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HIV TREATMENT, PREVENTION
JULY+AUGUST 2022

FIRST AID FOR MENTAL HEALTH
Creating calm in the clinic

MY JOURNEY TO WELLNESS
A change of view leads to a new outlook on life

STEWART, TAMMY, and **CHERYL:** Overcoming hepatitis and other challenges

THE 10TH ANNUAL
HEPATITIS DRUG GUIDE
Your guide to treatment and care for viral hepatitis

ACTING UP FOR PEOPLE WHO USE DRUGS

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TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals living with HIV 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.

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THE 10TH ANNUAL **HEPATITIS DRUG GUIDE**

JULY+AUGUST 2022

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THIS ISSUE

EVERY ISSUE

THE 10TH ANNUAL HEPATITIS DRUG GUIDE

PULL-OUT HEPATITIS DRUG CHART
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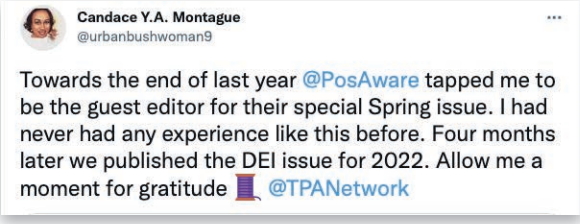
THE CONVERSATION

We all have a stake in overcoming disparities in HIV treatment, care and research. That was the focus of POSITIVELY AWARE's **Spring 2022** special issue on diversity, equity, and inclusion. *All in* was the main cover line, making the point that we all need to be *all in*—fully committed and fully engaged if there's to be change. Those words resonated with playwright Dominic Colón, who appeared on one of the two versions of the cover, along with Tonia Poteat, associate professor of Social Medicine at the University of North Carolina System in Durham, NC. Candace Y.A. Montague signed on as guest editor for the issue, bringing aboard a diverse group of writers. The response to the special issue reflected the need for the values of DEI in all aspects of HIV work.



Transgender actor, activist, and educator Alexandra Billings has a history with POSITIVELY AWARE and TPAN, the community-based nonprofit HIV/AIDS service organization that publishes the magazine. So, Billings was happy to take time out after teaching her students in Long Beach, California to pose for the cover story for the **May+June** issue.

Louise Moon, who did Billings' hair and makeup for the shoot, emailed afterward, "Thank you so much! It was such a beautiful day. She looks really relaxed and beautiful in these photos! I look forward to reading the interview!"

"To be in the same magazine as Alexandra Billings is just thrilling! I'm excited to read," wrote Jill Blumenthal, MD MAS, who also appears in the issue, for her work on hormone therapy and PrEP for transgender individuals.

JOIN IN THE CONVERSATION

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NOTE FROM THE HEPATITIS C EDITOR

ANDREW REYNOLDS
@AndrewKnowsHepC

Lessons learned

Viral hepatitis in the COVID-19 pandemic

There was a time when hepatitis C patients and advocates who were fighting for change and improved access to medical care, treatment, resources, and funding were able to make an ignominious claim: HCV was the deadliest disease in the United States, and it was more deadly than the next 59 infectious diseases combined. We would use this terrible statistic to highlight the suffering that comes from not sufficiently addressing a preventable and curable disease.

We can no longer say that, as we have a new infectious disease that has proven itself far more deadly: COVID-19. At the time of this writing, the U.S. surpassed more than one million deaths from COVID-19. This is a devastating and overwhelming number, but one that could have been so much worse were it not for a massive effort to study COVID-19, build a massive public health response, and develop a vaccine. I think it's fair to say that the U.S. was far from perfect in our response to COVID-19, but we did have our successes that we can learn from and apply to other public health issues, including viral hepatitis.

What lessons has the COVID-19 epidemic taught us?

Testing works

The NIH made the following statement about COVID-19 testing: "Testing of all people for SARS-CoV-2, including those who have no symptoms, who show symptoms of infection such as trouble breathing, fever, sore throat, or loss of the sense of smell and taste, and who may have been exposed to the virus will help prevent the spread of COVID-19 by identifying people who are in need of care in a timely fashion. A positive test early in the course of the illness enables individuals to isolate themselves—reducing the chances that they will infect others and allowing them to seek treatment earlier, likely reducing disease severity and the risk of long-term disability or death."

Replace the word "SARS-CoV-2" with *hepatitis B* or *hepatitis C* and you can pretty much say the same thing. Most folks with viral hepatitis don't know that they have it: HCV is called the "silent epidemic" because most people who have it are asymptomatic: 67% of people with HBV and 51% of people with HCV don't know they have it. If we launched a mass viral hepatitis awareness and testing campaign, we could reduce those numbers dramatically and connect people to medical care and treatment. A "positive test early in the course of the illness" for HBV or HCV means getting people engaged in care and treatment in the case of HBV, or cure in the case of HCV, and preventing long-term complications from cirrhosis like liver cancer or death. Treating and curing HCV among people who inject drugs reduces the risk of transmission and reinfection.

Vaccines save lives

The speed with which COVID-19 vaccines were developed was remarkable. The genetic sequence of COVID-19 was discovered and widely published in January 2020, and the race to develop a vaccine was on! It was a united effort between world governments, corporations, foundations, international health bodies, and universities, spending billions of dollars and implementing innovative clinical trial models. The result was a therapeutic vaccine that was effective in preventing serious illness and death in less than a year.

The COVID-19 vaccines worked: Even for people who acquired COVID, the vaccines reduced serious illness and hospitalizations, saving countless numbers of lives!

We have a vaccine for hepatitis B. It's a safe and effective vaccine that prevents infection. It's recommended for essentially everyone. Of course, if someone already had HBV, the vaccine isn't necessary, but for these people we can monitor the health of their liver and offer treatments to slow down the course of the disease until a cure is found. We don't yet have a vaccine for HCV, and to date we have invested limited resources in the development of one. Although there are challenges to overcome to develop an HCV vaccine, the mobilization of resources to develop COVID-19 vaccines is a model of inspiration for HCV vaccine advocates.

Health disparities and inequities in care need to be overcome

The social determinants of health—including racism, poverty, and access to healthcare and other services—had a dramatic impact on our COVID-19 outcomes. We know this is also the case for viral hepatitis, with the added barrier of stigma and criminalization of drug use that pushes people to the margins. If we want to eliminate viral hepatitis, we need more than just testing, vaccines, and medications: We need a fair and equitable system of healthcare delivery that people trust will be responsive to their needs in a non-judgmental manner.

Again, our response to COVID-19 was not perfect by any measure. That said, we did so much and we have had many victories that we can build upon to address viral hepatitis. Changing hearts and minds, and strengthening our political will, can help us overcome the failures in our COVID response. And it can certainly do the same for our response to viral hepatitis.

Andrew

Although there are challenges to overcome to develop an HCV vaccine, the mobilization of resources to develop COVID-19 vaccines is a model of inspiration for HCV vaccine advocates.

Briefly

ENID VÁZQUEZ @ENIDVAZQUEZPA

FDA lifts clinical hold on lenacapavir

The U.S. Food and Drug Administration (FDA) has lifted its clinical hold on the investigational long-acting medication lenacapavir, being developed for both treatment and prevention of HIV. The agency had halted development back in December 2021 due to issues with the borosilicate glass vials being used in research trials. On May 16, Gilead Sciences announced that the hold had been lifted "following the agency's review of Gilead's comprehensive plan and corresponding data on the storage and compatibility of lenacapavir injection with an alternative vial made from aluminosilicate glass." During the hold, research with the oral long-lasting formulation had continued. **Enrollment for the injectable doses of the studies can now be re-started.** In May 2019, lenacapavir received FDA Breakthrough Therapy Designation for development of HIV in heavily treatment-experienced patients with multi-drug resistance in combination with other antiviral drugs. It is the first of a new class of drugs, HIV capsid inhibitors.

Despite vaccination, breakthrough COVID-19 occurs more often in HIV

Among people vaccinated against COVID-19, **individuals living with HIV had a higher rate of contracting the disease** (known as "breakthrough infection") than people who were HIV-negative.

The finding came from a research team at Johns Hopkins University Bloomberg School of Public Health. Although their study found a low rate of COVID-19 infections for both positive and negative people, it was still 28% higher for those with HIV. The difference was 3.8% breakthrough COVID infections for the non-HIV group vs. 4.4% for the people living with HIV. Both rates are much lower than is seen with unvaccinated people.

The study looked at health records of almost 114,000 fully vaccinated individuals, of whom 33,000 were positive. It was published June 7 in *JAMA Network Open*.

The research team noted that the recommendation from the U.S. Centers for Disease Control and Prevention (CDC) is for people who are "moderately or severely immunocompromised" to receive an extra dose of vaccine as part of their primary vaccination series, followed by a booster. This category includes people living with HIV who are not receiving antiviral medication or who have less than 200 T cells.

HIV and Long COVID

The recently created Network for Long COVID Justice brings together the HIV and other chronic illness communities to advocate for information and resources as well as provide mutual support. In May, the network released a comprehensive report, *Resourcing the HIV Community to Face COVID and Long COVID in 2022*, that covers much of its work at the intersection of HIV and Long COVID, with embedded videos online: bit.ly/HIVreport.

According to the report, "**Increasing evidence indicates that PLHIV [people living with HIV] may be at significantly higher risk of Long COVID**, an umbrella term for a range of potentially severe, chronic conditions in people following a COVID-19 infection, including those that initially manifest as asymptomatic or mild cases." It discusses post-exertional malaise (PEM), the worsening of symptoms after mental, physical, or emotional exertion. HIV activists and medical providers discuss strategies and study findings. There is also a list of support groups.

WATCH a short video of Phillip Shubin telling his compelling story of contracting HIV and COVID-19 early in both epidemics and the dramatic effects on his mental and physical health: bit.ly/strategies4highimpact. **CHECK OUT** the network at their website home, springboardhealthlab.org/long-covid-justice.

FAQs for injectable PrEP

NASTAD (the National Alliance of State and Territorial AIDS Directors) in May added an FAQ (frequently asked questions) document on injectable PrEP (pre-exposure prophylaxis, or prevention) to its website. **The document includes insurance coverage information and is part of NASTAD's PrEP "microsite."** Apretude is the first, and still the only, injectable PrEP approved by the U.S. Food and Drug Administration (FDA). **GO TO** nastad.org/long-acting-injectable-prep; the microsite is at nastad.org/prep-access.

Telehealth and PrEP

The Kaiser Family Foundation has issued a report on the use of telehealth in PrEP, with funding from Southern California HIV/AIDS Policy Research Centers (SCHPRC). "Even before the COVID-19 pandemic, HIV pre-exposure prophylaxis (PrEP) became more accessible outside of traditional clinical settings through websites, apps, and other programs that offer PrEP via telehealth," SCHPRC noted upon the report's release in May. "The **use of telehealth to provide PrEP ("telePrEP") has the potential to address longstanding disparities** in PrEP use, but little is known about the current telePrEP environment." **GO TO** chprc.org/

TOP OF THE NEWS

➤ FAQs for injectable PrEP ➤ Telehealth and PrEP ➤ Abortion rights and trans people ➤ ViiV launches anti-stigma campaign ➤ CDC recommendations guide for detained and recently incarcerated ➤ Pediatric hepatitis of unknown origin ➤ Funding for Native American HIV and hepatitis efforts ➤ Syphilis rate in gay men finally decreases

HEPATITIS UPDATE

Pediatric hepatitis of unknown origin

The U.S. Centers for Disease Control and Prevention (CDC) reported on May 6 that it is working with health departments across the country to identify pediatric cases of hepatitis of unknown origin.

A hospital in Alabama had five such cases in October 2021. Four additional pediatric cases were found after a review of hospital records. Liver illness was severe and a liver transplant was necessary in some instances. **None of the children had evidence of hepatitis A, B, C, D, or E or of SARS-CoV-2 (the virus that causes COVID-19), but some tested positive for adenovirus, which causes cold- or flu-like illness.** In particular, they tested positive for adenovirus type 41, which is more likely to cause severe stomach illness in children. Symptoms include fever, diarrhea, vomiting, and abdominal pain. Respiratory symptoms may also occur.

The children ranged in age from one to six years old and were previously healthy, with no significant underlying medical conditions. They were from different parts of the state and had no common exposure. As of the date of the report, they were all recovering.

CDC asked parents to keep children up-to-date on vaccinations and to be aware of signs of liver inflammation:

- fever
- fatigue
- loss of appetite
- nausea
- vomiting
- abdominal pain
- dark urine
- light-colored stools (poop)
- joint pain
- jaundice (yellowing of the skin)

Parents should also help children with regular disease-prevention practices, particularly washing hands often; avoiding people who are sick; covering coughs and sneezes; and teaching them to avoid touching the eyes, nose, or mouth.

READ the CDC's report to the public at cdc.gov/ncird/investigation/hepatitis-unknown-cause/overview-what-to-know.html.

Native American HIV and hepatitis efforts get federal funding

The Indian Health Service (IHS) in April announced a funding opportunity for its new *Ending the HIV and Hepatitis C Virus (HCV) Epidemics in Indian Country* (ETHIC) program. ETHIC is part of IHS work in the *Ending the HIV Epidemic in the U.S.* (EHE) initiative. Hear IHS National HIV/HCV Consultant Rick Haverkate speak briefly to the **funding for community expertise from Indian tribes and urban Indian health organizations** at bit.ly/endHIVinIndianCountry. In a press release, IHS reported that, "Among people living with HIV, American Indians and Alaska Natives have the largest percentage of persons with undiagnosed HIV infection."

