholic fatty liver disease," or "NAFLD," even in the absence of HCV or HBV. NAFLD is related to metabolic disorders that are common in people living with HIV, including diabetes, high cholesterol, and obesity (high body mass index, or BMI, a fancy way of saying "overweight"). These lead to excess fat getting stored in a person's liver that can lead to problems over time, including cirrhosis and liver cancer. Talk to your medical provider about your risk of NAFLD and monitor liver health after you've been cured of HCV. There are no treatments for NAFLD, but many are being studied. Stay tuned to POSITIVELY AWARE for updates on NAFLD and its treatment.

## Closing

We can end co-infection. Through improved HCV awareness, routine HCV testing, and expanding HCV treatment, the health and well-being of people living with HIV, will improve. It's not easy, but we have the tools and the ability.

If you have any questions about HCV treatment, call The Support Partnership's national hepatitis C helpline: **HELP-4-HEP**, 1-877-435-7443. **PA**

# Helping providers treat people with hepatitis C, HIV, and other conditions

Project ECHO reviews cases, provides insurance codes, and more

BY ENID VÁZQUEZ

When pharmacist Brooke N. Stevens, PharmD, BCPS, AAHIVP, generously stepped up to review this year's POSITIVELY AWARE hepatitis drug and treatment guide, she mentioned her work with Project ECHO.

Dr. Stevens is a clinical HIV/HCV pharmacist for Indiana University Health, in Indianapolis. The Project ECHO program—Extension for Community Healthcare Outcomes—teams up specialists such as Dr. Stevens, from larger towns and cities, with health care providers in smaller towns, offering the expertise needed to help serve patients.

“One of the big things that a lot of these providers have learned—in the hep C ECHO specifically—is checking for fibrosis, to be sure they have all their T’s crossed and I’s dotted, whether the patient has cirrhosis or not,” said Dr. Stevens. “That question comes up a lot, and the providers are able to give various examples of what to expect in lab values and what kind of tests to order. Not all of these primary care providers have the same access to tests that the hepatology team has.”

The specialists also help their colleagues with the information they need to work with insurance companies and the bureaucratic maze of paperwork and rules involved. This is especially helpful for smaller clinics that have fewer staff—and less time for chasing down the right insurance forms, authorization codes, and other requirements.

“Providers will tell us ‘I’ve spent two hours on the phone and I can’t even figure out how to get a PA [prior authorization] form.’ [An insurance company can refuse to make payment if prior authorization for care was

not given.] So we’ve been able to give them specific numbers for contacts at the insurance companies and we’ve been able to give them specific forms. I think that has taken a lot of time off the process for them, especially considering that a lot of the primary care teams don’t have social workers, pharmacists, and pharmacy technicians working on their team. They’re trying to see patients and do all of this other work at the same time—that’s a lot to take on for them.

“Ultimately, that wastes a lot of the provider’s time and it also delays therapy for the patient,” Dr. Stevens said. “We’ve dealt with all insurance companies and know the different quirks, and we’ve been able to give the other providers a lot of that information. So hopefully that makes it smoother for everyone, including the patients.”

Thanks to Project ECHO, patients can stay with the provider they prefer, rather than

being forced to travel far to see a specialist. In rural areas, a trip to a specialist can take hours.

“Especially in the smaller towns in Indiana, it’s been really good. The patients don’t have to travel three hours

to get to an expert. This has really expanded options for patients,” Dr. Stevens said.

She often wonders what patients think about delays as providers struggle with insurance companies. “They probably don’t understand how complex that whole process is. We really are trying to get you medicine!”

## PROJECT ECHO

Project ECHO is based on a hub-and-spokes model. At the “hub” are experts and specialists, comprising the “spokes” are primary care providers. In a video conference where everyone can see one another, a total of one or two cases are presented by the spokes



of patients under their care. (No private or personal patient information is given.) These providers also discuss whatever issues have come up in their work and learn from one another. The hub of specialists then also provide

clarification on the issues and make recommendations. There is also a 15-minute presentation on a particular topic.

“It’s mostly case-based learning rather than a lecture-like environment, and everyone learns from the cases,” said Dr. Stevens.

Hubs may be made up of a particular specialty, such as LGBTQ health, substance use disorder, or hepatitis C. Dr. Stevens serves on a hepatitis C hub.

Project ECHO is available across the U.S. and even around the world. Providers can learn more and register at [echo.unm.edu/join-the-movement/join-an-echo](https://echo.unm.edu/join-the-movement/join-an-echo).

**SPECIAL THANKS to Dr. Brooke N. Stevens** for reviewing the 2019 POSITIVELY AWARE Hepatitis Drug Guide. Dr. Stevens is an HIV clinical pharmacist at the LifeCare Clinic at Methodist Hospital and The Ryan White Center for Pediatric Infectious Disease and Global Health at Riley Hospital for Children, both at Indiana University Health (IU Health) in Indianapolis. In addition, she works closely with providers at the Digestive and Liver Disorders Clinic at University Hospital and other smaller clinics to assist with obtaining and educating on hepatitis C treatment. She currently serves as a clinical preceptor (training pharmacy students) at IU Health,

and is on the clinical faculty of the Midwest AIDS Training and Education Center. She serves on the “hub team” for the HCV Project ECHO (Extension for Community Healthcare Outcomes) at the Richard M. Fairbanks School of Public Health (RMFSPH). Dr. Stevens graduated from Butler University with her Doctor of Pharmacy in 2014. After pharmacy school, she did a two-year residency at IU Health, with her second year specializing in infectious disease. She is credentialed as a Board Certified Pharmacotherapy Specialist through the Board of Pharmacy Specialties as well as an HIV Specialist through the American Academy of HIV Medicine.



# Hepatitis B—An overview

A cheat sheet from **Andrew Reynolds** on the most common infectious disease in the world

**H**epatitis B (HBV) is a virus that infects the liver, and it is the most common infectious disease in the world. Over 2 billion people worldwide have been infected with it at some point in their lives, and approximately 240 million of those are chronically infected (living with HBV). Worldwide, it leads to more than 780,000 deaths every year. In the United States, an estimated 850,000 to 2.2 million people live with HBV, and about 10% of people living with HIV are co-infected with HBV.

