POSITIVELY AWARE

JULY+AUGUST 2024

PETER McLOYD has made a life as a peer educator living with HIV and hepatitis

TEXAS HOLD 'EM
The struggle to make Cabenuva accessible for uninsured Texans

A 'VITAL' GAP IN PUERTO RICO?
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Choosing your words in the fight to modernize and repeal outdated laws

ADVANCING THE CONVERSATION
A young advocate uses personal storytelling to share knowledge and strength

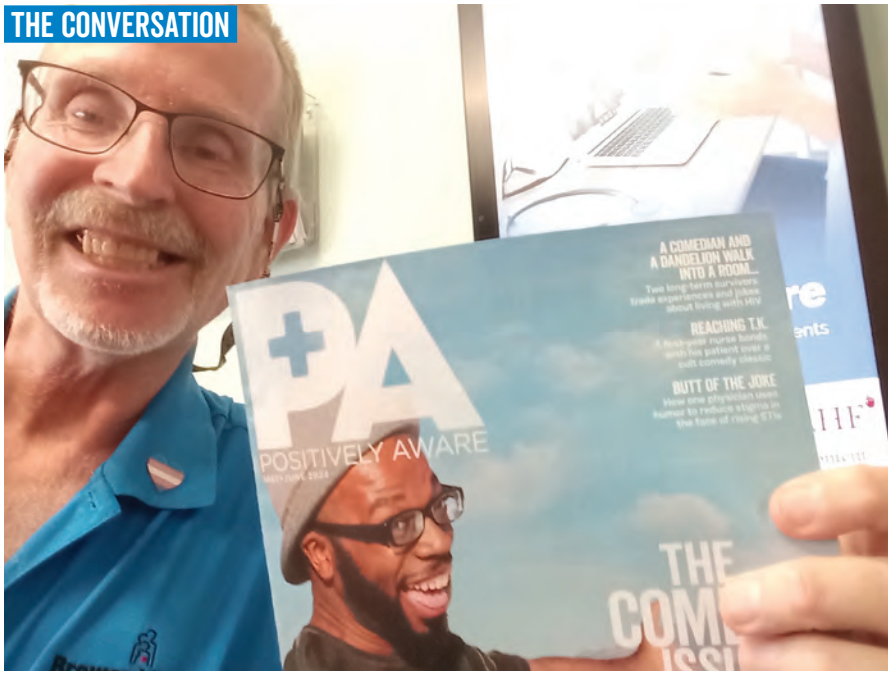
THE HEPATITIS DRUG GUIDE

LATE BREAKING

Curing and eliminating hepatitis B

Listen to Jeanne Marrazzo, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID), as she helps open the meeting of the Coalition for Global Hepatitis Elimination during a webinar August 8. In her short presentation, Dr. Marrazzo provides **a quick review of the current global state of hepatitis B and lists medications in new drug classes in development** for its treatment and cure. These include long-acting therapies for both hepatitis B and C, pediatric formulas and vaccine work. She also mentioned the tests in development to achieve a faster and simpler diagnosis. U.S. research includes speeding up the search for a cure for people living with both HIV and hepatitis B. "So, exciting areas," said Dr. Marrazzo. "Lots of promise, but also lots of work." **GO TO** bit.ly/3YCIYgc.

THE CONVERSATION



During a regular checkup I spotted POSITIVELY AWARE—it's here in Florida—at AHF NorthPoint Healthcare Center.

—**ROBERT HADLEY** VIA FACEBOOK

WHERE DO YOU FIND PA? Send us a picture of where you pick up the magazine (email inbox@positivelyaware.com or tag @posware), and it could appear in the next issue.

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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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EVERY ISSUE

THIS ISSUE

HEPATITIS DRUG GUIDE

PETER McLOYD, PHOTOGRAPHED BY JOHN GRESS FOR POSITIVELY AWARE.

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SUNDAY, SEPTEMBER 22
MAKE IT YOUR DAY.

POSITIVELY AWARE's anti-stigma project, **A Day with HIV**, portrays 24 hours in the lives on people living with and affected by HIV —all taken on the same day.

ON SUNDAY, SEPTEMBER 22, grab your camera or smartphone and take a picture of whatever you're doing and who you're with. Post it on social media with a caption that includes the time and location and what inspired you to take the photo; include the hashtag #adaywithhiv.

Select photos will be featured in the November+December issue of POSITIVELY AWARE—four high-resolution images will be chosen for different versions of the cover.