Ending hepatitis is something we can all do every day

That's the title of a short blog for Hepatitis Awareness Month in May and for Hepatitis Awareness Day (May 19) by Carl Schmid, executive director of the HIV+Hepatitis Policy Institute and a member of the Presidential Advisory Council on HIV/AIDS (PACHA). Schmid points to **the need for prevention, testing, and treating, all in the face of continuing stigma and discrimination**. He notes that there are vaccines to prevent hepatitis A and B and an outright cure for hepatitis C.

"You have heard it said before, 'We have the tools to end it.' I would add the saying, 'Easier said than done.' To end infectious diseases, we always need more scientific advances, but it is going to take a strategic, coordinated, and resourced public health response," writes Schmid.

GO TO hiv.gov/blog/ending-hepatitis-something-we-can-all-do-every-day.

prep-access-in-the-united-states-the-role-of-telehealth.

Patients illegally billed for PrEP

PrEP medication for the prevention of HIV is now free, including associated lab work, but **some insurance companies are still charging patients for various costs**.

READ the April report by Larry Buhl at TheBody.com at thebody.com/article/insurers-illegally-charging-prep?ic=700100&mcid=2940f-9d348&vhid=.

"There's evidence showing that the problem of overcharging [for PrEP] is huge and widespread," says Kenyon Farrow, managing director of advocacy and organizing at PrEP4All, in the report. Bills have totalled in the hundreds of dollars.

Abortion rights and trans people

"Transgender people get pregnant. And sometimes trans people need abortions," writes Imara Jones, founder of TransLash Media, and Kierra Johnson, executive director of the National LGBTQ Task Force. Their short but powerful commentary at *LGBTQ Nation* online addresses many aspects of the harms of both the anti-abortion movement, including the assault on body autonomy, and the abortion rights movement. "As is often the case, **the forces opposed to body autonomy for cisgender women also oppose it for trans people**," they write. "It is clear that this is one fight, but for decades, there has

Briefly

Syphilis rate in gay men finally decreases

The following blog post, reprinted here in its entirety, addresses several **issues related to the syphilis epidemic, including the effect on newborns in the U.S. and the need for HIV PrEP**. It was written by Leandro Mena, MD, MPH, director of the Division of STD Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention and published April 13. GO TO the CDC surveillance report at cdc.gov/std/statistics/2020.

"Syphilis continues to disproportionately affect gay, bisexual and other men who have sex with men (MSM), but a decades-long increase in reported cases may be reversing, according to Sexually Transmitted Disease (STD) Surveillance, 2020. The CDC annual report was published this week during STD Awareness Week 2022.

"This apparent leveling-off in reported primary and secondary (P&S) syphilis cases among gay and bisexual men is a small glimmer of hope in an otherwise concerning report. The data collected in 2020 for this report show that even in the first year of the COVID-19 pandemic, 2.4 million cases of chlamydia, gonorrhea, and syphilis were reported in the United States.

"Nationally, the number of P&S (the most infectious stages of the disease) syphilis cases among MSM slightly declined—2.2 percent—during 2019-2020. However, this population remains disproportionately affected—comprising 43 percent of all P&S cases.

"Tried and true prevention strategies work against this very preventable infection.

"For anyone who gets syphilis, diagnosis and timely treatment are essential. CDC recommends that all MSM be tested at least annually for syphilis. Some may need to be tested more frequently, including those with multiple sex partners. Syphilis can be cured with the right antibiotics. If not treated, syphilis can cause serious health problems, including neurologic (brain and nerve) problems, eye problems, and even blindness.


MENA

"While syphilis can increase the risk of HIV transmission, a syphilis diagnosis can also open the door to HIV prevention, including pre-exposure prophylaxis (or PrEP). STD surveillance data show us that the HIV prevention opportunity here is great—in 2020, over 8,400 MSM diagnosed with P&S syphilis were HIV-negative and an additional 2,300 had unknown HIV status. Each person diagnosed with syphilis represents an HIV prevention opportunity. And for those who are living with HIV and are diagnosed with syphilis, their syphilis diagnosis can be a critical HIV care touchpoint.

"*Ending the HIV Epidemic in the U.S.* (EHE) has provided a pathway to address this overlap. As part of EHE, CDC is investing in resources to scale up quality HIV prevention services in STD clinics. By addressing syphilis and other STIs alongside HIV, we are tackling this problematic syndemic, or interconnected epidemics.

"We have a long way to go. Despite the small national decline in reported cases of P&S syphilis among MSM, some states still reported increases among MSM in 2020. Simultaneously, preliminary 2021 data show that reported P&S syphilis continues to increase in the United States, particularly among women, which is resulting in sobering increases in syphilis among newborns.

"Amidst these challenges, the first-ever *STI National Strategic Plan* is providing much-needed direction in addressing not only syphilis, but other STIs and related infections. The Plan includes a call to address the syndemics of not only STIs and HIV, but also of viral hepatitis and substance use disorders. It challenges federal and nonfederal stakeholders at all levels and sectors to collaborate on a whole-of-nation, whole-person response, going beyond a diagnosis of disease to address the health and well-being of every person in the nation. It's a tall order, but we can do it.

"We are encouraged with even small signs of progress among this population disproportionately affected by STIs. I believe we can build on this momentum to meet the goals of decreasing the dramatic toll of STIs."

been an over-emphasis on cisgender women in the reproductive rights movement and transgender people have been left out and left behind." The online piece includes two short films from TransLash's "Trans Bodies, Trans choices" series, including "My Abortion Saved My Life." GO TO lgbtqnation.com/2022/03/transgender-people-get-pregnant-sometimes-trans-people-need-abortion. SUBSCRIBE to TransLash at TransLash.org.

Me in You, You in Me anti-stigma campaign

ViiV Healthcare announced a new anti-stigma campaign "aimed at increasing conversations around HIV prevention and addressing the stigma that can stand in the way of action." *Me in You, You in Me* "reflects ViiV's belief that if we can put an end to stigma, we can put an end to HIV."

"Recognizing that the communities most disproportionately affected by HIV are those who have benefited the least from the advances in HIV prevention, **the campaign seeks to ensure that all people are aware of the role they can play in preventing HIV** and to connect them to resources," the HIV pharmaceutical company reported.

In addition to providing videos, the campaign directs people to HIV services at locator.hiv.gov. Special activities are scheduled for Atlanta, Chicago, Dallas, and Miami/Ft. Lauderdale. GO TO the campaign and other cultural initiatives at viivhealthcare.com/en-us/ending-hiv/viivs-initiative.

Correction

The annual HIV Drug Guide (March+April 2022) inadvertently added "generic available" to the page for Isentress HD and Isentress. Neither medication is available as a generic. POSITIVELY AWARE apologizes for the error.

CDC recommendations for people who are detained

The U.S. Centers for Disease Control and Prevention (CDC) in April issued a new—first-time—**quick reference document addressing its recommendations for the testing, vaccination, and treatment of HIV, tuberculosis (TB), viral hepatitis, and sexually transmitted infections (STIs)** for people who are detained or incarcerated. The quick guide does not include all the CDC recommendations for people who are incarcerated. The agency noted that it recognizes that a facility's ability to follow the recommendations depends on such things as funding, capacity, and population turnover.

In a letter to healthcare professionals, Jonathan H. Mermin, MD, MPH, and Donna Hubbard, PhD, MPH, RPh, of the CDC noted that the rate of the following conditions are more common among people who are detained or incarcerated compared to the country's population at large:

- HIV is 3 times higher in state and federal prisons
- Hepatitis C is 10 times higher in jails and prisons
- TB is 6 times higher in jails and federal prisons
- Rates of STIs, chlamydia, and gonorrhea are higher among people aged 35 years and younger in juvenile and adult detention facilities

In addition, about 4% of women entering prisons or jails are pregnant, and recommendations address their needs as well.

At entry:

- Everyone should be screened for hepatitis B and hepatitis C, and for symptoms of pulmonary TB
- Testing for HIV and syphilis depends on prevalence of undiagnosed infections of these conditions in the facility, as well as local prevalence for syphilis
- All women ages 35 and younger and all men ages 30 and under should be screened for gonorrhea and chlamydia
- All women ages 35 and younger should be screened for trichomonas
- There are different recommendations during stays, depending on such factors as ongoing susceptibility (basically, exposure)

Screening should be opt-out, meaning that testing will be done unless a person specifically refuses the test (probably through paperwork that needs to be filled out).

Testing recommendations for pregnant persons follow the same guidelines as for the general population: HIV (with repeat testing as warranted), hepatitis B and C, and syphilis. Testing for chlamydia and gonorrhea should be done for all pregnant persons under age 25 and for those 25 and older who have increased vulnerability for these infections.

Vaccines:

- Everyone ages 18 and younger should be vaccinated with the series of shots against hepatitis A
- All adults at risk for hepatitis A (including men who have sex with men; people who inject drugs; and persons experiencing homelessness) should be vaccinated against hepatitis A
- All juveniles and adults should be vaccinated with the series of shots for hepatitis B
- HPV (human papillomavirus) shots can be started at age 9, with routine vaccination beginning around age 11; catch-up vaccination for all individuals who are not adequately vaccinated is recommended for people up to age 26

Treatment recommendations follow various medical guidelines for the particular condition.

At the time of release, people living with HIV should be given an adequate supply of antiviral medication to bridge the gap until they can enter into healthcare. HIV-negative individuals with known HIV risk factors should be told about PrEP (pre-exposure prophylaxis). Prevention counseling for both groups should include information on risk reduction and condom use.

"Correctional health is community health," wrote Mermin and Hubbard. "Together, we can improve the health of people who are incarcerated or detained, their families and the communities to which most people return by testing and treating HIV, viral hepatitis, STIs, and TB while people are incarcerated or detained."

GO to the new document at cdc.gov/correctionalhealth/rec-guide.html. **ALSO SEE** education material at cdc.gov/correctionalhealth/health-ed.html.

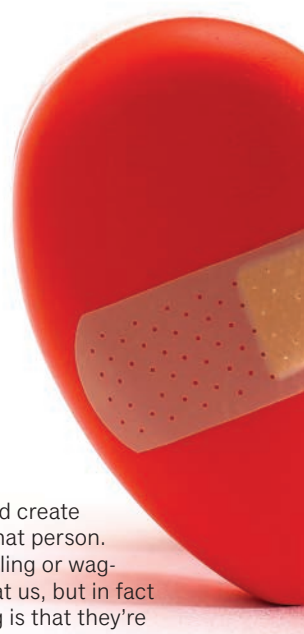
If you've been justice-involved...

For an **upcoming issue focusing on HIV criminalization and peope who are justice-involved**, POSITIVELY AWARE invites reader submissions, especially from currently or formerly incarcerated people. **SEND** letters, notes, stories, photos, drawings, and poems to POSITIVELY AWARE, 5537 N. Broadway, Chicago, IL 60640-1405; **EMAIL TO** inbox@tpan.com. If currently incarcerated, please state whether or not your name and contact information may be used. **The deadline is Friday, July 22.** There is no guarantee of publication or that items will be returned, especially within correctional facilities.

FIRST AID FOR MENTAL HEALTH

Creating calm in the clinic

INTERVIEW BY **ENID VÁZQUEZ**



Special populations most affected by the HIV epidemic face many stressors such as racism, homophobia, financial constraints, and stigma around drug use—all of which can lead to distress. Understanding that someone is distressed, rather than labeling them as "difficult," is essential, says Mathew R. Roosa, LCSW-R. A negative label distracts from working well together to resolve challenges to a person's health care.

"You're trying to figure out how to continue providing care while managing a person's distress within a limited amount of time and resources," says Roosa. "How can we pivot to address the distress so we can get back to providing the care that is our primary goal?"

Roosa has worked on a number of research projects designed to enhance mental health support in HIV care settings. His clinical work includes serving as a mental health and substance use therapist, agency administrator, and government planner for mental health and substance use services. Now working as a consultant, Roosa helped put together a presentation, *Creating Calm: Engaging People Who are Distressed*, for the Mental Health Technology Transfer Center (MHTTC). He speaks here to key points for creating calm, why we need to avoid language such as "acting out," and to the magic of empathy.

MENTAL HEALTH FIRST AID FOR EVERYONE

"**We find** that there is a lot of good training for clinical staff—social workers, psychologists, counselors, marriage and family therapists—for effective response to people who are having a lot of strong emotional dysregulation. By that we mean stressors that are creating intense emotional reactions that might be getting in the way of their functioning, causing them to struggle or not be able to think clearly or solve problems in the moment. There isn't, however, so much stuff out there for individuals who are not working as a mental health clinician, such as people sitting at the front desk or coming in to do research surveys.

"There's now this field of mental health first aid, which lets us know that there are core things that all of us can do to help someone who's having a crisis or a strong emotional challenge. It's like regular first aid. We can all apply some physical first aid now. We don't need to be a nurse or a doctor."

PIVOTING

"**We know** what it's like when someone's really upset and we're trying to just push them through the service. And they're reluctant to do that because they're upset. If we can just take a minute to do something else, we may be able to re-establish our connection and de-escalate their level of distress, and then we can more efficiently move back into that care.