In recent years there have been increases in HBV infections among people who inject drugs (PWID) and in mother-to-child transmission in the U.S., directly related to the opioid crisis. Screening, vaccination and prevention, and HBV treatment are essential tools for addressing this public health problem. This brief article will provide you with basic information on HBV.

## Hepatitis B transmission

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

### THE FOLLOWING ACTIVITIES HAVE BEEN ASSOCIATED WITH RISK OF TRANSMISSION:

- Vertical (mother-to-child) transmission
- 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 needle sticks or other risks of blood-to-blood contact

## Testing for hepatitis B

Most people who become infected with

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 is damaged, noticeable symptoms may arise, but screening (testing) for the virus is the only way to determine if you have HBV.

## Who should get tested for HBV:

### PERSONS FROM ENDEMIC REGIONS OF THE WORLD:

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

### PERSONS WITH CERTAIN MEDICAL SITUATIONS OR CONDITIONS:

- Women who are pregnant
- Babies born to mothers who are HBV-infected
- Individuals on hemodialysis
- People needing immunosuppressive therapy (such as chemotherapy or those receiving organ transplants)
- People with chronic HCV infection before undergoing DAA therapy
- Donors of blood, plasma, organs, tissues, or semen
- Anyone with an unexplained elevated ALT/AST

### RISK-BASED

- People who inject drugs
- Men who have sex with men
- People living with HIV
- Household, needle-sharing (including injection equipment), or sex partners of people with chronic HBV

- People who are the sources of blood or body fluids resulting in a potential HBV exposure (such as an occupational needle stick or blood splash or sexual assault) where post-exposure prophylaxis may be necessary

SOURCE: CENTERS FOR DISEASE CONTROL AND PREVENTION [cdc.gov/hepatitis](https://www.cdc.gov/hepatitis)

## Vaccination for hepatitis B

Hepatitis B is preventable by vaccine. It is safe and highly effective in preventing HBV, successful over 95% of the time. After the first dose, the vaccine is administered one month and six months later. Adults may be eligible for a 2-dose sequence, where the first dose is administered and the second one is given at least one month later (minimum of 28 days after the first one). The vaccine remains effective the rest of your life with no need for a booster shot ever.

### THE FOLLOWING SHOULD BE VACCINATED AGAINST HBV:

- All infants, beginning at birth
- All children under the age of 19 years 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 (e.g., more than one sex partner during the previous 6 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 living with HIV
- Unvaccinated adults with diabetes mellitus ages 19–59 years (at the discretion of clinicians for unvaccinated adults with diabetes mellitus who are aged 60 years and older)
- Anyone seeking protection from HBV infection—acknowledgment of a specific risk factor is not a requirement for vaccination

If a person already has HBV, the vaccination will offer no protection against disease progression or 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 for Hepatitis B

While HBV is vaccine preventable, 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 seem to improve the chances of clearing it. If someone is chronically infected, but has a normal liver function test called ALT or elevated ALT with low or undetectable HBV viral loads, then that individual does not need treatment. They should, however, 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 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.

## TEN WAYS TO LOVE YOUR LIVER

Health and wellness tips for living well with HBV and HCV

### 1. LEARN ABOUT HBV AND HCV.

Hepatitis B and C 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 and C resources page (page 40) 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 B AND C AND HIV.

Co-infection with any two of the three diseases can increase the risk of liver damage in a shorter amount of time. Knowing your status for HBV, HCV, and HIV is also important for treatment decisions for all three viruses.

### 4. AVOID ALCOHOL.

Ideally, people with HBV and HCV 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- or HCV-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. Its 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 burn fat, maintain or lose 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.

### 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 do so.

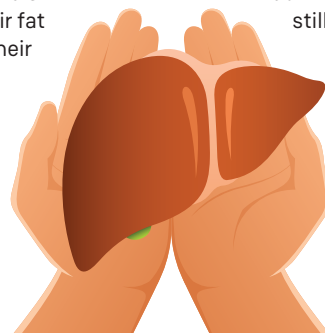
### 9. PRACTICE SAFE

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

### 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 check-ups to monitor your liver and get regular checkups.



# A forgotten risk

## Hepatitis B prevention for people who inject drugs



**W**hile 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, including pregnant women who, if untreated, risk transmission to their children. See below for some prevention and harm reduction tips to reduce the risk of infection among PWID.

### HBV prevention tips for people who inject drugs:

#### ✓ 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 31). 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 re-use 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](https://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 do 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 (but keep each person's equipment separate) and carry naloxone to reverse an overdose should one occur.

#### ✓ 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. **PA**

# Hepatitis B medications

BY CLASS AND PREFERRED REGIMENS

CLASS	BRAND NAME	GENERIC/COMMON NAME	PREFERRED	STATUS	MANUFACTURER
Nucleoside reverse transcriptase inhibitor (NRTI)	<b>EpiVir-HBV</b>	lamivudine (3TC)	✗	APPROVED	GlaxoSmithKline
	<b>Hepsera</b>	adefovir (ADV)	✗	APPROVED	Gilead Sciences
	<b>Baraclude</b>	entecavir (ETV)	✓	APPROVED	Bristol-Myers Squibb
	<b>Vemlidy</b>	tenofovir alafenamide (TAF)	✓	APPROVED	Gilead Sciences
	<b>Viread</b>	tenofovir disoproxil fumarate (TDF)	✓	APPROVED	Gilead Sciences
Interferon-alfa	<b>Intron A</b>	interferon alfa-2b	✓	APPROVED	Merck
	<b>Pegasys</b>	peginterferon alfa-2a	✓	APPROVED	Genentech

## BLACK BOX WARNING

### Hepatitis B reactivation

HBV reactivation has occurred in people co-infected with HCV/HBV while they were either on or shortly after HCV Direct-Acting Antiviral therapy, 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 2.5 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 31).