NOTE FROM THE HEPATITIS C EDITOR

ANDREW REYNOLDS
@AndrewKnowsHepC

Hepatitis C: The state of elimination

We can't get there without harm reduction

In 2016, the World Health Assembly unanimously voted for a call to eliminate viral hepatitis by 2030. The World Health Organization immediately followed suit and called for all member states to eliminate hepatitis B and hepatitis C. Elimination is defined as a 90% reduction of new cases and a 65% reduction in deaths associated with these two viral infections. It's a worthy goal: The WHO estimates that approximately 7 million deaths could be prevented worldwide if we met these goals.

In 2021, the United States introduced its most recent plan to address viral hepatitis—*The Viral Hepatitis National Strategic Plan: A Roadmap to Elimination (2021–2025)*. This plan outlines five goals over five years:

1. Prevent new viral hepatitis acquisition
2. Improve viral hepatitis-related health outcomes
3. Reduce viral hepatitis-related disparities and health inequities
4. Improve viral hepatitis surveillance and data usage
5. Achieve integrated, coordinated efforts that address the viral hepatitis epidemics among partners and stakeholders

This plan is excellent and there is no doubt that it could dramatically impact viral hepatitis in the U.S. But there is a long way to go and a lot of work to do. Right now, at our pace, we will not achieve HCV elimination by 2030. In fact, many experts think it won't happen until well after 2030.

Indeed, we won't get there without harm reduction. Harm reduction is a set of practices and ideas that are aimed at reducing the negative consequences around drug use and other behaviors that could lead to infectious disease, drug overdose and other issues. Harm reduction is also a philosophy: It believes in the non-judgmental provision of services to people who use drugs, respects the rights of people who use drugs and centers people in the work for prevention and treatment.

If we expand harm reduction tools like syringe programs and medications for opioid use (methadone, buprenorphine and, rarely used, naltrexone) and increase HCV testing and treatment, we can get there. In this 2024 Hepatitis Drug Guide, we wanted to focus on the testing and treatment side of things, and give an overview of HCV reinfection. The more we test and treat, and the more reinfections we can prevent, the sooner we will get to a country without hepatitis C.

This is easier said than done. We aren't providing people with the harm reduction tools they need. Syringe access programs remain illegal in seven states; but even in the 43 where they exist, there is not nearly enough coverage to reach everyone who needs it. Providing people with new and unused syringes and injecting equipment is essential to prevent new HCV cases.

We aren't testing enough people. Approximately 40–50% of people living with HCV don't know they have it. In fact, we don't even have very good estimates of how many people are currently living with HCV in the U.S. Estimates from the Centers for Disease Control and Prevention put it at 2.4 million people, but some statistics suggest it's more likely to be over 4 million. We need to expand testing, especially among folks who use drugs.

We aren't treating and curing enough people, especially the people who use drugs. Treating and curing HCV has a host of benefits for individuals living with HCV, but they also offer important public health benefits. The more people we cure, the less HCV transmission we will see.

We need harm reduction to prevent reinfections. We can treat and cure people who use drugs, and then provide them with sterile syringes and other safer use supplies, plus access to medication-assisted treatment and other services. Same with sexual transmission of HCV for men who have sex with men who are living with HIV. Provide people with reinfection education, condoms and other services after they are cured, and we will see less HCV transmission.

Hepatitis B and C **elimination is** defined as a **90% reduction of new cases** and a **65% reduction in deaths** associated with these two viral infections.

Most importantly, we need the *philosophy* of harm reduction. We need to provide services in a non-judgmental and non-stigmatizing way. We need to create welcoming spaces for people to come and receive new injection equipment, talk to someone about buprenorphine, and get tested for HCV—and get cured. Harm reduction does that. Syringe service programs offer all of that.

We will reach HCV elimination, but we need to expand harm reduction to get there.

Andrew

Briefly

ENID VÁZQUEZ @enidvazquezpa

Follow the research: TAG's pipeline reports

The national Treatment Action Group (TAG), based in New York and born of the city's early ACT UP struggles, has released five of its annual research pipeline reports online.

Comprehensive yet readable, the TAG reports take you **step-by-step through some of the most important research being conducted today**. They cover far more than is possible in your average newspaper or magazine story.

Frustrated by the lack of an HIV vaccine? Get a deeper understanding of the process in the vaccine update. (Yes, there's still hope for a vaccine, but not in the near future. We probably have at least a decade to go before testing for efficacy in a trial begins, the report tells us.)