"Rather than leaning in, try to lean back. Rather than asserting, try to ask questions. Try to provide an opportunity for the person to communicate with you, rather than you trying to dictate to the person. That's hard when things are stressful, because we all want for things to get less stressful quickly. So we often engage in behaviors that inadvertently create more stress. Avoid that quick reaction and create some space for that person. They might be yelling or wagging their finger at us, but in fact what's happening is that they're worried. So much of a person's distress can be managed if you're sharing empathy and building trust."

DON'T WORRY ABOUT OPENING A CAN OF WORMS

"**I've talked** to a lot of providers and some very skilled, excellent ones who will say, 'Gosh, I really don't want to ask those questions because I don't feel like I have the time, the staff, or the resources to respond.' No one feels good about that. The challenge is to come up with some clear, simple strategies to respond effectively." (See page 12.)

SPEAKING UP

"**I've seen** it over and over that when someone becomes very upset, either because they're angry, frustrated, worried, or concerned, there is a frequent tendency to ease that burden by telling the person what they should do, giving them specific directions, or telling them that they should try to calm down. It's almost always well intentioned. And it almost never works, because we all know what it's like when someone tells us to calm down when we're feeling upset. We generally feel like our experience is being discredited, disrespected, or ignored, and we usually get more upset. It's like, *I'm being loud so that you can hear me. You're telling me to calm down, which means you're not hearing me, which means I need to get louder in order for you to hear me.*"

WORDS MATTER

"**Using the words** 'acting out'—that's a tremendous judgment. I put you in

'Rather than leaning in, try to lean back. Rather than asserting, try to ask questions. Try to provide an opportunity for the person to communicate with you.'

a one down [lower] position, and I put myself in a position of judgment, power, and control. That is the opposite of what we want to do when we're trying to help someone feel more in control and more able to make decisions. My belief about your behavior might determine how we understand and address the situation. 'Acting out' is terrible language and is also infantilizing because it is language that's associated with children. And so when we use it in reference to adults, that's another way that it's stigmatizing and disrespectful.

"The language that we're using here, in terms of creating calm for people who are distressed, is what I like to think of as a much more empathic and person-centered language. We see a lot of language related to 'difficult' or 'challenging' people. And those are versions of judgmental language which tend to distance us from empathy toward that individual. We are all difficult at times."

TRAUMA-INFORMED

"**We traditionally** used to think about trauma as a 'yes or no' question. You either experienced these things that were very difficult, which have resulted in some challenges for you currently, or you were able to resolve that trauma and so you're not struggling with it currently. But we didn't think of it as a universal phenomenon.

"The reality is that it's more of a spectrum. Most everyone has some experiences from their earlier years that caused pain. They have a legacy in their current life that might impact how they see the world or how they react to stressful situations. So, rather than *yes* or *no*, it's *what is my history of trauma? How much did I experience? And how is it impacting me now?*"

CULTURAL DIVIDE

"**I had** one training with several people where a trainer responded to two African American women sharing ideas with each other by saying, 'Well, there's no reason to get angry about it.' The whole room fell apart. The women just had a slight disagreement with each other and were a little bit animated in their expression of their ideas. He was a white man who saw the discussion as a fight. We had to do all this damage control discussing this harsh judgment and this cross-cultural barrier. That's a good example of a lack of empathy. He did not understand what they were thinking or feeling and he didn't have a cultural lens that allowed him to understand them."

EMPATHY IS NOT TOLERANCE

"**There are** times when people need to get kicked out. Someone comes in and tries to punch someone at the front desk, they should get arrested. We can't tolerate that. At the end of the day, we have to keep people safe and healthy and able to deliver care and support. And if there's exposure to that kind of hurt, they won't be able to do it.

"I think it's actually lacking in empathy when you tolerate problematic behaviors because then you allow that person to get further away from healthy behaviors. It allows them to get closer to high risk for themselves and for others. That's not an empathic and compassionate response. We're not expecting much of them. We're not appreciating their humanity and their capacity to improve and move towards healthier behaviors. Healthy boundaries are part of an empathic compassionate response. 'We want to have you aspire to healthy behavior and that is not what this is.'

"Concerns include anger and rage. Second-most common is anxiety and panic. Distrust and paranoia feed on each other. Distrust-related paranoia often can result in risks to safety because people feel like they're being mistreated or that they're at risk, or that someone's trying to harm them. And so they might feel a need to protect themselves. That can create some pretty serious risks.

"Calling the cops, however, can cause great harm. We need to find alternatives to calling the police in some types of situations. Involving emergency services like the police is a last resort."

EMPATHY, NOT SYMPATHY

"**Understanding empathy** is maybe the most important part of all of this because most people don't appreciate empathy for what it is. It is not sympathy. It is not a warm, fuzzy feeling sorry for someone.

"Empathy is more head than it is heart. Empathy is more about understanding what the person is experiencing, trying to put yourself in their shoes and appreciate what they're thinking and feeling, and how that relates to what they're doing. 'Understanding' is a better word to use when defining empathy."

Also GO TO mentalhealthfirstaid.org. For copies of the *Creating Calm for People Who are Distressed* PowerPoint presentation, email greatlakes@MHTTCnetwork.org. MHTTC supports resource development and dissemination along with training and technical assistance for the mental health field. In addition to regional centers, the network includes a center for American Indians and Alaskan Natives and another for Latinx people. *Creating Calm* was produced with funding from the Health Resources and Services Administration (HRSA) under a cooperative agreement from the Substance Abuse and Mental Health Services Administration (SAMHSA). PA

How to create calm
while engaging with distressed people

ADAPTED FROM **MATTHEW R. ROOSA**

HELPFUL TOOLS

Use the empathy/trust spiral. Use empathy by listening, which creates trust, which brings about dialogue. If you have the time, you can ask, *Why does that happen?* Remember that big problems have multiple causes.

Similarly, don't just do something, sit there. Hear the person out through a compassionate presence. Compassion is empathy in action.

Control the "righting reflex," the urge to fix the problem right away and telling the person what to do. When people are in crisis, however, a clear direction is needed.

Use empathy. Empathy is not sympathy. It's not feeling sorry for someone or excusing reckless or dangerous behavior. Empathy means understanding. It means trying to understand the thoughts and feelings that led to a person's words or actions.

Be aware of your triggers. What causes strong emotional reactions in you? Beware of transference and countertransference—such as someone blaming you as a result of something that was done to them and your reacting instead of remaining neutral.

EVERY PERSON IS UNIQUE

If you've seen one distressed person, you've seen one distressed person. There are some generalities that can be explored, but it's important to think about each person as an individual and to keep trying to understand that individual person's experience.

Use elements of grounding. The process of grounding takes people out of their upsetting thoughts or emotions and brings them back into their body and surroundings. This helps clear their mind and their thinking ability. Ask them to squeeze their hands tightly for a few seconds, then relax them. Taking a deep breath can be grounding. People do not have to close their eyes; they may not feel comfortable doing so. Simple shortcuts like talking with them about the weather can bring them back into their surroundings. *I like your hat. Some weather we're having. How did you get here today? Is that chair comfortable?* It focuses on their physical present moment, helping them feel less anxious and probably safer, because they'll have an awareness that they are okay right now, that they're in a safe space. That's better than telling them they're safe, because when people are feeling really anxious, they won't necessarily trust that message. Noticing something about their surroundings can be a helpful strategy to engage people. Although probably not practical in the moment, meditation is a grounding practice. Grounding may not work for some angry people, who may feel that their concerns are being discounted.

Use elements of motivational interviewing (MI). Motivational interviewing uses open-ended questions to help people figure out for themselves what they really want or need. Provide them with the dignity and respect of exploring their options rather than telling them what to do. Motivational interviewing uses reflective listening, repeating back your understanding of what someone said. "Do I have this right?" It affirms people by giving them positive responses and regard for their challenges. "I'm sorry that you're struggling with this." It helps people make their own arguments for changing their life as they desire and the best way to do so, which helps avoid the pushing and pulling sometimes associated with getting help and then resisting suggestions. Help them focus on an area of concern, talk about maybe doing something differently or figuring something out, and then help them to plan.

FOUR MOTIVATIONAL INTERVIEWING PROCESSES

Engage. Ask open-ended questions. *Why? How? Tell me more.* Questions lead to ideas, and ideas lead to solutions.
Focus. Ask, *What are you hoping for?* Use "agenda-mapping"—set the agenda. Form a collaboration with the person, especially when there are time or other constraints: *What are your concerns? Here's what I need to get done.* Look at options. Zoom in on them.
Evoke. Use *DARN* to prepare for change: *Desire* to change. *Ability* to change. *Reason* to change. *Need* to change. Use CAT for talking about change: *Commitment* to change. *Activation* to change. *Taking* steps to change.
Plan. Is the person ready to make a plan? Is the path clear? Does the person want support for change? Use *OARS* for planning. *Open*-ended questions. *Affirmations*. *Reflections*. *Summarizing*.

BE AWARE OF INEFFECTIVE RESPONSES

Feeling fear or anger—pulling back, pushing away, flight or fight impulses (see "Safety first,"below).

A tendency to want to fix it fast—intolerance of distress; frustration over the time needed for dealing with distress; difficulty in sitting with someone's distress. Use a few minutes to listen.

Using rule-based responses and language based in power, judgement, direction, and control:

- *Try to calm down.*
- *We do not do that here.*
- *I can't help you with that.*
- *Our policy is …*
- *Please do not take that tone with me.*
- *If you continue to do this, I am going to need to …*
- *The form clearly states …*
- *Yelling at me is not going to change the fact that …*

SAFETY FIRST

Rule No. 1 for safety: Never go it alone. Get help when your safety may be at risk, no matter your level of experience. It requires a team. Moreover, different staff members can offer different expertise and solutions.

De-escalation strategies include:

- using a calm voice and manner
- showing support and concern
- avoiding logic and argument
- limiting stimulation and eye contact
- providing space
- moving slowly
- announcing an action before doing it
- offering options for moving forward
- soothing activities such as music and grounding (may include deep breathing and muscle relaxation)

The POSITIVELY AWARE Viral Hepatitis Drug Guide includes medications for the treatment of hepatitis B (HBV) and hepatitis C (HCV) that are FDA approved. The information provided comes from the package labels, conference presentations, and peer reviewed journal articles, as well as sources such as the AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C (HCV Guidance), and AASLD Hepatitis B Guidance.

Treatment

HCV treatment is a cure for hepatitis C. It consists of two or more medications—all pills—taken together. Most are a fixed-dose combination (FDC) that contains medications from two different classes in one pill. In certain situations, some regimens may include weight-based ribavirin. Pegylated interferon is no longer used for HCV treatment.

HBV is treated with one medication at a time—either an antiviral or pegylated interferon. HBV treatment slows or prevents the progression of liver disease. To date, there is no cure for HBV, but research continues to look for one.

Drug names

Drug names can be confusing. We include the brand name, generic name, and an abbreviation. For example, Mavyret is a combination of glecaprevir and pibrentasvir; its abbreviation is GLE/PIB.

Drug class (HCV only)

The "direct-acting antiviral" or DAA era of HCV treatment has seen the development of several different drug classes. Currently, there are five:

- 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. This guide only refers to GT 1–6. In the U.S., GT 1–4 are prevalent, with GT 1 the most common. Each genotype has subtypes indicated by numbers and letters—GT 1a, GT 1b, and so on. We list the genotypes that the HCV medication works against.

Average Wholesale Price (AWP)

The AWP is the measure used by insurers—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 place on programs such as Medicaid and Medicare, as well as the Veterans Administration and private insurance carriers. Each of the pharmaceutical companies has a Patient Assistance Program (PAP) to help people who are uninsured or underinsured 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 24.

Potential side effects and adverse events

This section offers information about side effects and adverse events associated with a drug. It's not an exhaustive list. Everyone experiences side effects differently. Just because it's listed doesn't mean you will necessarily get it. Talk to your medical provider about any side effects that you may have during treatment, and get blood tests as directed.

Potential drug interactions

This section provides information about the variety of known and potential drug interactions. Again, it's not an exhaustive list. 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 (including over-the-counter ones) you are taking.

More information

This section contains information that is useful to know.

A note on hepatitis B reactivation

In 2016, the FDA added a "Boxed Warning" about the potential risk of HBV reactivation in some patients taking any hepatitis C DAA. See page 27 for more information.

SPECIAL THANKS TO BROOKE N. STEVENS, PHARMD, BCPS, AAHIVP, for reviewing the 2022 POSITIVELY AWARE Hepatitis Drug Guide. Dr. Stevens is the Specialty Pharmacy Clinical Manager at Indiana University Health in Indianapolis. She is also 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 IU Health. She currently trains pharmacy students and residents, is on the clinical faculty of the Midwest AIDS Training and Education Center (MATEC), and serves on the "hub team" for the HCV Project ECHO.

10 THINGS TO 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, and other diseases as well as viruses. Hepatitis can be both short-lived (called "acute") or ongoing (called "chronic").

Hepatitis C virus (HCV) is transmitted from blood-to-blood contact and it can lead to long-term liver damage. If chronically infected, HCV infects the cells of the liver, where it reproduces. Over time, this can lead to scarring and as more and more scarring occurs, it can lead to cirrhosis (where the scars build up and cause liver malfunction) and serious liver problems. Fortunately, 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 transmitted from blood: When HCV-infected blood gets into you. The main way it is transmitted today is through the sharing of injection equipment: syringes, cookers, cotton, and water. If HCV infected blood gets in or on any of these injection items ("works"), they can transmit HCV to the next person who uses them.