**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:

**A 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, or fatigue. If you experience any of these symptoms, call your medical provider and let her/him know.

**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 they 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.



# Baraclude

entecavir (ETV)

**DRUG CLASS**

Nucleoside reverse transcriptase inhibitor (NRTI), “nuke”

**MANUFACTURER**

Bristol-Myers Squibb

**AWP**BRAND, 0.5 MG AND 1 MG TABLETS: **\$1,647 / month**GENERIC, 0.5 MG AND 1 MG TABLETS: **\$216-\$1,800 / month****DOSE**

**ADULT (AGE 16 AND OLDER):** Treatment-naïve with no known or suspected resistance, one 0.5 mg tablet once daily. If lamivudine refractory (did not achieve adequate results) or lamivudine or telbivudine (brand name Tyzeka, discontinued for use since December 2016) resistant, one 1 mg tablet once daily. Decompensated liver disease: one 1 mg once per day. Baraclude should always be taken on an empty stomach (no food 2 hours before or 2 hours after taking pill). Dose adjustments needed for individuals with kidney disease and CrCl less than 50 mL/min. See drug page online and consult a medical provider for more details.

**PEDIATRIC (AGE 2-15, WEIGHING AT LEAST 10 KG):** Weight-based dosing, which is complicated and should be managed in consultation with an experienced medical provider, is required. Baraclude is available as an oral solution (liquid) and can be used in children up to 30 kg.

**■ 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: (1) 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; (2) 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, and pain, 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 herbal products 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 medications 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 tenofovir 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. Before starting Baraclude, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV to prevent resistance mutations in the HIV. You should be checked for HBV resistance to Epivir (lamivudine) before starting Baraclude: Epivir resistance decreases the effectiveness of Baraclude at the 0.5 mg dose, and it must be increased to 1 mg daily.

Abrupt discontinuation of Baraclude may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Baraclude is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first.

For individuals with HBV/HCV co-infection, or those at risk of HBV reactivation while undergoing HCV DAA treatment, Baraclude may be one of the medications you could be prescribed to prevent it from happening. See HBV Reactivation on page 34 for more information and consult your medical provider.

**Dosage requirements for patients with kidney disease**

Creatinine clearance (mL/min)	Lamivudine-refractory, lamivudine/telbivudine resistant, or decompensated cirrhosis: 1 mg	
	Treatment-naïve: 0.5 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

**NOTES:** Doses less than 0.5 mg daily should be given as the oral solution (liquid). If a person is on hemodialysis, Baraclude should be given after the dialysis session. See pediatric treatment table online.

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# Vemlidy

tenofovir alafenamide (TAF)

**DRUG CLASS**

Nucleoside reverse transcriptase inhibitor (NRTI), “nuke”

**MANUFACTURER**

Gilead Sciences

**AWP**

\$1,343 / month

**DOSE**

**One 25 mg tablet once per day, with food. There is no dose adjustment for people with creatinine clearance (CrCl) greater than 15 mL/min or for people with end stage kidney disease who are on hemodialysis. On days of dialysis, Vemlidy should be taken upon completion of dialysis. Vemlidy is safe for people with mild liver damage (Child-Pugh A), but it should not be used in patients with decompensated cirrhosis (Child-Pugh B or C). Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.**

### ■ Potential side effects and 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, and 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, although the risk is significantly lower compared to a similar medication, Viread. Before starting it, patients should have their 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 aching/pain, or fractures with or without muscular pain, consult your medical provider immediately.

There are two potential serious side effects when taking Vemlidy: lactic acidosis and two serious liver conditions. These are, however, more common with older medications in the same class as Viread (NRTI) and are unlikely to occur. (1) Lactic acidosis: The buildup 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. (2) 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, and pain, 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 herbal products 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 disoproxil fumarate, TDF), the two medications cannot be taken together. Vemlidy cannot be taken with any of the following HIV combination medications, as they also contain tenofovir (duplicate therapy): Atripla, Symfi, Symfi Lo, Complera, Odefsey, Descovy, Truvada, Biktarvy, Stribild, Genvoya, Cimduo, or Delstrigo. If taken with the anticonvulsant carbamazepine, Vemlidy dosage should be increased to two tablets (50 mg) once per day. Vemlidy should not be taken with oxcarbazepine, phenobarbital, or phenytoin as they reduce the concentrations of tenofovir and may reduce its effectiveness. Vemlidy

should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, and rifapentine. Vemlidy should not be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction.

### ■ More information

Vemlidy was approved for treatment of HBV in 2016. It's related to Viread, but is given as a smaller dose that is more efficiently delivered so the risks of kidney disease and loss of bone density appear to be less. Before starting Vemlidy, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV to prevent resistance mutations in the HIV. Two other HIV medications —Eпивir and Emtriva —also work against HBV, although Epivir is no longer preferred for the treatment of HBV. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV.

Abrupt discontinuation of Vemlidy may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Vemlidy is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first.

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 this from happening. See HBV Reactivation on page 34 for more information and consult your medical provider.

Vemlidy is not currently approved for use in children for treatment of HBV.



# Viread

tenofovir disoproxil fumarate (TDF)

## DRUG CLASS

Nucleoside reverse transcriptase inhibitor (NRTI), “nuke”

## MANUFACTURER

BRAND: Gilead Sciences

## AWP

TABLET (BRAND): \$1,435 / month

TABLET (GENERIC): \$110–\$1,216 / month

POWDER (BRAND ONLY): \$2,934 / month

## DOSE

**One 300 mg tablet once per day, with or without food. Approved for children age 2 and older weighing at least 22 pounds (10 kg). Oral powder and smaller tablets are available for children. Brand and generic tablets are available and are equivalent to one another.**