- ***The Antiretroviral Therapy Pipeline*** report covers the clinical research for new antiretroviral drugs for treating HIV that are on the way
- ***The HIV Vaccines and Passive Immunization Pipeline*** report covers progress toward designing vaccines capable of inducing broadly neutralizing antibodies (bNAbs) and plans for a new efficacy trial of passive immunization (direct antibody infusion) involving a triple bNAb combination

- ***The PrEP and Microbicides Pipeline*** report provides an update on the latest PrEP efficacy results with the long-acting drug lenacapavir (Sunlenca) and covers newly initiated trials of microbicide inserts for vaginal or rectal use
- ***The Research Toward a Cure and Immune-Based Therapies Pipeline*** report highlights the recent launching of large phase 2 clinical trials for several candidate approaches and documents an increase in the number of new cure-related studies with sites in Africa
- ***The Long-Acting Therapies Trials Tracker for Hepatitis C, Opioid Use and Overdose Prevention Therapy, and Malaria*** covers how long-acting therapies offer a choice and an opportunity, and address pill fatigue

TAG dedicates itself "to ensure that all people living with or impacted by HIV, TB or HCV—especially communities of color and other marginalized communities experiencing inequities—receive life-saving prevention, diagnosis, treatment, care and information."

A tuberculosis report is scheduled for release this fall. To view the reports, GO TO treatmentactiongroup.org.

Ryan White program may now cover security deposits

The Ryan White HIV/AIDS Program (RWHAP) for the first time will be able to cover the cost of a housing security deposit. **Not all program recipients will be eligible for deposit funds, and the money will have to be returned to the program**, not the individuals. The Health Resources and Services Administration (HRSA) announced its new policy action in June.

According to HRSA, the Ryan White program provides care and treatment services to more than 560,000 low-income people living with HIV, "addressing factors like access to housing and transportation that directly affect clients' ability to enter and stay in care."

To read HRSA's statement on the policy update, GO TO bit.ly/46APLt4. The statement links to the HRSA letter explaining the policy to RWHAP agencies.

Between the lines of TAG's reports on new drugs for HIV treatment and prevention

Richard Jefferys, a longtime member of TAG and the group's Basic Science, Vaccines and Cure project director, **shared his thoughts about the reports and HIV drug development** during a Zoom conversation with POSITIVELY AWARE.

"Our ideal world is one where people have maximum choice," Jefferys said. "I think advocates think that there's still room for better or daily oral drugs. We don't really want to see development of those completely stop, but the [pharmaceutical] industry has shifted to these more kind of intermittent types of [long-acting injectable] regimens.

"There is obviously interest out there in the community for long-acting options, where people don't have to worry so much about daily adherence. There's also the fact that for some people, it's a reminder, they don't want to have to think about it every day.

"The longest-acting drug is lenacapavir [an injection that's every] six months," he said. Jefferys added that the search is on to find a partner for lenacapavir, another antiretroviral drug or a different strategy that, combined, could become a new, long-acting complete regimen. Among the candidates are broadly neutralizing antibodies (bNAbs), a type of antibody that can identify and block different strains of HIV from infecting healthy cells.

TOP OF THE NEWS

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But bNAbs are not without their own issues. Y-shaped antibodies are best at neutralizing a virus. The surface of a virus is covered with "spikes" of proteins. To block infection, both arms of an antibody's "Y" have to be able to bind to and block two protein spikes at more or less the same time. A bNAb's "arms," though, don't always have enough reach.

"And so I think ideally, that [researchers] are hoping to get to a point where you can have maybe two or three antiretrovirals that are given every six months [as a complete regimen], and lenacapavir will be one of them," Jefferys said. "But they're not quite there yet. I think it's going to be another year or two at least. I don't think there's an obvious antiretroviral candidate out there at the moment."

Still, the recent announcement that lenacapavir was 100% effective in preventing HIV among a group of cisgender women in the phase 2 of the PURPOSE 1 clinical study was a game changer. "We had to rewrite this year's PrEP pipeline report because the news came out in June, which was a pretty amazing and historic result," he said.

"I think now it's a case of waiting for the PURPOSE 2 results. It's a large study of cisgender men who have sex with men plus transgender and nonbinary people, to make sure that efficacy also is there. If it is, they [Gilead, the maker of lenacapavir] will be looking to file for approval, and have some kind of access plan, which is still a bit vague for now."

Jefferys is hopeful that more effective treatments and a vaccine will be developed but believes it will take more time than people realize.

"I'm still optimistic that a highly effective vaccine is possible, if a way of inducing bNABs can be figured out. I doubt it's going to happen within the next five years. Hopefully we're going to see an efficacy trial of a bNAb-inducing vaccine sometime over the next decade."