Hepatitis C is not commonly transmitted through sex. In people living with HIV, especially men who have sex with men (MSM), the risk is higher and sexual transmission of HCV does happen in this group. HCV has been found in the semen and rectal fluids of HIV-positive MSM. Certain sexual practices that can lead to bleeding, including but not limited to fisting and rough sex toy play, can also transmit the virus during sex.

3. Who should be tested for hepatitis C?

Everyone! HCV testing is now recommended for everyone over the age of 18 without the need to ask about potential risk factors. If one has on-going risk for HCV, such as people who inject drugs or people living with HIV, then they should test for HCV more routinely: At least once per year. Test for it routinely so that on the off chance that you get infected, you can get treated and cured as soon as possible.

4. How do I test for hepatitis C?

Hepatitis C testing is a two-step process: first, you take an HCV antibody test; and second, you confirm the result with a viral load (HCV RNA) test.

The HCV antibody test will come up either negative or positive. There's a window period before antibodies appear, similar to HIV. It may take up to 6 months to develop HCV antibodies after your most recent exposure. Additionally, about 1 in 4 persons will clear hepatitis C on their own within six months of infection, but they'll still always show "positive" on an antibody test. Therefore, you'll need to get a viral load test too. If you clear HCV, these antibodies cannot protect you from another hepatitis C infection. So, it's important to protect yourself from re-infection.

A viral load test confirms a positive antibody test. If it comes back positive, then you are chronically infected, meaning that you will have it until you get cured. If you test positive for the HCV virus, talk to your medical provider about treatment options.

5. Can hepatitis C be cured?

Yes, and it is pretty easy to cure these days! The old days of HCV treatment where you had to take pills every day and do an injection once a week for a year and maybe get lucky and get cured are long behind us. Today, HCV direct-acting antivirals, or DAAs, are all oral (pills only), and taken once per day for as little as 8-12 weeks (rarely longer). They are usually very well tolerated with few side effects, all of which are usually very mild. Once cured, your risk of ongoing HCV-related liver disease will stop and you'll likely reap a host of additional health benefits.

The term we use for hepatitis C cure is "sustained virologic response" or SVR. Sometimes, though very rarely, the virus can bounce back after you've finished treatment. When you're done with treatment, you will wait 12 weeks for your final HCV viral load. If the viral load is undetectable, you have been cured and you don't have to worry about the virus coming back unless you get exposed and re-infected with the virus again.

6. What HCV medications should I use?

You'll work with your medical provider to pick the right HCV treatment for you, but there aren't too many options to pick so it will be pretty easy to choose one. Your treatment decision will also be based on things like treatment experience, drug to drug interactions with other medications you may be taking and other medical conditions you might have. Check out the medications we discuss in this guide to give you a better idea of which one might be best for you.

7. Can I get hepatitis C again?

You can get hepatitis C again: It's called HCV reinfection. With hepatitis A and hepatitis B, if you get it once and clear it, you can't get it again. You'll be naturally immune to reinfection. This is not the case with HCV. Whether you are one of those 20-25% of people who clear the virus naturally (see above) or you clear the virus because you got cured, you can get HCV again. Taking precautions to prevent reinfection, such not sharing any injection equipment, will help you stay HCV negative.

If you've had HCV and cleared it or were cured, you will always test positive for the HCV antibodies. In order to know if you've gotten it again, you will need to do an HCV viral load test.

8. Is there a vaccine for hepatitis C?

There is no vaccine for HCV. It's a point of great disappointment for those of us in the HCV world, as a vaccine would play an essential role in preventing new infections and helping us achieve hepatitis

elimination. That said, HCV has proven tricky for vaccine development for a number of reasons, including limited options for animal models in early research and the fact that it has a lot of genetic diversity which makes finding a vaccine candidate that protects against all types of HCV tough. There have been attempts in the past to come with a vaccine, and there are a few clinical trials currently underway, but we are a long way from having an effective HCV vaccine

There is a vaccine for hepatitis A (HAV) and hepatitis B (HBV). If you have HCV you should get vaccinated against HAV and HBV. Talk to your medical provider about the vaccines if you have any questions and want to see if you need to get them.

9. Is there a PrEP or PEP for hepatitis C?
There is PrEP and PEP for HIV, where HIV uninfected persons can take medications before (pre-exposure prophylaxis or "PrEP") or after (post-exposure prophylaxis or "PEP") to prevent infection. There is even a PEP for hepatitis B. Unfortunately, there is no PrEP or PEP for HCV. If you are HCV uninfected and concerned about a potential risk of HCV exposure, you should get tested and see if you've been infected. Talk with your medical provider about the timing and need for follow-up testing to see if you have it. If you test negative 3 to 6 months after the exposure, you didn't get it. If you test positive for the virus, you will be treated and cured.

10. How can I be engaged in my medical care and address my concerns?
Playing an active role in your health care is important: Your provider will be an expert in HCV medicine, but you are an expert in your life. Clear and honest lines of communication between you and your physician.

Here are a few tips to help you make the most out of your medical appointments:

- Be your best advocate: Study about HCV to understand the disease. Use this Guide to study the medications. Call the Help-4-Hep (1-877-435-7443) phoneline and talk with a peer counselor. You don't need to be an expert, but having some background on HCV and its treatment will help you be a more informed patient.
- Write down a list of questions or concerns you have before your appointment and bring them with you so you can ask them at your visit.
- Take notes about what your medical provider says during your visit.
- Keep a health journal: Write down any symptoms you may have. Keep a list of all of your medications. Track your adherence (pill taking) of your HCV treatment.
- Access other local health resources: Many organizations have HCV support and educational groups and case managers and health educators who can help you. Nurses and pharmacists are excellent sources of medical information.

ADAPTED FROM RUI MARINHO, 2014

HCV testing now free

According to the Hepatitis Plan (see Briefly), "In 2020, the U.S. Preventive Services Task Force (USPSTF) issued a Grade B recommendation that all adults aged 18–79 years be screened for hepatitis C, which will result in hepatitis C screening without cost-sharing [such as co-pays] for most people with Medicare, Medicaid, or private health insurance. These updated screening recommendations should result in greater numbers of adults being diagnosed with hepatitis C. However, these screening recommendations will only reach people engaged in the health care system."

Hepatitis C Direct-Acting Antivirals (DAAs)

Preferred regimens based on treatment guidelines from the American Association for the Study of Liver Diseases. Available at hcvguidelines.org
MEDICATIONS LISTED IN ALPHABETICAL ORDER

BRAND NAME	GENERIC (COMMON) NAME	MANUFACTURER	GENOTYPE	COPAY CARD	PATIENT ASSISTANCE PROGRAM	GENERIC AVAILABLE
Epclusa	**sofosbuvir/velpatasvir** (SOF/VEL)	Gilead AUTHORIZED GENERIC: Asegua Therapeutics LLC	1 2 3 4 5 6	✔*	✔	✔*
Harvoni	**sofosbuvir/ledipasvir** (SOF/LDV)	Gilead AUTHORIZED GENERIC: Asegua Therapeutics LLC	1 4 5 6	✔*	✔	✔*
Mavyret	**glecaprevir/pibrentasvir** (GLE/PIB)	AbbVie	1 2 3 4 5 6	✔	✔	✘
Vosevi	**sofosbuvir/velpatasvir/voxilaprevir** (SOF/VEL/VOX)	Gilead	1 2 3 4 5 6	✔	✔	✘
Zepatier	**grazoprevir/elbasvir** (GZR/EBR)	Merck	1 4	✘	✔	✘

* Authorized generic, with co-pay card, available

Epclusa

sofosbuvir/velpatasvir (SOF/VEL)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
sofosbuvir: Nucleotide analog NS5B polymerase inhibitor **velpatasvir:** NS5A inhibitor	1 2 3 4 5 6	BRAND: **Gilead Sciences** AUTHORIZED GENERIC: **Asegua Therapeutics LLC**	BRAND (400/100 MG AND 250/50 mg TABLETS): **$29,904 / month** AUTHORIZED GENERIC (400/100 mg TABLETS ONLY): **$9,600 / month**

DOSE

One tablet once daily with or without food. Pellets for pediatric use are available. Treatment is usually 12 weeks, but ribavirin may be added, or treatment may be extended to 24 weeks for certain patients.

Each tablet used for adults contains 400 mg of sofosbuvir and 100 mg of velpatasvir. New oral pellet formulations were approved in June 2021 (200 mg SOF/50 mg VEL or 150 mg SOF/37.5 mg VEL), which allows dosing in children at least 3 years old (as opposed to 6 years and older previously) and weighing at least 17 kg.

The brand name is dispensed in a bottle; 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.

Take your missed dose as soon as possible unless it is less than 12 hours until 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 clinical trials, very few people—0.2%— discontinued treatment due to side effects, and real-world experience has been similar. In patients without cirrhosis or in those with compensated cirrhosis, the most commonly reported side effects are headache and fatigue. Less frequently reported included 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, in addition to diarrhea. Again, these are all considered mild to moderate in severity; very few people have to discontinue treatment because of them. Epclusa has not been studied in pregnant women or nursing mothers, so its impact 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 important to report any changes to your medications as they happen during treatment. Epclusa should not be taken within 4 hours of antacids. If taking H2-receptor antagonists (used for heartburn), 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. Avoid use of Epclusa if taking tenofovir disoproxil fumarate (TDF) with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions, such as decreased renal function. 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 both components of Epclusa 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 determine if your statin should be continued or changed during treatment with Epclusa. No sofosbuvir-based HCV regimens may be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). 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 is a pangenotypic (active against all 6 genotypes), once-per-day regimen that has minimal side effects and high cure rates.

Epclusa can be used in several special populations. It can safely be used in people with kidney disease, including those on dialysis, with no need for dosage adjustment. Epclusa is approved for children aged 3 years and older. It is also recommended for use in people after they receive a liver or kidney transplant.

Epclusa is taken for 12 weeks by people without cirrhosis or who have compensated cirrhosis. Ribavirin is added for people who have decompensated cirrhosis, or treatment is extended to 24 weeks if someone is not eligible for ribavirin.

GO TO 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 worsen 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 27 for more information and consult your medical provider.

Harvoni

sofosbuvir/ledipasvir (SOF/LDV)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
sofosbuvir: Nucleotide analog NS5B polymerase inhibitor **ledipasvir:** NS5A inhibitor	1 4 5 6	BRAND: **Gilead Sciences** AUTHORIZED GENERIC: **Asegua Therapeutics LLC**	BRAND (ALL AVAILABLE DOSES): **$37,800/ month** AUTHORIZED GENERIC 400/90 mg TABLETS ONLY: **$14,400 / month**

DOSE

One tablet once daily with or without food. Treatment is usually 12 weeks, but ribavirin may be added or treatment may be extended to 24 weeks for certain patients. In some cases, an 8-week treatment duration is possible.

Each tablet used for adults contains 400 mg of sofosbuvir and 90 mg of ledipasvir. Dosing in children ages 3 and older is based on body weight (see below), and smaller tablets as well as packets of pellets are available to use in pediatrics. The brand name is dispensed in a bottle; 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.

Take missed dose as soon as possible unless it is less than 12 hours until 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 need to discontinue treatment due to side effects. 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 people 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 individuals, so its impact on fetal development or nursing babies is unknown. Pregnant persons or anyone 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 to your medications 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). Harvoni should not be taken with the HIV medication tipranavir/ritonavir. Avoid use if taking tenofovir disoproxil fumarate (TDF) with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions, such as decreased renal function. 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 both components of Harvoni and may reduce its effectiveness. Do not take Harvoni with St. John's wort; 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 Harvoni. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). 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 cure rates with treatment durations ranging from 8 to 24 weeks. Although there are now many treatment options available, Harvoni is still used.

Harvoni can be used in several special populations. It can safely be used in people with kidney disease, including those on dialysis, with no need for dosage adjustment. It is FDA approved for use in children ages 3 and older. It is also recommended to be used in people after they receive a liver or kidney transplant.

GO TO 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 worsen 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 27 for more information and consult your medical provider.**

Harvoni dosing

BODY WEIGHT	DOSING OF TABLETS OR ORAL PELLETS	HARVONI DAILY DOSE
At least 77 lbs. (35 kg)	One 400/90 mg tablet daily **or:** Two 200/45 mg tablets daily **or**: Two 200/45 mg packets of pellets daily	400/90 mg daily
37.4–77 lbs. (17 kg to less than 35 kg)	One 200/45 mg tablet daily **or**: One 200/45 mg packet of pellets daily	200/45 mg daily
Less than 37.4 lbs. (17 kg)	One 150/33.75 mg packet of pellets daily	150/33.75 mg daily

Zepatier

grazoprevir/elbasvir (GZR/EBR)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
grazoprevir: HCV NS3/4A protease inhibitor **elbasvir:** HCV NS5A inhibitor	1 4	Merck	$8,736 / month

DOSE

One tablet once daily with or without food. Each tablet contains 100 mg of grazoprevir and 50 mg of elbasvir. The number of weeks on treatment depends on genotype, previous therapy, and presence of NS5A polymorphisms (mutations that may make the Zepatier less effective). Ribavirin may also be added in patients with certain baseline NS5A polymorphisms. See treatment duration tables at positivelyaware.com/drug-guides/zepatier**.**

Take missed dose as soon as possible unless it is less than 12 hours until 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 its impact on fetal development or nursing babies is unknown. Pregnant persons or individuals 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 important to report any changes to your medications 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 determine if your statin may 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; 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 due to potential need for an additional lab test, possible need for ribavirin addition, and limited genotypes (only 1 and 4) covered. If you have HCV genotype 1a, you will need to get an HCV drug resistance blood 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.