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

## ■ Potential side effects and 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. All Viread products contain lactose and may exacerbate symptoms in someone who is lactose intolerant. Viread may lead to decreases in bone mineral density (BMD), and patients should be monitored for osteopenia or osteoporosis. This decrease in BMD is likely reversed when the medication is stopped. As Viread is processed by the kidneys, there is risk of kidney toxicity, including acute renal failure and Fanconi Syndrome (injury to kidney tubules and high levels of phosphorus). 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 and the serious liver conditions. They are, however, more common with older medications in the same class as Viread (NRTI) and are unlikely to occur. (1) Lactic acidosis: The buildup 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. (2) 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, and pain, 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 herbal products you take, whether 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 (adefovir) due for possible worsening of renal function in combination. Viread cannot be taken with any of the following HIV combination medications, as they also contain tenofovir (duplicate therapy): Atripla, Symfi, Symfi Lo, Complera, Odefsey, Descovy, Truvada, Biktarvy, Stribild, Genvoya, Cimduo, or Delstrigo. Another HIV medication, Reyataz, must always be “boosted” (meaning given with ritonavir 100 mg or cobicistat 150 mg daily to increase levels in the body) when taken with Viread. Use caution when taking Viread with other 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 most HCV DAAs, but renal function should be monitored when taken with Epclusa, Harvoni, or Vosevi, especially if a “booster” is also being used.

## ■ More information

Viread (and its related drug Vemlidy) are also HIV medications. Before starting Viread, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV to prevent resistance mutations in the HIV. Two other HIV medications —Egipvir and Emtriva —also work against HBV, although Egipvir is no longer preferred for the treatment of HBV. In people with HBV/HIV co-infection, the combination of Emtriva and Viread (or Vemlidy) is the preferred regimen for treatment of HBV.

Abrupt discontinuation of Viread may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Viread is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first.

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 this from happening. See HBV Reactivation on page 34 for more information and consult your medical provider.

Viread is safe to use in children age 2 and older, weighing at least 22 pounds (10 kg) or more. Dose adjustments may be needed and should be done in consultation with an experienced medical provider. For people with kidney disease, there may also be a need for dose adjustments. See the chart below for recommendations, and make sure you are routinely monitored by your medical provider while taking this treatment.

## Dosage interval adjustment for adults with altered creatinine clearance

	Creatinine clearance (mL/min)			
	50 OR GREATER	30-49	10-29	HEMODIALYSIS PATIENTS
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72–96 hours	Every 7 days or after a total of approximately 12 hours of dialysis*

\*Assuming 3 hemodialysis sessions/week, each lasting approximately 4 hours.



# Pegasis; Intron A

peginterferon alfa-2a; interferon alfa-2b

## DRUG CLASS

Interferon-alfa

## MANUFACTURER

PEGASYS: Genentech

INTRON A: Merck

## AWP

PEGASYS: \$ 1,225.79 / week

INTRON A: Varies based on product and weight-based dosing

## DOSE

### Pegasis

**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/m<sup>2</sup> three times a week (TIW) for the first week of therapy followed by dose escalation to 6 million IU/m<sup>2</sup> 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 has a high number of side effects associated with it: 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), pruritus (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. However, be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether prescribed, over-the-counter, or illicit, before starting

this drug, and inform them of any changes as they happen. 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. Use caution when used in combination with other medications with similar side effects, such as neutropenia, as this could cause worsening symptoms.

## ■ More information

Although interferon is no longer used in HCV treatment, it still has a potential role for treating HBV. That said, it is rarely used for HBV. 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 difficult medication to take (injection) and tolerate. Other medications are easier to take (oral) with fewer side effects. Interferon is less safe for people who have any level of cirrhosis and should never be used by someone with decompensated cirrhosis. The AASLD Guidelines for the Treatment of Hepatitis B do include pegylated interferon alfa, along with Baraclade (entecavir or ETV), Viread (tenofovir disoproxil fumarate or TDF), and Vemlidy (tenofovir alafenamide or TAF) 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.



# Hepatitis B medication 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 following organizations can help you find low-cost medical care, navigate the health care access and insurance field, or provide financial assistance to help with HBV costs and related healthcare expenses. These programs have different eligibility requirements, and some have limited funds each year. Call each one for more information:

## HealthWell Foundation

(800) 675-8416

[HealthWellFoundation.org](http://HealthWellFoundation.org)

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.

## Needy Meds

[needymeds.com](http://needymeds.com)

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.

## Partnership for Prescription Assistance

[pparx.org](http://pparx.org)

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 about 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.

## Patient Access Network Foundation

(866) 316-7263

[panfoundation.org](http://panfoundation.org)

Has an HBV-specific program, and can offer up to \$4,500 in financial assistance for eligible individuals.

## Patient Advocate Foundation

(800) 532-5274

[copays.org/diseases/hepatitis-b](http://copays.org/diseases/hepatitis-b)

Has an HBV-specific program, and can offer up to \$4,000 in co-pay assistance for eligible individuals. They also assist patients with insurance denials and access to care issues.

### Additional financial assistance and access advocacy programs

MEDICATION	MANUFACTURER	WEBSITE	PHONE NUMBER
<b>Baraclude</b> (entecavir)	Bristol-Myers Squibb	<a href="http://bms.com/patient-and-caregiver/get-help-paying-for-your-medications.html">bms.com/patient-and-caregiver/get-help-paying-for-your-medications.html</a>	855-898-0267
<b>Viread</b> (tenofovir disoproxil)	Gilead	<a href="http://gileadadvancingaccess.com">gileadadvancingaccess.com</a>	800-226-2056
<b>Vemlidy</b> (tenofovir alafenamide)	Gilead	<a href="http://gileadadvancingaccess.com">gileadadvancingaccess.com</a>	800-226-2056
<b>Intron A</b> (interferon alfa)	Merck	<a href="http://merckaccessprogram.com/hcp/intron-a/">merckaccessprogram.com/hcp/intron-a/</a>	855-257-3932
<b>Pegasys</b> (pegylated interferon)	Genentech	<a href="http://www.genentech-access.com/patient/brands/pegasys/how-we-help-you.html">www.genentech-access.com/patient/brands/pegasys/how-we-help-you.html</a>	888-422-2377

## Hepatitis B

RESOURCES, SERVICES, AND INFORMATION

### Hepatitis B Foundation

[hepb.org](http://hepb.org)

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. Information is offered in a variety of languages.