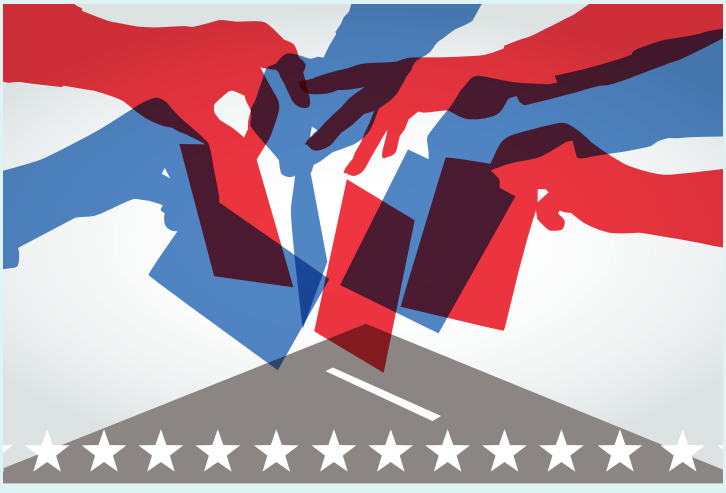
—RICK GUASCO

NMAC's Get Out The Vote campaign

November's elections could be key to sustaining the federal Ending the HIV Epidemic (EHE) Initiative, says NMAC, a national organization advocating for people living with HIV that "leads with race." As such, NMAC has launched its Get Out The Vote (GOTV) campaign.

GOTV kicks off a tour of historically Black colleges and universities (HBCUs) this fall as part of its focus on people of color but particularly young people ages 18–35. NMAC reported that youth are "increasingly disengaged and uninterested" in this year's choices. One survey found that nearly two-thirds of respondents in this age group were unsure if they would vote at all. Young people make up nearly 40 million potential voters.

NMAC also reported a growing racial gap in voting since 2012 resulting from voter suppression laws.



These included **nearly 100 restrictive voting laws in 29 states since 2013 that put barriers to voting in place that primarily affect people of color**.

GOTV is working with several other national advocacy groups: the National Action Network (civil rights organization), the Human Rights Campaign (LGBTQ+ advocacy), Advocates for Youth, LGBTQ+ Task Force, LGBTQ+ Victory Fund, the National Urban League and HBCUs.

The campaign also focuses on people living with HIV and their allies. To help mobilize the vote, GO TO nmac.org. The NMAC Coalition for Justice and Equality will gather for its annual meeting after the November 5 elections to explore the question, "Where Do We Go From Here After the 2024 Election?"

ISTOCK

Frequent cannabis use associated with heart attacks and strokes

According to a study of 435,000 individuals, frequent cannabis smoking may significantly increase the risk of heart attack or stroke. Cannabis, in several forms, is used for treating many debilitating symptoms of illness, including those found with HIV/AIDS and chronic hepatitis.

The study reported a **25% greater likelihood of heart attack and 42% greater possibility of stroke with daily use of cannabis, predominantly smoking**. Weekly use was associated with a much smaller increased risk, 3% for heart attack and 5% for stroke. About 75% of respondents said they usually smoke it.

"We've known for a long time that smoking tobacco is linked to heart disease, and this study is evidence that smoking cannabis appears to also be a risk factor for cardiovascular disease, which is the leading cause of death in the United States," lead author Abra Jeffers, PhD, of Massachusetts General Hospital in Boston, said in a press release issued by the primary funder of the study, the National Heart, Lung and Blood Institute (NHLBI).

She said toxins released by weed smoking are similar to those found with tobacco smoking. Research has also found that THC, the main psychoactive ingredient in cannabis, attaches to receptors of cells which are widely distributed throughout the cardiovascular system.

The study, published February 28 in the *Journal of the American Heart Association*, was based on 2016–2020 data from the Behavioral Risk Factor Surveillance Survey of the Centers for Disease Control and Prevention (CDC). The report took into account other potential risk factors such as age, race and obesity.

To read the press statement, GO TO bit.ly/3WP4Aoo. GO TO bit.ly/4d7GH1c.

HUD awards $26 million to EHE

The U.S. Department of Housing and Urban Development (HUD) announced in June a $26 million award for Housing Interventions (HINT) to End the HIV Epidemic (EHE). Housing is a key element to ending the epidemic, says HUD. The money will go to 11 communities around the country. **Programs and organizations will receive a one-time funding award supporting housing assistance and supportive services for families and individuals**. HINT is part of HUD's Housing Opportunities for Persons with AIDS (HOPWA) program. Earlier this year, HUD provided $455 million to 130 grantees through HOPWA. To read the press statement, with a list of grantees, GO TO bit.ly/3SEPGi7.