It is an excellent regimen for patients with kidney disease, including those on hemodialysis, with 99% achieving a cure. NS3/4A protease inhibitors, such as grazoprevir, are contraindicated in people 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 (a liver enzyme).

For more information, GO TO hcvguidelines.org.

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 worsen 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 27 for more information and consult your medical provider.

Mavyret

glecaprevir/pibrentasvir (GLE/PIB)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
glecaprevir: NS3/4A protease inhibitor **pibrentasvir:** NS5A inhibitor	1 2 3 4 5 6	**AbbVie**	100 40 mg TABLETS: **$15,840 / month** 3–6 PACKETS/DAY OF 50/20 mg PACKETS: **$9,505–$19,009 / month**

DOSE

Three tablets once daily with food in adults and children weighing at least 45 kg. 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 tables below. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. New oral pellet formula was approved in June 2021, which now allows dosing in children ages 3 and older, without cirrhosis or with compensated cirrhosis, based on weight.

Take your missed dose as soon as possible unless it is less than 12 hours until 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 fatigue and headaches were reported by clinical trial participants at rates higher than 10% (11% and 16%, 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, or adolescence. There are no serious lab abnormalities expected. Mavyret has not been studied in pregnant women or nursing mothers, so its impact 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 important to report any changes to your medications as they happen during treatment. Mavyret should not be taken with HIV medications that require ritonavir as a booster, such as atazanavir and darunavir, to increase drug levels. Mavyret should not be taken with the HIV medications efavirenz or etravirine. It should also not be taken with rifampin or carbamazepine due to decreased concentrations of both components of Mavyret. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should determine if your statin may 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 a potential increase in ALT (a liver enzyme). Mavyret should not be used with cyclosporine doses higher than 100 mg daily. It cannot be taken with St. John's wort; in general, herbal products should be avoided due to lack of information regarding potential for interaction.

MORE INFORMATION

Mavyret is a pan-genotypic (active against all 6 genotypes) 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%. It is an excellent regimen for people with kidney disease, including people on hemodialysis, curing 98% who had severe kidney disease in 12 weeks of treatment (EXPEDITION-4) as well as for patients who are post-liver or kidney transplant.

NS3/4A protease inhibitors, such as glecaprevir, are not recommended for people with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis.

For more information, GO TO hcvguidelines.org.

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 worsen 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 27 for more information and consult your medical provider.

Treatment-naïve patients: If you've never taken HCV treatment before, you'll take it as follows

Genotype	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1 2 3 4 5 6	8 weeks	8 weeks

Treatment-experienced patients: If you have taken HCV treatment before, you'll take it as follows

Genotype	Previous treatment regimen	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1	**NS5A inhibitor*** without prior treatment with an NS3/4A protease inhibitor**	16 weeks	16 weeks
1	**NS3/4A protease inhibitor**** without prior treatment with an NS5A inhibitor*	12 weeks	12 weeks
1 2 4 5 6	**Prior treatment** with (peg)interferon, ribavirin and/or sofosbuvir but no other HCV treatment	8 weeks	12 weeks
3	**Prior treatment** with (peg)interferon, ribavirin, and/or sofosbuvir but no other HCV treatment	16 weeks	16 weeks

* In clinical studies, this included ledipasvir/sofosbuvir or daclatasvir + (peg)interferon + ribavirin. Other NS5A inhibitors include elbasvir, velpatasvir, and ombitasvir.

** In clinical studies, this included simeprevir + sofosbuvir, simeprevir, boceprevir, or telaprevir + (peg)interferon + ribavirin.

Vosevi

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

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
sofosbuvir: Nucleotide NS5B **velpatasvir:** NS5A inhibitor **voxilaprevir:** NS3/4A protease inhibitor	1 2 3 4 5 6	**Gilead Sciences**	**$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.

Take missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Vosevi is very well tolerated with minimal side effects. In fact, in clinical trials, very few people—0.2%—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 its impact on fetal development or nursing babies is unknown.

POTENTIAL DRUG INTERACTIONS

Before starting Vosevi, 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 important to report any changes to your medications as they happen during treatment. Vosevi should not be taken within 4 hours of antacids. If taking H2-receptor antagonists (used for heartburn), 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 (TDF). 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 about the 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 determine if your statin may be continued or should be changed during treatment with Vosevi. No sofosbuvir-based HCV regimens may be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). 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 medications for treatment of HCV and provides people whose previous treatment failed with a new option to get cured. Of particular importance is Vosevi's effectiveness in people with previous DAA treatment experience and HCV drug resistance. In POLARIS-1, 97% of people 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 who have previously failed to achieve cure after treatment.

NS3/4A protease inhibitors, such as voxilaprevir, are not recommended for people 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 (a liver enzyme).

In 2019, the FDA approved Vosevi's use for people with kidney disease, including people on dialysis, with no need for dosage adjustment. Although it is not FDA approved for use in HIV co-infection, it may be considered if drug interactions are also assessed. Vosevi is currently only approved for use in adults.

See the chart below for general treatment recommendations and hcvguidelines.org for additional information.

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 worsen 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 27 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
1a 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

Ribavirin

ribavirin (RBV)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP (based on 1,200mg/day dosing)
Nucleoside analog	1 2 3 4 5 6	GENERIC CAPSULES/TABLETS: **Manufacturers vary**	GENERIC 200 mg TABLET: **$1,389 / month** GENERIC 200 mg CAPSULE: **$1,601–$1,668 / month**

DOSE

Ribavirin dosage depends on several factors, including 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. Ribavirin is now only available as a generic tablet or capsule; other products have been discontinued. 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 for treatment of hepatitis C. 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 less than 12 hours until 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/stillbirth. 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, women who are trying to become pregnant, and males whose female partners are pregnant should not take ribavirin. Women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. It is unknown if ribavirin passes through breast milk or the impact it could have on breastfeeding babies.

Other side effects that have been reported with ribavirin include rash, itching, and 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 consult a medical provider 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, ddI) as this combination can lead to potentially fatal levels of ddI. Similarly, azathioprine (an immunosuppressive) cannot be used due to increased concentrations of azathioprine. Use caution if ribavirin is 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 now 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 can be expensive, but the good news is that help is out there. All of the pharmaceutical companies have a patient assistance program (PAP) to help uninsured people, and some also provide help for underinsured people to cover all or part of the costs of their drug. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. Check with each program for details.

Harbor Path
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
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.

Link2Labs
Link2labs.com
A discount lab service for uninsured, low income and high deductible insured persons. They have lab services in all states except California, Massachusetts, New Jersey, New York, and Rhode Island. Their easy to use website allows you enter the labs you need, pay for them, find a lab near your zip code and receive your results securely online.

Medicine Assistance Tool
medicineassistancetool.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 around 200 offered by the drug companies themselves. They also have a directory of over 10,000 free or low-cost clinics that can be searched by ZIP code.

Needy Meds
needymeds.org
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.

Patient Access Network Foundation
(866) 316-7263
panfoundation.org
Has an HCV-specific program, and can offer up to $5,600 in financial assistance for eligible individuals.

DRUG NAME	MANUFACTURER	CONTACT INFORMATION
Harvoni	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284 mysupportpath.com
Sovaldi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Epclusa	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Vosevi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Mavyret	AbbVie	(800) 222-6885 abbvie.com/patients/patient-assistance.html
Zepatier	Merck	(800) 727-5400 merckhelps.com/zepatier

HEPATITIS C RESOURCES, SERVICES, AND INFORMATION

Caring Ambassadors
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.

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–7pm EST.

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

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

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

The Hepatitis C Mentor and Support Group, Inc.
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.

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

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

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

Hepatitis C treatment for HIV/HCV co-infected persons

It wasn't that long ago that 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, injecting one of them, suffering severe side effects, and worst of all, they were not a very effective cure. Today, HCV treatment is easier than ever—for most people it can be completed in 8–12 weeks (although some people may need 24 weeks), with few pills (and no injections!), and manageable side effects that are usually quite mild. Best of all, there's a high cure rate—between 90 to 100%. 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.

Following are some key points for people living with HIV and HCV. This information comes from the recommendations from the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and from AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C, the two leading sets of professional guidelines for managing and treating HIV and HCV. They inform your medical providers in their practice, and offer valuable information for you, too. Read more at clinicalinfo.hiv.gov and hcvguidelines.org.

Managing HIV in co-infected persons

Managing and treating your HIV maintains your immune system and keeps your HIV viral load undetectable, but it's 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 could be drug interactions between your HIV and HCV medications, however. In these cases, you may need to switch your HIV regimen to accommodate the HCV treatment. If you can't (or don't want) to switch, you may be able to try an HCV treatment that doesn't interact with your HIV meds. Make sure your HIV and HCV care providers both 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 medication in order to take HCV treatment. You can take both at the same time.

HCV treatment in persons who are co-infected

Everyone with HCV should get treated, regardless of the amount of liver damage; persons who are co-infected with HCV and HIV are no exception. In fact, 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.

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

When to begin HCV treatment for co-infected persons

As soon as possible. Co-infected persons who are cured of HCV have a 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 consequences. 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 until your 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.

Maximizing treatment effectiveness

Adherence to your HIV medications is extremely important for keeping your viral load suppressed and to minimize the risk of developing drug resistance. The same is true for your HCV medications: The better you are at taking them, the better your chance at achieving the cure.

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, over-the-counter, or recreational—to make sure you can take them safely and to maximize your chance at a cure.

Preventing reinfection after treatment

You can get hepatitis C more than once. After you've been cured, it will still be important to prevent re-infection with HCV. If you inject drugs, use new syringes and injecting equipment, and avoid sharing them. People who are HIV-positive are more vulnerable to sexual transmission of HCV, so minimizing your risk of exposure to HCV through safer sex practices (condoms for anal sex and gloves for fisting, for example) and other forms of harm reduction 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 by taking 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 for 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 clinical 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 current treatments for NAFLD, but many are being studied. Follow POSITIVELY AWARE for updates on NAFLD research news and its treatment.

Closing

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

IF YOU HAVE QUESTIONS about HCV treatment, call The Support Partnership's national hepatitis C helpline: HELP-4-HEP, (877) 435-7443.

ISTOCK

Hepatitis B—An overview

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

Hepatitis B (HBV) is a virus that infects the liver, and is the most common infectious disease in the world. In the United States, an estimated 850,000 to 2.2 million people live with HBV; about 10% of people living with HIV in the U.S. also have HBV. In recent years there have been increases in HBV cases among people who inject drugs (PWID) and in mother-to-child (known as vertical) 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 issue.

Hepatitis B transmission

Hepatitis B is transmitted in much the same way as HIV. It's spread when blood, semen, vaginal fluids, and other bodily fluids get into a person who does not have the virus or is not protected by immunity (through vaccination or cleared infection). It is also commonly transmitted during birth. The following have been associated with risk of transmission:

- vertical (perinatal) 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 needlesticks or other risks of blood-to-blood contact.

Testing for hepatitis B

Most people who acquire HBV don't know it because there are rarely 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:

People 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%

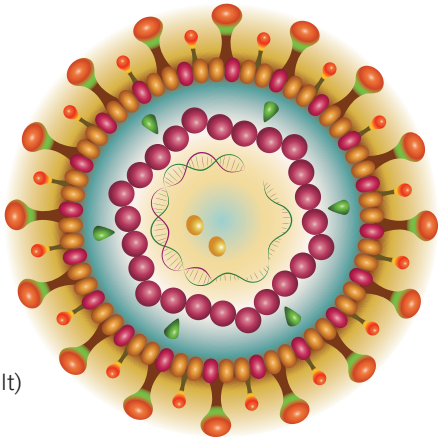
People with certain medical conditions:

- individuals who are pregnant
- babies born to persons who have acquired HBV
- 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)



ISTOCK

Vaccination for hepatitis B

Hepatitis B is vaccine preventable. Vaccination against HBV is safe and highly effective; it is 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 two-dose sequence, in which the first dose is administered and the second dose is given at least one month (minimum of 28 days) later. The vaccine remains effective the rest of your life with no need for a booster shot ever.

Who should be vaccinated against HBV:
On April 1 this year, the CDC's Advisory Committee on Immunization Practices issued updated and simplified hepatitis B vaccination recommendations:

"HepB vaccination is recommended for adults aged 19 to 59 years and adults ≥ 60 years with risk factors for hepatitis B. Adults aged ≥60 years without known risk factors for hepatitis B may also receive HepB vaccines. Infants and all other persons aged <19 years are already recommended to receive HepB vaccines."

In other words: Everyone from the age of 19 to 59 should get vaccinated! Universal vaccination is a simple way to make sure that no one falls through the cracks, and takes away the stigma of having to ask people for specific risk factors for HBV. Everyone younger than 19 has already had universal screening recs, so routine vaccines should be happening. If not, get vaccinated whenever you can make it happen...again, with no questions asked.

For anyone over the age of 60, the following risk factors should be considered for hep B vaccination:

Persons at risk for sexual transmission of HBV, including:

- 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 care for a sexually transmitted disease

- men who have sex with men

People who are at risk of blood-borne exposures, including:

- People who inject drugs
- susceptible household contacts of HBsAg-positive persons
- health care and public safety workers at risk for blood exposure
- anyone with end-stage renal disease
- residents and staff of facilities for developmentally disabled persons

Other people:

- Travelers to regions with intermediate or high rates of endemic HBV infection
- People living with hepatitis C
- People living with chronic liver diseases
- People living with HIV
- adults with diabetes ages 19–59 years (at the discretion of clinicians for people with diabetes aged 60 and older)
- People who are incarcerated
- Anyone over the age of 60 who wants to be vaccinated.