### HepBUnited

[hepbunited.org](http://hepbunited.org)

A national coalition devoted to reducing the health disparities associated with hepatitis B by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the U.S. This is an excellent site if you want to keep up with HBV news and updates, and well as policy and advocacy.

### Asian Liver Center, Stanford University

[Stanford.edu/liver.html](http://Stanford.edu/liver.html)

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 U.S. and Asians throughout the world. It is an excellent resource for patients and providers.

### American Liver Foundation

[liverfoundation.org](http://liverfoundation.org)

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.

### Know Hepatitis B

[cdc.gov/knowhepatitisB/index.htm](http://cdc.gov/knowhepatitisB/index.htm)

An education and social campaign, Know Hepatitis B has a number of materials, 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.

## Hepatitis C

RESOURCES, SERVICES, AND INFORMATION

### HELP-4-HEP

877-435-7443 toll-free

National hepatitis C support line staffed by peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9 am–7 pm EST.

### The HCV Advocate

[hcvadvocate.org](http://hcvadvocate.org)

Offers a wealth of HCV informational fact sheets and booklets. This website will stop producing new and updated materials as of August 2019, but their blog will continue on an on-going basis and their fact sheets and guides will remain available (just not regularly updated).

### HEP Mag

[hepmag.com](http://hepmag.com)

An excellent resource for hepatitis B and C news and information. Their blog series, written by people with HCV as well as other HCV advocates, is a great source of practical information and inspiration.

### The Hepatitis C Mentor and Support Group, Inc.

[hepatitiscmsg.org](http://hepatitiscmsg.org)

An excellent resource for HCV support groups throughout New York, with links to many other resources for people living with HCV. They publish an excellent newsletter, too.

### Hep C Association

[hepcassoc.org](http://hepcassoc.org)

An excellent source for HCV news and information.

### infohep

[infohep.org](http://infohep.org)

Based in the U.K., this is an excellent resource for viral hepatitis news and education.

### Liver Health Connection

[liverhealthconnection.org](http://liverhealthconnection.org)

Array of services for people throughout Colorado. Excellent site for news and information.

### Treatment Action Group

[treatmentactiongroup.org](http://treatmentactiongroup.org)

National advocacy, research, and policy think tank on HIV, hepatitis C, and tuberculosis. They produce fact sheets, policy papers, and annual Pipeline Report.

### National AIDS Treatment Advocacy Project

[natap.org](http://natap.org)

Easily the best website for scientific results from HIV and HCV conferences and academic articles.

### Hepatitis C.net

[hepatitisc.net](http://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.

### Caring Ambassadors

[hepcchallenge.org](http://hepcchallenge.org)

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.

# What you need to know about **hepatitis A**

Although not normally fatal, hep A can lead to death for those with liver disease

**A**FTER YEARS OF DECLINE, hepatitis A outbreaks and infections have dramatically increased throughout the United States in recent years: From 2016 to 2018, the CDC reported a nearly 300% increase in HAV infections. Many of these new infections are the result of contaminated food, but there have also been increases among men who have sex with men (MSM), people who inject drugs (PWID), and those who are homeless. Hepatitis A is normally not fatal, but for individuals with pre-existing liver disease, it can lead to death. Consequently, these recent outbreaks have led to a significant number of deaths. This page is designed to give you very basic information about HAV, including ways to prevent it, so we can avoid unnecessary loss of life from a disease that is preventable with a vaccine.

## What is hepatitis A?

**HEPATITIS A IS A** type of viral hepatitis. It is a virus that infects the liver, but it differs from hepatitis B (HBV) and C (HCV), in that it doesn't become chronic: Once infected, people will likely feel symptoms for around 2 months, with some people experiencing them for as long as 6 months. Like HBV, HAV is vaccine preventable.

Hepatitis A is transmitted from fecal to oral contact—when poop (fecal matter) is inadvertently eaten. It is commonly a food-borne illness, where someone eats something that has not been properly cleaned or cooked, or the preparer hasn't properly washed their hands, but it can also be sexually transmitted through oral to anal contact.

## What are the symptoms of hepatitis A?

**ONCE INFECTED** with HAV, it usually takes about 2–6 weeks for symptoms to develop. Whereas hepatitis B and C are usually asymptomatic (no symptoms), hepatitis A

almost always has symptoms, some that can feel quite severe:

- Jaundice (yellowing of skin and eyes)
- Fever
- Fatigue
- Loss of appetite
- Nausea and/or vomiting
- Abdominal pain
- Joint pain
- Dark urine
- Clay-colored stools (shit or poop)

These symptoms can last 2–3 months, with some people experiencing them as long as 6 months. There is no treatment for hep A to get rid of these symptoms, but there are ways to help manage them. Don't take any medications—either over-the-counter or prescribed—to deal with your symptoms without consulting your medical provider. You don't want to put any added pressure on your liver, and some medications can do that.

## How is hepatitis A prevented?

**THERE ARE TWO WAYS** to

absolutely prevent HAV: Get vaccinated or do post-exposure prophylaxis after getting exposed to it (if you have not been vaccinated).

The HAV vaccine is a safe and effective way to prevent infection. The vaccine is a two-shot sequence—and you need them both to ensure long-lasting protection: You get the first shot, and then followup with the second one 6 months later. Depending upon the brand of vaccine used, the second dose can be given as long as 12–18 months after the first one.

There are also vaccines that prevent both HAV and HBV.

If a person misses the vaccination within the allotted time period, it's safe to start over as extra doses are not harmful. The HAV vaccine is safe for people living with HIV, as well as those with HBV or HCV. Indeed, people living with any of these infections should be vaccinated against HAV.

If you have not been vaccinated, but think you've been exposed, call your medical provider immediately. You can get immune globulin (a medication) or the HAV vaccine. It has to be administered within the first two weeks of an exposure.