Mini-grants for women: NMAC

NMAC's community-driven GLOW (Growing Leadership Opportunities for Women) continues its rounds of training and engagement gatherings around the country with a **session in the Bronx, New York, October 3–6**. Most women registered will be local, but travel can be arranged for women from nearby states and locales. All will receive hotel accommodations. GLOW aspires to help women of color learn about sexual health and wellness and explore their experiences in life in a safe space. Other training topics will cover financial health, holistic care and entrepreneurship. Participants will have the opportunity to apply for mini-grants for projects providing women with tools and resources to support their leadership capabilities. "Women" means women—cis and trans. The Bronx forum is in Spanish. For a list of GLOW opportunities, GO TO nmac.org.

ISTOCK

Overdose and suicide prevention with HIV care: NIDA

Earlier this year, the New York City Department of Health and Mental Hygiene published a study showing that people living with HIV in the city had twice the rate of overdose than NYC's general population.

In response to the findings, the director of the National Institute of Drug Abuse (NIDA) and the director of the National Institute of Allergy and Infectious Diseases (NIAID) published a blog entry over the summer on combatting overdose and suicide among people living with HIV (PLWH).

Because the majority of PLWH in both New York City and across the country are in HIV care, both reports point to the failure of the health care system to save lives by providing simple and inexpensive interventions.

The New York City report showed that **nearly all of the PLWH (98%) who died from overdose had been connected to HIV care and three-quarters of them (75%) had remained in care, with more than half of them virally suppressed** (had undetectable viral load).

That finding is "shocking," write NIDA director Nora D. Volkow, MD, and NIAID director Jeanne Marrazzo, MD.

"In other words, the victims of fatal overdose were not unreached, or on the margins of the system—the stereotype of people with addiction," the doctors wrote on July 22. "They were engaged in care. Their drug use put them at greatly increased risk of overdose death, but because they were living with HIV, they were engaged with healthcare settings where preventive interventions could have been provided."

They note that resources from federal agencies like the Substance Abuse and Mental Health Services Administration (SAMHSA) can facilitate the supply of Narcan (naloxone), an opioid overdose reversal medication, that is administered as a nasal spray, and many cities and states provide it for free.

"Delivering naloxone and overdose education in HIV care settings is an obvious and relatively easy way to prevent overdose deaths," the doctors write. "Readily available both as a nasal spray and in an injectable formulation, naloxone quickly and safely reverses the respiratory depression caused by opioids including fentanyl. Although it is not a magic bullet—someone must be nearby to administer it—dispensing naloxone to people at risk of overdose is now a core harm-reduction strategy, and clinics delivering HIV care are settings where this strategy could and should be implemented. Even if a given person does not use substances, they may know people who do, so giving them naloxone and instruction in how to use it could save a life."

In their blog entry, *We Should Leverage the Successes of HIV Care to Prevent Overdose Mortality*, the doctors point out that:

- Drug overdoses in New York City claimed more lives of PLWH than did HIV-related illness
- Nearly one in five PLWH had a substance use disorder, according to the National Survey on Drug Use and Health data (2015–2019)
- Other studies show that PLWH have a high prevalence of prescription opioid use and are at increased risk for drug overdose
- 81% of people diagnosed with HIV in the U.S. in 2019 were linked to HIV care within a month, two-thirds (66%) received care and half remained in care, according to the Centers for Disease Control and Prevention (CDC)

ISTOCK

"Enormous strides have been made in screening and treating people with HIV with antiretroviral drugs and then retaining them in care long-term. Now, overdose is among the greatest threats to people with HIV," Volkow and Marrazzo said in their conclusion. "Especially in a drug landscape now dominated by deadly fentanyl, clinicians serving people living with HIV have a critical role to play in preventing overdose deaths with a relatively simple and extremely effective harm-reduction measure."

To read the blog, GO TO bit.ly/3yoLc8m.

The NYC study, which examined data from 2007 to 2017, was published in the February 1 issue of the *Journal of Acquired Immune Deficiency Syndrome (JAIDS)*. In its conclusion, the authors note that, "A sizeable number of [PLWH] died of OD during 2007–2017, and OD death rates in recent years increased. Predeath care patterns reveal frequent interaction with the health care system, underscoring missed opportunities for harm-reduction and suicide prevention interventions for [PLWH]." To read the New York study abstract (brief report), GO TO bit.ly/4cdIaS6.