If a person already has HBV, vaccination offers no protection against disease progression or risk of liver disease. Check for immunity or chronic infection before getting vaccinated.

Most people will clear HBV naturally and achieve immunity. 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 scenarios where a person should be treated.

TACKTACK-ISTOCK

Hepatitis B medications

Preferred regimens based on AASLD treatment guidelines

CLASS	BRAND NAME	GENERIC/COMMON NAME	PREFERRED	MANUFACTURER
Nucleoside reverse transcriptase inhibitor (NRTI)	Epivir-HBV	lamivudine (3TC)	✘	GlaxoSmithKline
	Hepsera	adefovir (ADV)	✘	Gilead Sciences
	Baraclude	entecavir (ETV)	✔	Bristol-Myers Squibb
	Vemlidy	tenofovir alafenamide (TAF)	✔	Gilead Sciences
	Viread	tenofovir disoproxil fumarate (TDF)	✔	Gilead Sciences
Interferon alfa	Pegasys	peginterferon alfa-2a	✔ (in adults)	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:

People 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 26).

People who test negative for HBV should be vaccinated against it.

People who test positive for HBV should be assessed to see if they need HBV treatment prior to starting HCV treatment.

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

People 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	MANUFACTURER	AWP
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"	**Bristol-Myers Squibb**	BRAND—0.5 mg and 1 mg TABLETS: **$1,647 / month** GENERIC—0.5 mg and 1 mg TABLETS: **$1,332–1,800 / month**

DOSE

Adults (age 16 and older): Treatment-naïve with no resistance, one 0.5 mg tablet once daily. If lamivudine (Epivir) or telbivudine (Tyzeka, discontinued since December 2016) resistant, one 1 mg tablet once daily. Adults with decompensated liver disease (Child-Pugh B or C): one 1 mg tablet once daily. 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 (see chart below). Baraclude is safe to use in children ages 2 years and older, weighing at least 22 pounds (10 kg) or more. Dosing for children is based on weight and should be done in consultation with an experienced medical provider. An oral solution (0.05 mg/mL) is also available for children or as reduced doses in people with kidney disease.

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. Baraclude may lead to lactic acidosis, a buildup of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions—hepatomegaly (enlarged liver) or steatosis (fatty liver)—may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, 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 herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes to your medications 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 HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. Baraclude is one of several preferred medications, including Vemlidy, Viread, and pegylated interferon, for the treatment of HBV in both mono- and HBV/HIV co-infected persons. If you are dually diagnosed with HBV/HIV, you should not treat HBV without also treating your HIV. You should be checked for resistance to Epivir (lamivudine) before starting Baraclude. Epivir resistance decreases the effectiveness of Baraclude at the 0.5 mg dose, and it must be increased to 1 mg daily. For individuals with HBV/HCV co-infection, or people 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 and is safe to use while being treated for HCV. **See HBV Reactivation on page 27** for more information and consult your medical provider.

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.

DOSAGE REQUIREMENTS for patients with kidney disease

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

Vemlidy

tenofovir alafenamide (TAF)

DRUG CLASS	MANUFACTURER	AWP
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"	**Gilead Sciences**	**$1,557 / month**

DOSE

One 25 mg tablet once per day, with food. Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Never double your dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Vemlidy is a very well-tolerated medication with minimal side effects. The most commonly reported side effects are headache, abdominal pain, fatigue, cough, nausea, and back pain. Not everyone experiences side effects, and among those who do, approximately only 1% stopped taking Vemlidy. Vemlidy is processed by the kidneys, so there is some risk of decreased kidney function. Before starting treatment, 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. Although rare, Vemlidy may lead to lactic acidosis, a buildup of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions—hepatomegaly (enlarged liver) or steatosis (fatty liver)—may occur. Signs and symptoms of these liver conditions include yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, 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 herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes in your medications as they happen. Because Vemlidy is related to Viread (tenofovir disoproxil fumarate, TDF), the two medications cannot be taken together. Similarly, Vemlidy cannot be taken with any of the following HIV combination medications, as they contain tenofovir (TDF or TAF): Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Genvoya, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, or Truvada. If taken with the anticonvulsant carbamazepine, Vemlidy dosage should be increased to two tablets once per day. Vemlidy should not be taken with other anticonvulsants, such as oxcarbazepine, phenobarbital, or phenytoin. Vemlidy should also not be taken with the antimycobacterial medications, such as rifabutin, rifampin, and rifapentine, or St. John's wort.

MORE INFORMATION

Vemlidy will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. Vemlidy is related to Viread but uses 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 your HIV to prevent resistance mutations in the HIV. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. If you have HBV/HIV, and need to switch from any tenofovir-containing regimen—such as Vemlidy—there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. 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. See HBV Reactivation on page 27 for more information and consult your medical provider. For individuals with HBV/HCV co-infection, or who are at risk of HBV reactivation while undergoing HCV DAA treatment, Vemlidy is one of the medications that can be prescribed to prevent this from happening, and is safe to use while being treated for HCV.

There is no dosage adjustment requirement for people with kidney disease who have a CrCl greater than or equal to 15 mL per minute. People with end stage kidney disease (a CrCl below 15 mL per minute) can take Vemlidy as long as they are undergoing dialysis. 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). Vemlidy is currently only approved for use in adults.

Viread

tenofovir disoproxil fumarate (TDF)

DRUG CLASS	MANUFACTURER	AWP
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"	BRAND: **Gilead Sciences**	300 mg TABLET (BRAND): **$1,504 / month** 250 mg, 200 mg, and 150 mg PEDIATRIC TABLETS (BRAND): **$1,394** 300 mg TABLET (GENERIC): **$110–$1,216 / month** POWDER (BRAND ONLY): **$3,076 / month**

DOSE

One 300 mg tablet once per day (adults), with or without food. Oral powder and smaller, pediatric tablets are also available for children aged 2 and older weighing at least 22 pounds (10 kg). Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Never double your 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. Viread may lead to decreases in bone mineral density (BMD); patients should be monitored for osteoporosis or osteopenia. Viread is processed by the kidneys so there is risk of kidney toxicity, including acute renal failure. Before starting treatment, 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. Viread may lead to lactic acidosis, a buildup of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions—hepatomegaly (enlarged liver) or steatosis (fatty liver)—may occur. Signs and symptoms of these liver conditions include yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, 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 herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes to your medications as they happen. Do not take Viread with the HBV treatment Hepsera. Because Viread is related to Vemlidy (tenofovir alafenamide, TAF), the two medications cannot be taken together. Similarly, Viread cannot be taken with any of the following HIV combination medications, as they contain tenofovir (TDF or TAF): Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Genvoya, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, or Truvada. Viread reduces the level of Reyataz, meaning that Reyataz 300 mg must be boosted with Norvir 100 mg or Tybost 150 mg (taken with food) when used together. Kaletra, boosted Prezista and boosted Reyataz increase Viread levels but do not require dose adjustments. This interaction may increase Viread-related side effects; routine monitoring is recommended. Viread should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin).

MORE INFORMATION

Viread will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer.

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 your HIV to prevent resistance mutations in the HIV. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. For individuals with HBV/HCV co-infection, or who are 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. Viread is safe to take with HCV DAAs, but you should be monitored for side effects if it is used with Epclusa, Harvoni, or Vosevi and a boosted regimen for treatment of HIV.

Viread is safe to use in children aged 2 years and older, weighing at least 22 pounds (10 kg). Dosing in children is based on weight and should be done in consultation with an experienced medical provider. People with kidney disease may also need dose adjustments. See the chart below for recommendations; make sure you are routinely monitored by your medical provider while taking this treatment.

DOSAGE INTERVAL ADJUSTMENT for adults with altered 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 approximately 12 hours of dialysis; doses are to be taken after dialysis

Pegasys

peginterferon alfa-2a

DRUG CLASS	MANUFACTURER	AWP
Interferon-alfa	**Genentech**	**$ 1,225.79 / week**

DOSE

In adults, 180 mcg injected subcutaneously once per week for 48 weeks. Pediatric dosing available for age 3 years and older; dosing is based on body surface area.

There are no food restrictions. Take your missed dose as soon as possible on the same day or the next day and then continue 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 with interferon. It does not mean you can't take interferon (or another HBV treatment), but you want to watch for signs of worsening depression 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 to your medications 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 taken 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, and the World Health Organization does not include it in their HBV guidelines. Interferon will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. 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 Baraclude (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 market 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 provide some 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 health care expenses. These programs have different eligibility requirements, and some have limited funds each year. Call for more information:

HealthWell Foundation
(800) 675-8416
HealthWellFoundation.org
Currently does not have an HBV fund, but things may change as funding and donations come in. This is also a good resource for other diseases and conditions ranging from acute myeloid leukemia to urea cycle disorders.

Needy Meds
needymeds.com
A one-stop site of 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
medicineassistancetool.org
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop 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 searchable by ZIP code.

Patient Access Network Foundation
(866) 316-7263
panfoundation.org
Does not have a current HBV program, but this may change, depending on new funding and donations to the organization. A great site for other resources and tips for managing prescription medication costs.

Patient Advocate Foundation
(800) 532-5274
copays.org/diseases/hepatitis-c
Does not have a current HBV program, but this may change, based on new funding and donations to the organization. They also assist patients with insurance denials and access to care issues.

Hepatitis B resources, services and information

American Liver Foundation
liverfoundation.org
Provides information and fact sheets on a wide range of liver diseases, including HBV and HCV. 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.

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

Coalition Against Hepatitis for People of African Origin (CHIPO)
hepb.org/research-and-programs/chipo
African immigrants have high rates of HBV, anywhere from 5% to 15%. CHIPO is a national community coalition comprised of organizations and individuals interested in addressing the high rates of hepatitis B among African communities in the U.S. CHIPO serves as a forum for sharing information and best practices, and improving national capacity to improve hepatitis B awareness, testing, vaccination and treatment among highly affected African communities.

Hepatitis B Foundation
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.

HepB United
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, as well as policy and advocacy.

Know Hepatitis B
cdc.gov/knowhepatitisB/index.htm
An education and social campaign, Know Hepatitis B offers 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.

MEDICATION	MANUFACTURER	CONTACT INFORMATION
Vemlidy (tenofovir alafenamide)	Gilead	(800) 226-2056 gileadadvancingaccess.com
Pegasys (pegylated interferon)	Genentech	(877) GENENTECH (877) 436-3683 gene.com/patients/medicines/pegasys

HEPATITIS D: Keeping an eye on a new viral infection of the liver

BY **ANDREW REYNOLDS**

Hepatitis A, B, and C are very well-known in the United States: We have vaccines to prevent HAV and HBV, treatments for HBV, and a cure for HCV, along with a public health infrastructure to monitor and respond to these infections. This article provides an overview of another type of viral hepatitis—hepatitis D (HDV).

It's hard to get accurate numbers for HDV. There are no established testing or surveillance systems to monitor it. Worldwide, it's estimated that there are about 12 million people who are living with HDV. Hepatitis D is most common in Eastern and Southern Europe, throughout the Mediterranean and Middle East, and in parts of Asia and Africa. It is rare in the Americas, but it has been found in South America along the Amazon Basin. Although it is very rare in the U.S. it's estimated that about 3–8% of people living with HBV also have HDV. That said, testing for HDV is low and it is not a reportable disease, so estimates are hard to come by.

What is hepatitis D?

HDV, sometimes referred to as "hepatitis delta," is a liver infection caused by the hepatitis D virus. It is what's called a "satellite virus"—that is, it needs something else to make you vulnerable to infection. In this case, only people with hepatitis B can acquire HDV. You can get both viruses at the same time (co-infection), or you can get HDV later after already having HBV (superinfection, meaning one on top of the other).

HBV/HDV co-infection: This is when a person acquires both viruses at the same time. Symptoms may be felt, but most people can fight both viruses off, and fewer than 5% of people will keep infection chronically, when it will not go away.

HBV/HDV superinfection: This is when someone already has HBV, and then later acquires HDV. When this happens, the symptoms can be severe. In superinfection, HDV usually becomes chronic: About 90% of people who get HDV after already having HBV develop an HDV infection that will never go away. People with HBV/HDV superinfection also have a greater chance of developing more severe liver damage over time.

How is hepatitis D transmitted?

Hepatitis D is transmitted much the same way as HBV or HIV—through blood or sexual fluids. Vertical transmission (when the virus is passed to an infant during pregnancy) of HDV is very rare. Hepatitis D can be transmitted the following ways:

- condomless sex
- sharing syringes or other injecting equipment
- other blood to blood contact
- sharing of personal items (such as razors)

You cannot get HDV through casual or household contact from things such as sharing utensils or drinking glasses, hugging someone, or through airborne transmission.

What are the symptoms of hepatitis D?

When people first acquire HDV, also called acute infection, they generally experience the following symptoms:

- fatigue
- nausea and vomiting
- loss of appetite
- liver pain
- jaundice (yellowing of eyes and skin)
- light-colored stool
- dark-colored urine

After acute infection, symptoms tend to disappear, or you get used to them and just go about your life. Over time, however, HBV/HDV infection can lead to more and more scarring of the liver, eventually leading to cirrhosis and an increased risk for liver cancer or liver failure and the need for a liver transplant.