Other ways to prevent HAV include good hand washing, thoroughly cooking food, and boiling water (note, drinking water in the U.S. is treated to kill HAV), and minimizing oral-to-fecal contact during sex.

Once a person has been infected with HAV, they will have natural immunity and will not need to worry about future infections.

## Who should get vaccinated?

**IN THE U.S.**, all children have been vaccinated since 2005. Some states started earlier. There are no recommendations to vaccinate all adults, so don't assume that you've gotten the vaccine at a later date. The following people should get vaccinated against HAV:

- All children at age 1 year
- People traveling to countries where hepatitis A is common
- Family and caregivers of adoptees from countries where hepatitis A is common
- Men who have sex with men
- People who use drugs, either injected or non-injected
- Homeless persons
- People with chronic or long-term liver disease, including hepatitis B or hepatitis C
- People living with HIV
- People with clotting-factor disorders
- People with direct contact with others who have hepatitis A
- Any person wishing to obtain protection from the virus

Hepatitis A is a preventable disease. Don't assume you've been vaccinated: Talk with a medical provider to determine if you need to be vaccinated.

**FOR MORE INFORMATION,** check out the CDC's website on hepatitis A: [cdc.gov/hepatitis/hav/afaq.htm](https://www.cdc.gov/hepatitis/hav/afaq.htm).

# Hepatitis C and HIV

Recent reports looking at syphilis, overdose deaths, and sexual transmission

BY ENID VÁZQUEZ

**S**everal reports at this year's CROI highlighted connections between hepatitis C and HIV. Considered the most important HIV medical conference in the world, CROI took place this year in March in Seattle. Go to [croiconference.org](#) to see abstracts (research summaries), poster presentations, and webcasts.

## Sex, syphilis, and babies

**THE MAJORITY OF** syphilis cases in the United States are found among gay men. The increasing number of cases being seen, however, are also found in women and in turn, their newborns. Congenital syphilis is now at a 20-year high.

A U.S. research team reported higher rates of syphilis in women living with HIV compared to the general population.

Looking specifically at records from a database of 4,795 women living with HIV, they found an annual syphilis rate of 760 cases per 100,000 person years. This compared to 2.3 cases per 100,000 women in the general population.

Although that sounds scary, the overwhelming majority of the positive women, 91%, had never acquired syphilis (3,999 of the 4,416 women who had ever tested for it). The total number of women with syphilis was 119, or 2.8% of those ever tested. A surveillance report presented separately at CROI, however, showed a 155% increase in syphilis in women living with HIV between 2013 and 2017.

Although the numbers may be small, the differences are big. The research team said there's a need for a better understanding of risk factors in order to protect women and their infants. Also of concern is how subtle the symptoms of syphilis can be.

The researchers found that a history of hepatitis C was related to having had syphilis, along with previous use of intravenous drugs, later entry into HIV medical care, and being of black race.

"There appears to be a strong association between [injection drug use] and hepatitis C co-infection in this group of women that's persistent over time—and IVDU rates are increasing," said study presenter Jodie Dionne-Odom, of the University of Alabama at Birmingham.

CROI Vice Chair Sharon L. Hillier, PhD, of the University of Pittsburgh, said, "We have a resurgence of a pathogen that we thought we were going to see the end of in 2000 in the United States, and yet this year we have about a thousand cases of congenital syphilis in the U.S., which is astonishing when you think of it."

CDC recommends that all pregnant women be screened for syphilis. The frequency of syphilis screening in HIV after entry to care, however, is not well established, said Dionne-Odom. She noted that approximately 6,000 women living with HIV in the U.S. give birth each year. Pregnancy data, however, were not part of this report.

In response to questions, Dionne-Odom said transactional sex (sex in exchange for cash or goods, including a place to sleep) appears to be the underlying mechanism for a connection between injection

drug use and syphilis. "So it's sex for drugs that either makes your partners at higher risk than you'd expect, or there are a higher number of partners. So it's not the drug use itself. It's the behaviors that come with the drug use. But as we have an increasing opioid epidemic and methamphetamine abuse that we're all seeing in our clinic, it's interesting to see this intersection between the drug use epidemic in the country and the syphilis epidemic in the country."

Although 7% of the women reported having at least two sex partners in the previous six months (and this was found to be a greater risk for acquiring syphilis), 40% had not had a sex partner at all. Half reported 100% condom use and only 14% reported sex after using drugs or alcohol. Increases in STIs were seen in all women regardless of age. "So this is something that's happening in older women as well," said Dionne-Odom.

These risks are different from those found among men, she said, noting that the predictors of risk for syphilis in women needed to be understood in order to determine better prevention and screening for them.

All groups of women are affected by the drug and syphilis epidemics, with signs that the two are related.

"That said, since we know the rates are so high in women with HIV, we certainly need to be screening more frequently than we already are," said Dionne-Odom. "The next step is if you have women coming into drug treatment programs, you screen them for syphilis. If you have women using drugs and are pregnant, they need to be screened at entry to care, at 28 weeks, and at delivery—all of them."

The team looked at the Center for AIDS Research Clinical Networks and Integrated Clinical Services (CNICS) study at eight U.S. sites.

**READ Abstract 47, "Incident Syphilis Rates and Predictors in U.S. Women With HIV, 2005-2016."** A webcast is available.

## Overdose deaths in HIV

**UNRELATED TO** hep C, but related to one of its well-known routes of transmission—injection drug use—researchers looked at opioid overdose deaths specifically in people with HIV epidemic.

"The opioid epidemic has been declared a nationwide public health emergency in the U.S.," said study presenter Karin Bosh, of the CDC. "In the U.S. general population from 1999 to 2017, the rate of unintentional opioid overdose deaths increased about five-fold. This is fueled by changes in the drug supply [especially the introduction of fentanyl], a synthetic opioid that is 50 to 100 times stronger than morphine] and increases in the number of people using opioids. Our analysis sought to assess unintentional opioid overdose deaths specifically among persons with HIV because we know that people with HIV are more likely to have chronic pain and more likely to receive opioid analgesic treatments, and to take higher doses of opioids. In addition, they are more likely to have substance use disorder and mental illness than the general U.S. population."