Treatment behind bars

"It remains a common belief that simply stopping someone from taking drugs while in jail or prison is an effective approach to treatment. But that belief is inaccurate and dangerous," Dr. Volkow writes in a separate edition of Nora's Blog, along with co-author Tisha Wiley, PhD, associate director for social justice at NIDA. They lay out statistics and report on one successful model for preventing overdose in people after they've been incarcerated—including the use of all three FDA-approved opioid use disorder medications during incarceration (Franklin County, Massachusetts). *Everyone deserves addiction treatment that works—including those in jail* was published online on July 15. GO TO bit.ly/3A72Caf. The article was originally published online July 9 on *STAT*. The three opioid use disorder medications are methadone, buprenorphine and naltrexone.

Texas hold 'em

Advocates fight to get uninsured Texans access to Cabenuva

BY **LARRY BUHL**

Approved in January, 2021, Cabenuva was the first long-acting injectable for treatment of HIV. But in Texas, uninsured people living with HIV (PLWH) still have to pay out of pocket or make do with oral treatments. That's because the Texas HIV Medication Program (THMP), the state's AIDS Drug Assistance Program (ADAP), still hasn't added it to their formulary, and HIV advocates are crying foul.

Texas is one of seven states that do not include Cabenuva in their ADAP formularies.

Other Texas payers cover Cabenuva, including private insurers as well as Medicare and Medicaid. Without coverage, injections of cabotegravir plus rilpivirine cost more than $6,000 per treatment, out of pocket. THMP, the payer of last resort for people living with HIV, serves about one-sixth of the people with HIV in Texas, according to its annual report.

THMP does cover two long-acting injectable HIV treatments, Sunlenca (lenacapavir) and Trogarzo, but they're indicated for heavily treatment-experienced PLWH who have had difficulty finding an optimized functioning regimen, including those with multi-drug resistance.

Dora Martinez, a physician with Valley AIDS Council in south Texas and director of government relations at ViiV Healthcare, the maker of Cabenuva, has about 60 patients on a waiting list for Cabenuva. Martinez, who recommended adding Cabenuva to the Texas formulary when she served on the THMP Advisory Council, said that Texas is the only state with no avenue for uninsured PLWH to get the medication. "Many folks can't get on Medicaid and there's really no other program here," she said. "Some of the other states that don't have [Cabenuva] on their ADAP formulary will essentially pay for the premiums for someone to become insured."

The current maximum income for a single Texan to be eligible for Medicaid is just under $30,000. Forty states plus the District of Columbia have expanded Medicaid under the Affordable Care Act, providing another avenue of coverage for lower-income people. Texas has not expanded Medicaid, making it even more challenging for people to get covered.

About 4.9 million, or 17% of Texans, are without health insurance, according to 2022 Census data. The number of people with HIV in the state, as of 2019, was near 100,000, with Black and Hispanic/Latinx Texans making up the majority.

"Bottom line, if you're a Texan with HIV, and you have insurance, you potentially have access to Cabenuva and if you're uninsured, you don't," Martinez said. "You can go to a patient assistance program where otherwise your income would qualify, but because [ADAP] is considered insurance, you don't qualify."

'Specious' assumptions

THMP has given "specious reasoning" behind not providing Cabenuva, according to Michael Elizabeth, director of public health policy for the HIV advocacy organization Equality Federation. The assumption is that people switching from a less expensive oral medication could potentially bust the budget. But in crunching the numbers, Elizabeth said that assumes every Texan on oral meds would switch to Cabenuva. "ADAP says the number of people switching would add up to $6.4 million a year for Texas, but that assumes 100% of the virally suppressed patients on oral single-tablet regimens would switch to Cabenuva, but we don't see those [switching] numbers in other states. We're not seeing an exodus of people on Biktarvy, for example, immediately switching to Cabenuva."

Martinez agreed that THMP's assumptions are faulty. "We've seen from other states' ADAPs that maybe 2–5% have switched to Cabenuva."

"You can't have resistance to either of the components [in Cabenuva] and there's going to be individuals who may have developed resistance in their prior treatment history,"

TEXAS HOLD 'EM: MICROVONE-ISTOCK ADAPTED BY RICK GUASCO

she said. "And you have to be someone that actually wants injections. Not everybody is a fan of needles."

Recent data from the LATITUDE Phase 3 trial, presented at CROI in March, indicate that long-acting injectables may be better than daily pills for people who have difficulty with adherence. The Transgender Network of Texas (TENT), in a letter to the Texas Department of State Health Services (DSHS), the organization that oversees THMP, emphasized that trans Texans would benefit from Cabenuva.