How to prevent hepatitis D?

There is no vaccine to prevent HDV, but since you need to have acquired HBV in order to be vulnerable to HDV infection, getting vaccinated against HBV will protect against HDV.

In the absence of the HBV vaccine, you can prevent HDV infection by doing some of the same things that are done to prevent HBV and HCV (and, for that matter, HIV):

- don't share syringes or other injecting equipment
- use condoms during sex
- don't share razors, nail clippers, toothbrushes, or other household items that could have blood on them

Are there treatments or cures for hepatitis D?

There is no cure for HDV. There are treatments, but they can be difficult and are not very effective. Interferon can be used to treat HDV, but the impact on the course of disease is small and the side effects of the treatment can be very debilitating, making the risk-reward of taking it fairly low. There are medications that are under study, but nothing has been approved in the U.S.

While there are ineffective treatments and no cure, it is still important to stay engaged with your medical provider. You may benefit from HBV treatments, but it's also important to stay engaged with a medical provider so they can monitor the health of your liver, assess you for cirrhosis, and keep an eye on your health until cures become available.

Conclusions

Hepatitis D is very rare in the U.S., and you probably don't have anything to worry about in terms of having it or being at risk for it. That said, I believe in knowledge and empowering people to make educated choices about their healthcare and prevention needs. Remember, if you don't have HBV, you can't get HDV. Get vaccinated against HBV, and you're good and won't get HDV. If you're one of the rare folks who gets both HBV and HDV, stick with a medical provider for monitoring and evaluation, HBV treatment (when necessary), and to assess for liver damage. PA

ISTOCK

Acting up for people who use drugs

The struggle continues

BY **DREW GIBSON**

I'm not old enough to remember the early days of the HIV epidemic. I'm old enough to have been alive for most of them, but not old enough to really experience them. That's not to say I can't empathize with long-term survivors who found a way to live with HIV from then until now, because I can. I can only imagine the terror and paralysis of watching friends and partners contract a virus that cut their life expectancy from decades to days. I can only imagine what it must have been like to bury friends and partners who were healthy one month and dead the next, wondering when it was going to be my turn. But empathy and imagination are no match for experience and direct impact, especially as pandemics and their aftershocks are playing out in real time. People who hold the burden of living with illness and trauma know more about what has happened to them than those who treat and legislate their bodies, and they possess an urgency to act that is often reserved for those who don't have the luxury of ignoring a crisis. It's a lot harder to take a conservative approach to a problem when that problem wakes you up every morning and is literally trying to kill you.

Whatever it felt like to live through the harrowing peak of the AIDS crisis in the 1980s and '90s, I can't help but think it felt a lot like being someone who uses drugs or who loves someone who does in 2022. Statistics don't adequately convey the horror and magnitude of what is happening. Nearly 108,000 people died from overdose in the United States in 2021. 108,000—it's one of those numbers that is so large that it ceases to have meaning in the abstract. Think back to Queen's iconic Live Aid performance in 1985. You've got Freddie Mercury in his practically painted on jeans and little white tank top, belting out a capella *eeeeyyyy-oooooo*s with a capacity crowd at Wembley Stadium packed in like sardines to see him. Can you picture it? The crowd that day was about 72,000. Imagine every one of those people dying in a calendar year and that's still just two-thirds of U.S. overdose deaths in 2021.

But even more than the raw numbers and lives lost, I think it's the unending fog of grief and disappointment and rejection enveloping those of us who use drugs and our allies that links the present day overdose crisis to the worst days of the HIV epidemic. To work in harm reduction and drug user health right now is to know that there is a decent chance that when you say goodbye to a colleague, client, or friend it might be the last time you ever speak with them. On a monthly and sometimes even weekly basis, leaders of the harm reduction movement in the U.S. are killed by an unsafe drug supply poisoned by decades of entirely avoidable prohibitionist policies. We are exhausted, yet we burn our candles down to wax nubbins because to rest is not an option if we want to live.

There is reason for hope, though. Or maybe it's that there *was* reason for hope. In this year's State of the Union Address, President Joe Biden explicitly endorsed a harm reduction approach to ending the overdose epidemic and urged Congress to increase funding for harm reduction programs. At the same time, the Substance Use and Mental Health Service Administration (SAMHSA) was in the process of determining who would receive the first wave of $30 million worth of harm reduction funding that was included in the American Rescue Plan Act, the first time SAMHSA money had been specifically designated for harm reduction programs. In Congress, the House passed an appropriations bill that would have rescinded the harmful ban on funding for syringes and related materials, with Senate Democrats following suit. Overdose numbers were still rising, but there seemed to be a very real chance for a sea change in the federal government's approach to the overdose crisis.

I think it's the unending fog of grief and disappointment and rejection enveloping those of us who use drugs and our allies, that links the present day overdose crisis to the worst days of the HIV epidemic.

Unfortunately, our efforts to tear down the war on drugs from the inside out have since stalled, and in some instances reversed course. The increased harm reduction funding that President Biden called for in his address wasn't explicitly outlined in his Fiscal Year 2023 budget, the vast majority of harm reduction grants handed out by SAMHSA didn't go to organizations that were primarily focused on harm reduction, and the FY 2022 appropriations package kept the federal syringe ban in place.

On top of all this, the emergence of fentanyl as the primary driver of overdose in the U.S. has led to a reenactment of the crack panic of the late '80s and early '90s, complete with racist sentencing laws and a newfound embrace of drug war policies by many in the political middle.

There will be those of us—myself included—who continue to work behind the scenes with administration officials and members of Congress to push for the types of incremental changes to federal drug policy that reside within the comfort zone of many of our elected officials. But this is not enough. It never will be. The inertia of the federal government's support for drug warriors, *Just Say No* prevention zealots, and the substance use disorder treatment industrial complex cannot be halted through Congressional advocacy days and sign-on letters alone. We need radical, outside action too. We need an ACT UP for the overdose epidemic.

What would that look like in practice? Well, right now the overdose reversal drug naloxone is classified as being a prescription-only medication by the Food and Drug Administration. As a result, harm reduction service providers and individual citizens have to jump through a ridiculous number of legal and logistical hoops just to get their hands on these life-saving drugs. The FDA has the authority to switch naloxone from prescription-only to over-the-counter. They've already done it with antifungal and anti-flatulence medications, so what are they waiting for? Are ingrown toenails and some stomach bloat more urgent issues than drug overdose?

If the Biden administration and the FDA want to act of their own volition, do the right thing, and make naloxone available over-the-counter, or at the very least allow harm reduction organizations to buy naloxone in bulk from distributors, then god bless. But if they won't answer their phones, then we're going to have to show up at their door, dressed in bloody lab coats and with body bags and tombstones in hand like the AIDS activists who came before us did. We don't have time to wait and we don't have time to play nice. We just have time to act up. PA

DREW GIBSON (he/him) is a harm reduction and HIV advocate and writer living in the Greater Washington, D.C. area. He currently works for AIDS United as their Director of Advocacy and chairs the Coalition for Syringe Access.

KELLIE McALLISTER

My journey to wellness

A change of view leads to a new outlook on life

BY **VINCENT VALDEZ**

If you had asked me five years ago where I would have seen myself today, well, let me tell you, the answer would have been nothing like reality. In fact, I can say with confidence that at the time, I wasn't even able to muster the strength to look that far ahead. For me, there was nothing there, possibly the absence of life itself. I didn't think of my life as something to be valued, let alone celebrated.

Like a lot of people in the LGBTQ+ community, growing up my family wasn't as accepting as they are today—namely my parents. My mother was and still is the most loving woman I have ever known, but like some other mothers with gay children, her beliefs led our relationship to become estranged. Cutting all ties with most of my friends and family, I fell into relationships that were abusive and controlling in an attempt to fill the void of love that was left. These relationships only further solidified those negative thoughts that I carried with me most of my life—that I meant nothing. Love wasn't unconditional, it would always come at a price.

All of these slights, all of these chips and chunks taken away from my confidence and personality by false love, left me in such a dark place I couldn't see anything around me. Everything felt suffocating, it was almost unbearable. This inevitably led to random sex with an array of characters and questionable decisions that to this day I regret—but don't dwell on. I needed to get out.

They say that friendship is one of the most valuable and exciting parts of life. Friends make things understandable, bearable. They can change perspectives with just an opinion and affect lives with small or grand gestures, at least mine has. My best friend, Fletcher, saw the struggle and knew where it was headed. With one selfless decision on their end, I moved from California to Indiana in search of a fresh start—it is still the best decision I ever made.

Being in a new city in a state I had never visited was overwhelming in the best way possible. Although I was ready to begin anew, I still felt the need to seek that attention, and like most gay men I know, there's no better way to get attention than through dating apps. So, I downloaded Scruff and immediately started the search. Within those messages I found a man who turned out to be the love of my life, my now fiancé Rich, and although there is a bit of a backstory of our love filled with excitement and minor scandal, I knew that this was the start I needed to rebuild my life.

I thought nothing could bring down my high. I was wrapped up in such a whirlwind love scenario I missed the signs. The fever, the aches, the night sweats—I could feel something in my body changing. I knew this wasn't a cold. Terrified, I confided in Rich about my symptoms. At the time I didn't have any insurance; I was new to the state and didn't know where to go for care. That's when Rich told me about Damien Center. We made an appointment immediately and they were able to get me in for testing within that same day.

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BEING BRIDGETTE
BRIDGETTE PICOU

You are not how you feel

If you are living with HIV, you're allowed to feel what you feel

I have had a mild to moderate clinical diagnosis of depression for most of my adult life. Since I've felt like this for as long as I can remember, it's been longer than that, but I wasn't "diagnosed" until early adulthood. Because I'm not a huge medication taker, I've mostly dealt with it without them. I've been told it's called high-functioning depression, or PDD (Persistent Depressive Disorder). I get stuff done so it doesn't "look" like I'm depressed, but it takes a lot of focus. When I was diagnosed with HIV, I can say honestly that survival mode and navigating all of the changes I was going through at the time were my primary emotions. Survival, and fear and pretending I was fine, were my operating mode for a good amount of time. A sense of aloneness and isolation were ever present as well. The depression was there, lurking; it just wasn't the loudest voice in my head until about nine months later. When it decided to remind me that it was there, it hit me like a ton of bricks. It made all of the other emotions harder to manage, and in a moment of transparency, it almost took me out. Sheer stubbornness, a guilty feeling of not wanting to leave people with more questions than answers, and a bone-deep weariness are what keep me walking the planet, and I'm grateful for the lessons that period taught me.

Why share this now? I'm here writing and showing up for life so things must be good, right? Better to leave it as a lesson, and move on, right? Well, sort of...

I still live with depression. I take my meds to manage it, find joy triggers to manage the trauma triggers, and have learned to acknowledge it, but not let it run me or my life. It cycles, but I'm better able to manage the cycles. I talk about it because I know from experience someone out there thinks it's just them. Someone thinks they are being ridiculous or small or dumb for "allowing" themselves to feel what they feel. People who don't have depression don't understand depression. I know there have been times when people have asked me *why* I'm depressed when I *seem* to be doing well. Depression is not about lack of "have" or need of "wanting stuff." Isolation can happen in a room full of people because of feeling a sense of "otherness." Being a support or an ally for someone struggling with any of these emotions doesn't require you to understand or accept. You just need to be patient and not judge.

One thing I do want people who are not living with HIV and depression to understand is that HIV *itself* can carry an element of depression. Physiological changes in the body related to the virus, the inflammatory process the body is constantly under, and the medications used to treat HIV can all affect mood and a person's general sense of well-being. Any one of those taken alone is tiring, but all together it can be exhausting! Feeling tired 70–99.9 percent of the time is exhausting! The anxiety of disclosure of HIV can make you want to isolate yourself so you don't have to explain. Exhausting!

Know this: If you are living with HIV, you are not crazy. You are allowed to feel what you feel, I just encourage you not to unpack and live in those emotions. You deserve an amazing life, so please find someone to help you get there. Don't like meds to treat your depression? Cool, there are other tools you can use. Seek them out. Love on yourself. Not living with HIV but know someone who is? Be patient. Educate yourself. Love on them. HIV-triggered depression, isolation, and anxiety are real. Give people space to emote and heal.

Depression is not all there is or can be. You are not how you feel.

Be well. You matter.

BRIDGETTE PICOU is a licensed vocational nurse in Palm Springs, California. She uses her voice to speak for others as a member of the Board of Directors for HIV & Aging Research Project-Palm Springs (HARP-PS) and as a Community Advisory Board Member for The Well Project-HIV and Women. She is also an active HIV blogger and member of ANAC, the Association of Nurses in AIDS Care, Greater Palm Springs Chapter. Finding a voice in advocacy and activism is a natural progression, since she feels that every time she fights for someone else, she affirms her own life.

PICOU: CHAD SAIN · PHOTO: BLACKCAT -ISTOCK

POZ ADVOCATE
SCOTT SCHOETTES
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Strategic victory

How a federal court's ruling to end military discrimination against service members living with HIV affects all of us

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A FEDERAL DISTRICT COURT in Virginia ruled in April that the Department of Defense can no longer prevent servicemembers from deploying or commissioning as officers based solely on the fact that they are living with HIV. It took four years of litigation—in which I served as one of the lead attorneys—and a trip to the Fourth Circuit Court of Appeals, but we finally achieved the result we were seeking from the beginning. In fact, it was the Fourth Circuit's strong unanimous panel opinion affirming the preliminary injunction preventing the discharge of some members of the Air Force based on their HIV status that set the stage for the district court to rule in our favor on summary judgment.