CDC found 1,363 deaths due to opioid overdose among people with HIV between 2011 and 2015. In that time, death due to HIV complications decreased 13%, but opioid overdose deaths increased by 43%. An increase was seen in

## The next step is if you have women coming into drug treatment programs, you screen them for syphilis.

all ages, races, and ethnicities, as well as geographic categories (except for the Western U.S. Census region). Overdose deaths also increased in women of all ages.

There were also increases among all individuals regardless of their risk factor for HIV, but there was a substantially higher death rate in people whose most likely route of HIV transmission had been injection drug use. The rate increased 80% in this group.

“The findings from our analysis underscore the importance of overdose prevention by those providing care and services to persons with HIV, including better integration of HIV and substance use disorder treatment,” Bosh said.

CDC plans to look for trends for overdose deaths across different drugs, such as synthetics, heroin, and prescription opioids.

**READ Abstract 147, Opioid “Overdose Deaths Among Persons with HIV Infection, United States, 2011–2015.”** A webcast is available.

### Sexual transmission of HCV in gay men

A BRITISH research team reported that for gay men, there was a drop in hepatitis C cases after greater access to potent HCV treatment.

They found that new cases of hepatitis C decreased by 74% in gay men living with HIV in London since the HCV epidemic peaked there in 2015. This followed a greater access to direct-acting antivirals (DAAs) in the city.

There was also a 62% decrease of overall HCV incidence in positive gay men with greater access to the hepatitis C medications.

“However, re-infection rates remain high and may be

increasing,” the team reported. “Further interventions to reduce ongoing transmission including access to treatment for reinfection are likely needed if micro-elimination is to be achieved.”

**READ Abstract 85, “Fall in HCV Incidence in HIV+ MSM in London Following Wider Access to DAA therapy.”** A webcast is available.

In New York City, a research team also looked at HCV reinfection in gay men.

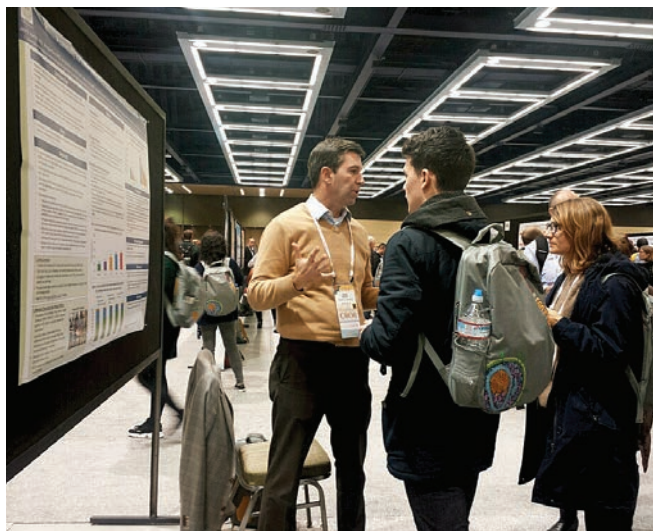
“The high HCV re-infection rate in our large cohort of [MSM living with HIV] in NYC was independent of whether clearance was by IFN [interferon] or DAA treatments, or by SC [spontaneous clearance], and comparable to Europe rates [re-infection rates of 3–15% following IFN treatment]. Most re-infections occurred within the first 2 years, but infections continued to occur for more than 11 years after clearance. These data suggest that long-term surveillance is warranted for all HIV-[positive] MSM after clearance of HCV infection. Further, strategies to reduce HCV re-infections are needed to meet the goal of eliminating HCV in these men who are at significant risk for HCV infection.”

**READ Abstract 86, “HCV Reinfection Among HIV-Infected MSM in New York City.”** A webcast is available.

Note: The two reports above were presented in the Wednesday morning oral abstract session, “Hepatitis C: Now You See Me; Soon You Won’t,” available via webcast.

A Thai research team found a relationship between hepatitis C infection and syphilis in HIV-positive gay men in Thailand.

“A recent surge in HCV incidence is noted among MSM [men who have



John Scott, MD, MSc, discusses his team’s poster presentation at CROI 2019 with interested providers, “A community intervention increased HCV screening and treatment in King County, Washington” (Abstract 583).

In their report, they noted that hepatitis C is common in people living with HIV, and that the number of cases of chronic liver disease and cancer related to hepatitis C continues to grow. This might be stemmed by simplified screening recommendations and the use of highly effective hepatitis C drugs, they said.

Their research demonstrated good results. “Using a combination of EMR [electronic medical record]-based healthcare system interventions, active linkage to care, and clinician education and training [including use of Project ECHO, see page 30], the number of patients screened for HCV tripled and those treated increased by ten-fold between baseline and Year 4,” the report summarized. “The interventions are scalable and foundational to the broader goal of HCV elimination.”

One of the team’s next steps: To help expand hep C treatment to places with a greater proportion of persons who inject drugs, such as syringe exchanges.

Dr. Scott is a physician at the Hepatitis and Liver Clinic at Harborview in Seattle and an associate professor of Allergy and Infectious Diseases at the University of Washington. The work presented at CROI was conducted in collaboration with the University of Washington; Seattle’s public health department (with three of its community health centers); three large multi-clinic health care systems (Swedish Medical Center, HealthPoint, and Kaiser Permanente Washington); and the Hepatitis Education Project, a hepatitis C patient education and advocacy group. Funding was provided by the Centers for Disease Control and Prevention (CDC) and the Washington State Department of Health.

sex with men] receiving chronic HIV care in Bangkok, Thailand. In the era of effective direct acting agents (DAAs) and ‘Undetectable = Untransmissible,’ sexually transmitted infections, including hepatitis C and syphilis, need to be routinely screened and treated in HIV+ MSM to prevent further transmission

to both HIV-positive and HIV-negative partners, particularly among resource-limited settings where the access to DAAs are still low,” the team reported in its conclusion.