"Due to the prevalence of housing instability, employment discrimination and other social determinants of health, many transgender Texans fluctuate between Medicaid and THMP based on income and other eligibility factors," TENT wrote. "Open and full formulary access to all FDA-approved HIV medications should not be made more difficult, especially for those most deeply affected by this epidemic."

Martinez added that a potential groundswell of PLWH switching to Cabenuva shouldn't break the state's budget. "The cost is on par [with oral medication], within the ballpark, and there was a good faith effort negotiation between ViiV and ADAPs to make Cabenuva cost neutral."

In an email, Douglas Loveday, a spokesperson for DSHS, said the department's estimate was based on an assumption that only 80 percent of THMP clients, not 100, would switch to Cabenuva (the estimated percentage of THMP clients virally suppressed and eligible to switch).

"The addition of Cabenuva will also require increased office and injection-only visits for clients," Loveday wrote. "The cost of an injection ranges from $25 as part of a nursing visit to $75 as part of a medical provider visit. The average cost for injection visits ranges from $75 to $125 per client per year. This will result in a projected increase of $857,175 to $1,428,625 annually."

The projected cost of office visits plus the medication would increase the cost to THMP up to $6.4 million annually, Loveday wrote. "DSHS is experiencing an increase in THMP enrollment which, if it continues, will exceed program funds. DSHS is completing further analysis to see how to best resolve this projected program shortfall."

'Bottom line, if you're a Texan with HIV, and you have insurance, you potentially have access to Cabenuva and if you're uninsured, you don't.'

The Texas legislature could apply pressure on the agency to add Cabenuva to the formulary, but the lawmakers meet only every other year, and the next session starts in January. Elizabeth adds that expecting the legislature to take up the issue, despite some advocates in the chamber, is dubious.

Any legislative effort to put Cabenuva on the THMP formulary will face strong headwinds, Elizabeth said. "Anything that tends to even remotely support marginalized communities has a hard fight ahead of it," he said. "The legislature is one of the drivers behind all the anti-LGBTQ bills that we're seeing across the nation... and have generally been anti- anything that can be seen as supportive of these communities."

Martinez said that the failure to provide Cabenuva for uninsured Texans could have consequences for ending the HIV epidemic, noting that five jurisdictions—Bexar, Dallas, Harris, Tarrant and Travis counties—are in the U.S. Ending the Epidemic (EHE) initiative.

The overall HIV viral suppression rate in Texas is estimated to be 63%, well below the state's goal of 75% by 2025.

"More data is coming out that long-acting injectables are potentially a means of getting folks to undetectable," Martinez said. "We're nowhere close to ending the HIV epidemic and meeting those goals, the 90-90-90 goals and we're especially not going to get there with this glaring disparity. We have to think about who are the folks that tend to have more challenges, and folks without insurance already tend to have more challenges." PA

PUERTO RICO AND BACKGROUND: POP_JOP-ISTOCK

A VITAL gap in Puerto Rico?

Puerto Rico, unlike Texas, has government-funded healthcare for people who need it. But a recent change to the plan has HIV advocates worried that people living with HIV (PLWH) will see gaps in coverage for all HIV meds.

As with Texas and other states, Puerto Rico provides ADAP coverage for PLWH who are not insured through a government health plan called VITAL. But **as of July 1, people who relied on VITAL for meds were switched to a Medicaid Drug Rebate Program (MDRP), affecting about 7,000 Puerto Ricans on the island who are living with HIV**, and possibly not for the better, advocates say.

Under the MDRP, pharmacies and clinics that provide meds will have to upfront the cost of meds then get reimbursed by the government. But some of the pharmacies and clinics do not have the cash flow to pay for medications for all their patients, according to Pedro Julio Serrano, manager of development and public policy at Waves Ahead, a San Juan-based LGBTQ+ services organization. "So this means pharmacies and clinics might not be able to buy medications in advance," he said.

To head off unintended roadblocks to getting meds, Waves Ahead and other advocates met with Mellado López, the Secretary of Health of Puerto Rico, and asked that HIV meds be excluded from the MDRP and make them available through ADAP instead, but they were unsuccessful.

"The government is saying that this allows for more pharmacies to be able to provide the meds, but in reality, some people can't be going to pharmacies or other places to get their meds because they can only afford one ride, to go to the clinic to get their meds and their labs," Serrano said. "This endangers people who are adherent to their medications."

The government did provide a temporary patch to make sure that the pharmacists and clinics have a sufficient allocation of medication through December. "But we don't know what will happen after January," he said. "That's why I worry."