Here's why this ruling is groundbreakingly important:

FIRST, unlike the ruling on the preliminary injunction—which was also a very strong opinion in our favor—this decision was based on a full record. Both sides had the opportunity to collect documents, ask written questions, and take depositions of key decision makers and experts presented by the other side. After reviewing all of the evidence that both sides had collected over many months, the court decided not only that the military's policies were discriminatory, but that they were completely irrational and therefore unconstitutional—the standard we had to meet in order to prevail.

SECOND, in reaching this conclusion, the court recognized and understood what an HIV diagnosis means—and doesn't mean—in the 21st century. As we all know, HIV has been transformed into a chronic, manageable condition through effective combination therapy consisting of one or two tablets a day—but this is one of the first times a court has used that fact to declare that an employer was engaged in discrimination. Just as important, the court recognized that the risk of a battlefield transmission is extremely low even when a person is not virally suppressed—and likely zero when they are. Because over 99.8% of servicemembers living with HIV reach viral suppression (yes, you read that number correctly), the court was comfortable issuing this ruling that covers all people with an undetectable viral load, which is essentially all people currently serving.

THIRD, the U.S. Department of Defense is the largest employer *in the world*. Because it is not subject to the Americans with Disabilities Act (or a similar statute that applies to most recipients of federal funds called the Rehabilitation Act), the U.S. military was arguably the only employer in the country that could still get away with this type of discrimination. By bringing a constitutional claim—and meeting the more stringent standard for establishing discrimination under the Equal Protection Clause—we were able to shut down the military's discriminatory employment practices. Not only does this send a message to every other employer contemplating denying a position to a person based on their HIV status, it also removes some of the last vestiges of discrimination being practiced by the federal government. A government leading the fight against HIV in the U.S.—and decrying stigma and discrimination based on HIV status—should not itself be engaging in such discrimination.

FINALLY, this decision takes us almost as far as we can go on this front. Some have criticized this decision as merely an incremental step toward true equality, one that reinforces the "viral divide" between those who have a suppressed viral load and those who do not. However, the belief that this decision is a form of "incrementalism" that inappropriately enforces the viral divide is based on a misunderstanding of military logistics and the

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Poz advocate

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primary function of a service member. To serve in the military, a person has to be deployable worldwide—which means the person must be able to go to any location needed, including combat zones with limited medical support. The medical resources in such locations are focused on tending to the wounded, providing interim care to those who must be returned stateside, and keeping the forces that remain battle ready. It is not designed or properly equipped to provide regular care and monitoring for a person with a chronic condition that has not yet reached a stable status with consistent (and minimal) treatment.

People who do not have a durably suppressed viral load—which signifies a degree of stability with respect to their HIV—should not be sent on a deployment to a combat zone. It would be irresponsible for the military to send someone who was still attempting to dial in their treatment regimen and to reach the necessary degree of adherence to bring their HIV under control—into a combat zone where viral load testing is not readily available and the wide variety of HIV medications are not maintained as a part of the formulary. And it would be irresponsible to advocate for people living with HIV in such circumstances to be deployed. Though there is a line being drawn here between the virally suppressed and unsuppressed, it is a line that protects people by not placing them in a medically tenuous situation.

If the reasoning of the opinion issued by the district court in Virginia is followed to its logical conclusion, people living with HIV will also be allowed to enlist or otherwise join the military on initial entry. Although this ruling only applies to those currently serving, the Biden administration has pledged to allow people living with HIV to enlist as well. Now we must hold the administration's feet to the fire in fulfilling the campaign promise it made—as well as halt the HIV criminalization prosecutions that still take place under military law—to ensure that all forms of discrimination by the U.S. military are ended once and for all.

Pentagon updates its HIV policy

Following a federal district court ruling, Secretary of Defense Lloyd Austin issued a memo on June 6 updating the Pentagon's policy on military personnel who are living with HIV.

"In view of significant advances in the diagnosis, treatment, and prevention of Human Immunodeficiency Virus (HIV), it is necessary to update DoD policy with respect to individuals who have been identified as HIV-positive," the memo said. "Individuals who have been identified as HIV positive, are asymptomatic, and who have a clinically confirmed undetectable viral load will have no restrictions applied to their deployability or to their ability to commission while a Service member solely on the basis of their HIV-positive status. Nor will such individuals be discharged or separated solely on the basis of their HIV-positive status."

SCOTT SCHOETTES is an attorney and advocate who lives openly with HIV. He engages in impact litigation, public policy work, and education to protect, enhance, and advance the rights of everyone living with HIV.

My journey to wellness

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I'll never forget the appointment, but at the same time the whole experience felt like a blur. "The rapid result does show as positive. So, we're going to schedule you for confirmation testing and care before you leave today. This isn't what it used to be. This isn't a death sentence, and we have options to take care of you." The impact of those words still gives me chills to this day. My toxic California life had left me with one more going away present—I was HIV-positive.

I wasn't sure how to feel in the days that followed, but I do remember contemplating the value of the opportunity I had been given—and the outlook wasn't too good. I thought, "This is a sign. I'm not worth even taking this medication. I did this to myself, and I have to live with the consequences as long as I can." It was all too much for me to handle, emotionally and physically. I didn't want to get up, I didn't want to try. I made the appointment with every intention of not keeping it. Of lying in the bed that I had made with decisions that were placed in front of me. If only I had known that there were options that could have helped me prevent this, like PrEP or PEP, which can prevent it after the fact, but no, because I was in a relatively conservative Mexican-American town, I didn't know to look for this information. I didn't even know it existed. You see, it doesn't matter if you're from a liberal state like California, your community dictates what you have access to, and where I'm from prevention was just another word for sin.

After making my decision to refuse care, I tried to shut down. I tried to ignore the topic altogether hoping no one would notice that I'd casually missed my treatment appointment. I was met with no such luck. On the day of the appointment, Rich did everything in his power and will to get me there. He got me up, made me get dressed, and even drove me to the appointment. He stayed with me throughout the entire process. This was in the fall of 2017.

Flashforward to today. I am a man living and thriving with HIV, who has been undetectable for four-plus years now and going strong. I have an amazing fiancé who is HIV-negative and is so loving and accepting of my status. Over the years I've struggled with mental health revolving around my HIV. For the first few years I continuously had negative thoughts about not only my HIV but about my life itself. Through much love, support, and therapy, I was able to climb out of that dark place I was trapped in for so long. Now, I am a telePrEP navigator for the same organization that gave me my life back, Damien Center. My life is something I would never have imagined for myself. I never would have imagined that all of those tribulations would lead up to who and what I'm supposed to be—just happy.

I know not everyone who is HIV-positive has that kind of support system. I know that there are people who are still alone and afraid of what's happening to them, but I'm here to say that it's possible to be comfortable with your status and live an amazing life. I'm here to say for the first time publicly, and without shame, that I have HIV and I deserved my happy ending. And to the people living with HIV reading this who are still a little lost, it's okay. If my story can have a happy ending, maybe yours can too.

VINCENT VALDEZ loves to write in several genres and says expressing himself through writing brings him a sense of peace. He is from Madera, in Central California.

‘I chose to live’

Overcoming hepatitis and other challenges

BY **RICK GUASCO**
PHOTOGRAPHY BY **HABEEB MUKASA**


CHERYL

Hepatitis C doesn’t exist on its own; a variety of conditions and circumstances often exist beforehand and come into play. That was the takeaway in hearing the life experiences of Cheryl, Tammy Kinney, and Stewart Nelson-Reid, who met at Exchange Park, just outside of Atlanta, to be photographed by Habeeb Mukasa for the cover of this issue, POSITIVELY AWARE’s annual Hepatitis Drug Guide.

For **Cheryl**, the news that she had hepatitis C (HCV) was unexpected and could hardly have come at a worse time. It was 2003, and she had just moved to Georgia when she got sick and had to go to the hospital. There, she learned she had neurosyphilis. She had contracted syphilis sometime earlier, long enough that, untreated, it had spread to different parts of her body, including her brain. But then, the nurse told Cheryl that her liver “wasn’t right.”

Tests concluded she had HCV, and she was started on treatment. But with the first shot of interferon, a hepatitis treatment at the time, she became sick to her stomach. A change in treatment marked a turning point for Cheryl; she eventually cleared the HCV, received treatment for the syphilis, and went on HIV medication.

Today Cheryl is undetectable for HIV, and is a peer advocate, talking primarily with other Black women about HIV prevention and how they can take better care of themselves. She’s candid about her experiences, and isn’t afraid to talk about her past drug use.

“I overdosed in jail once,” she says. “It was the scariest moment of my life. Other inmates brought me back to life, giving me CPR and giving me milk to drink.”

“There is hope,” she adds. “It’s up to us, but there are medications that will help us to take care of ourselves.”

Sixty-two-year-old **Tammy Kinney** had gone 12 years since her diagnosis of hepatitis C in 2002 before getting treatment. Because of her depression, IV drug use, and inconsistency in taking her HIV medication, she was deemed not a candidate for the series of injections of interferon for HCV treatment.

Diagnosed with HIV in 1987, she had gone in and out of treatment and care. Kinney often missed appointments with her nurse practitioner. When she did show up, her mood was usually either extremely down or unusually upbeat. She was often distracted and lost in her own thoughts. Kinney was eventually diagnosed with "manic depression," now called bipolar disorder. This kept her from being treated with interferon, the standard HCV treatment at the time, because one of interferon's possible side effects is depression. (A difficult drug for most people to tolerate, interferon is no longer used as an HCV treatment.)

"I remember going into the doctor's office, and it just seemed like I could not get it together, mentally and emotionally," Kinney says. "I was all over the place, wasn't adherent to the medication. I was fortunate that I had a health care team that saw something in me, that I could have a healthy productive life, that I didn't see in myself. One day, the nurse practitioner was almost in tears. She asked me, *do you want to live?* In my state, I was like, let me think about this. I literally paused and thought, *let me think about this.* That's when I made the conscious decision and said I want to live. It was a struggle. It was a real struggle, but I made it. I'm in long-term recovery—11 years."

Today, Kinney is a certified peer specialist in mental health and a case manager at Advantage Behavioral Health. She's also the founder of Rural Women in Action and member of Common Threads, an HIV prevention and vocational development organization for Black women. While her work focuses on Black women and HIV, she believes in raising awareness about hepatitis.

"A lot of people don't understand that hepatitis C needs to be talked about just like HIV," she says. "The focus has been on HIV, but we have drugs that make hepatitis C curable. I can bear witness to that today. I didn't really know that I was going to make it, having HIV. I was diagnosed with HPV, and then hepatitis C. I was like, am I gonna make it through having all these *H*s? But keeping up with treatment played a part in me being here today. And I'm grateful."


TAMMY KINNEY

Between the HIV and the rectal cancer diagnoses, **Stewart Nelson-Reid** was told he had hepatitis C and cirrhosis of the liver. It was the year 2000, and Nelson-Reid was about to undergo


STEWART NELSON REID

chemotherapy and radiation treatment for the cancer. The treatment had been grueling; although he had tolerated the chemo, Nelson-Reid was burned from the radiation.

"After they treated the cancer they wanted to treat the hepatitis C," he says, "and at the time they didn't have anything [for treating HCV], except a shot—interferon."

"But after my first dose, I got deathly sick from it," he adds. The interferon caused him to feel "unbalanced," he says. So, his doctor took him off the drug, and Nelson-Reid decided to wait for something better. In October 2014, Harvoni, the first once daily single-tablet-regimen for hepatitis C, was approved.

"My doctor said, '*We have a new pill. It'll take eight weeks for you to clear your hepatitis C but if you take it, you'll be good.*' And I did. And it went away. Harvoni was a lifesaver."

Nelson-Reid, who turned 65 in December, has been cancer free since 2001, and his HIV is undetectable. He's had other health challenges along the way, however—Legionnaire's disease, diabetes, and painful swelling from gout, all while working as a professional makeup artist.

"I was never surprised when I found out that I had HIV—I grew up in the '70s, I did a lot of things." he says. "I watched my friends pass. I had that *why them and not me* kind of thing going on for a minute. But when I found out about the hepatitis C, it was kind of scary because they didn't at the time have a cure for it. I was scared that something would happen to my liver and my kidneys because I had chronic kidney disease and cirrhosis of the liver at the same time because of the hepatitis C. Harvoni saved my liver from any more trauma. I don't have scarring on my liver like I did when I had hepatitis C.

He also attributes smoking to the damage done to his liver and his health. "I realized I had to stop smoking cigarettes. I was a smoker. Smoking can kill you in a lot of ways people don't realize, especially when you have gout and HIV and hepatitis C all at one time. That's a lot to manage."

"I am feeling much better every day as I move along," he adds. "These medications, I am amazed that they're working. But you gotta be dedicated to going to the doctor and getting checked out on a regular basis. If I sneeze wrong, I'm calling my doctor."

This year marks his 25th anniversary married to Malcolm Reid, cofounder of THRIVE-SS, an HIV/AIDS service organization for Black men who have sex with men.

"We all have an expiration date," he says. "You can't control when you pass, but you can control how you live, and I chose to live. My purpose is to bring happiness to people that I meet and uplift my family, my friends, my husband. It was not my time. Since I've been involved with my husband, my purpose is for us to have a happy life and do what God gave me the will to do—be my authentic self."