**READ Abstract 599, “Surge in Hepatitis C Incidence Associated with Syphilis Infection Among Thai MSM.”** A poster presentation is available.

# A night that was ‘For All Ages’

Older and younger folks living with HIV share their experiences

BY RICK GUASCO PHOTOS BY JOHN GRESS



HIV ADVOCATE AND EDUCATOR SANFORD GAYLORD, A LONG-TERM SURVIVOR HIMSELF, ADDRESSES THE OTHER ATTENDEES

**“I was 19 years old when I was diagnosed,” said Reid. “I’m 49 now. I’m going to be 50 and I’m not going to be fucking afraid anymore. I am who I am, and I’m proud of it, and I’m very happy to be here.”**

As a long-term survivor of HIV myself, having been diagnosed in 1992, this was one of the messages I was hoping to hear, and why I organized this event. Billed as a town hall style intergenerational gathering, “For All Ages” attracted long-term survivors and other people living with HIV for an informal and lively discussion. An art gallery in Chicago’s River North neighborhood provided the intimate setting

for attendees to share their experiences and thoughts.

The evening was made possible by a mini-grant from NMAC (formerly the National Minority AIDS Council) I had received through their HIV 50+ Strong and Healthy program. My proposal was to present a forum for people— young and old alike—who are living with HIV to share their experiences with each other. And because I work at TPAN

(the publisher of POSITIVELY AWARE), I also saw this as an opportunity to connect them with my colleagues and other professionals—case managers, therapists, and educators—from agencies that serve people living with HIV. In fact, my co-host for the evening was Darnell Thurmond, who does outreach and recruitment for TPAN’s youth programs.

Stigma is one aspect of life with HIV that people of all ages face. Joseph, an early thirty-something gay man who directs his own dance company, talked about how he was asked by other members of his company

not to share his HIV status in his personal social media posts promoting the troupe. An older woman described the discomfort her family felt about her HIV status. A retired gentleman who had been out as gay and HIV positive was now facing the prospect of a smaller social circle of acquaintances and having to go back into the closet.

One long-term survivor who works with African American youth described the stigma he’s seen on the city’s South Side. Many young people who faced homelessness declined housing, he said, because they didn’t want to disclose to peers how

EVENT CO-HOST DARNELL THURMOND AND PrEP EDUCATOR D'eva LONGORIA



pushed back against the stigma they faced, and took charge of the situation. Judging from the reactions of others in attendance, while not everyone felt they were in a position to take control, they were heartened and encouraged by what

they were eligible for it.

In spite of good health, one long-term survivor said, “No matter what I do, I can’t get to undetectable.” He added that so much emphasis on U=U (“Undetectable Equals Untransmittable”) and even PrEP had made him feel marginalized.

Another said, “I’ve been positive for decades and I’m tired.”

Over the course of the evening, a number of attendees gradually opened up to the group, sharing more details of their experiences while also seeming to gain more confidence in sharing.

Another attendee expressed frustration and shame when first learning he was HIV positive. But as he contributed to the discussion he revealed more of his journey—his years dealing with Atripla side effects, depression, and drinking—culminating in self-acceptance, sobriety, and now having a mortgage.

In each of these personal stories, participants said they

they heard.

“It was such an emotional rollercoaster for me, when I was first diagnosed,” said D’Eva, a transgender heterosexual Latina. “At first I didn’t want to take any pills. But then I got a case manager, someone who became like a guardian angel, who helped get me onto treatment. And then I met my husband. He said, ‘Come on, you have to take your pills.’ I would say you first have to accept your diagnosis. Get support—you can’t do it alone. Anxiety will take over you, but it’s part of growing up. Get real friends, and let go of the toxic ones.”

“The decision of how to live is more important than any guilt of why you’re in the position you’re in—let go of it,” said one gentleman. “Let go of the stigma—what I really want to say is, let go of the *bullshit*, and live. Being on daily medication can be a reminder that you have this virus, but it’s also a reminder that the power to control HIV is in your hands.”

FROM LEFT: ANTHONY RAIOLA, LILLBETH GONZALEZ, ELIZABETH GORDON-DUDU, AND MICHELLE LOPEZ



## ‘We’re still here!’

THE NEW YORK CITY Department of Health with the Long-Term Survivors Wellness Coalition honored HIV Long-Term Survivors Awareness Day, June 5, with a day of health information and special activities called “We’re Still Here!” “As long-term survivors of HIV, we know how to be strong and resilient, and advocate for our health,” said Graham Harriman, Director of the Care and Treatment Program for the city’s Bureau of HIV/AIDS Prevention and Control. “Many of us struggled to make it to today through opportunistic infections, extreme fatigue, stigma from family, medication side effects, and the loss of so many loved ones. But today, we come together to celebrate in a spirit of radical self-love, knowing that in order to support each other and nurture a world that embraces all of us living with and affected by HIV, we need to start by being mindful of our bodies, our diet, our mental health, our relationships, and our ability to be present with each other as a community.”

According to the organizers, studies show that older people living with HIV experience higher rates of social isolation, stigma, and comorbid physical and mental health conditions compared to the general population. “Many experience a fragmented care system that increases the difficulty of effectively managing their health,” they added.

BELOW: GRAHAM HARRIMAN; JULIA SANCHEZ AND OCTAVIA LEWIS, MPA



LONG-TERM SURVIVORS: COURTESY OF LILLIBETH GONZALEZ; HARRIMAN, SANCHEZ AND LEWIS: CAREN BROWNING, KING + COMPANY



## More than a ride.

**It's about saving lives.** Become a part of TPAN's Ride for Life Chicago from anywhere you live. As a Virtual Participant or Legacy Rider, you can help TPAN and POSITIVELY AWARE impact lives affected by HIV. Because today, a full and healthy life with HIV is about much more than a diagnosis.

[rideforlifechicago.org](http://rideforlifechicago.org)



Hill-Rom



CARL A. BRANCH • MICHAEL "MURPH" MURPHY • SUSAN MURPHY