Adding to the uncertainty are the November elections. Serrano fears that a wave of new right-wing candidates "fostering a climate of hate that is inciting violence against LGBTQ+ people" may be voted into office.

"Some candidates are jockeying for votes from the right-wing sector that is proposing things that are dangerous for [people with HIV]. So we're worried that some of the successes that we've had in terms of adherence in Puerto Rico, and services and projects, might be in jeopardy if more candidates from the right wing are elected."

So far there's been no disruption in obtaining HIV meds on the island, Serrano said.

—LARRY BUHL

REMOVING THE HURDLES

California tries to 'cleanup' a law that was intended to improve PrEP access

BY **LARRY BUHL**

Become an early adopter in allowing pharmacists to provide pre-exposure prophylaxis (PrEP), and post-exposure prophylaxis (PEP), advocates say, because it's taking years to revise the California law to ensure maximum coverage. Although several other states have surpassed California, the state legislature is proposing a so-called "cleanup law" that will ensure pharmacists face fewer hurdles—such as payment—in providing the meds.

ISTOCK

Only one in four people in the U.S. who could benefit from PrEP is taking the medication, which is a key reason the National HIV/AIDS Strategy for the United States called for PrEP and PEP to be prescribed and provided by pharmacists. The idea is, asking for these meds in a less stigmatizing setting like a pharmacy would expand access in communities that need it most and could cut out some steps and travel. By allowing pharmacists to prescribe and provide PrEP and PEP, a patient would, in theory, no longer need to get HIV test results from a lab, take them to a doctor to get a prescription, then head to the pharmacy for the meds—several times a year, assuming the pharmacy also offers HIV testing—not a sure thing. Research has shown that LGBTQ+ people in the U.S., especially Black, Latinx and younger people—the groups who could most benefit from PrEP—are less likely to access healthcare. Sexual health clinics often provide one-stop shopping for PrEP, but these facilities are more often in urban areas. In other areas, pharmacists are the most accessible healthcare providers.

According to the American Pharmacists Association, as of last fall, 17 states had expanded pharmacists' authority to provide PrEP or PEP at community pharmacies or clinics. But not all of those states provide reimbursement to the pharmacies for the extra staffing and testing services, which has limited the benefits of these expansions.

California was the first state to authorize pharmacies to provide PrEP and PEP, through Senate Bill 159, but since the law went into effect in 2020, lawmakers have since been trying to plug holes in the law. Shortly after SB 159 was passed, I reported for the Center for Health Journalism that pharmacists were unlikely to opt-in to provide PrEP because the law didn't authorize payment for on-site HIV testing or any of the training or staffing needed to provide the meds. The likeliest scenario was, if a pharmacist did choose to provide the meds, customers would have to get their labs at a testing center if there was one in the community, then come back for PrEP or PEP, an extra step that could make some think twice. A negative HIV test is required to obtain PrEP/PEP, and the Affordable Care Act mandates that HIV testing must be free for those with insurance. But it's not always easy to find a place offering HIV tests, especially in pharmacies, which don't necessarily get paid by insurers for the service.

A recent study conducted by the California HIV/AIDS Policy Research Centers and the Center on Reproductive Health, Law and Policy at UCLA concluded that SB 159 did not expand availability of PrEP in the way lawmakers hoped. In this survey of 900 California pharmacists and pharmacy students an overwhelming majority said they never furnished PrEP or PEP services and less than two-thirds had heard of SB 159.

Last year the California legislature introduced Senate Bill 339, which was signed into law in January, to address some of these issues. The law extends the supply of PrEP and PEP meds that pharmacists may supply from 60 days to 90 days, and requires health plans to pay for the meds, as well as the pharmacist's time and testing services. But according to some California pharmacists, SB 339 still falls short of ensuring equitable access to HIV testing and PrEP/PEP.

In a survey of 900 California pharmacists and pharmacy students an overwhelming majority said they never furnished PrEP or PEP services and less than two-thirds had heard of SB 159.

"Pharmacists must be reimbursed in order for the chain and independent pharmacies to devote resources to their staff to provide the services [and] they can't do it unless there is a path to payment," wrote Maria Lopez, president of Mission Wellness Pharmacy in San Francisco. One problem with the latest law, she said, is that California doesn't enforce payment for new workflows, education, testing or the meds.

Picking up after the cleanup law

In late April, the California legislature heard testimony from Lopez and others supporting yet another bill to revise the current law and eliminate regulatory hurdles preventing more pharmacists from offering the prevention meds. If passed, the new bill, SB 966, would put some enforcement behind the previous law's mandate to pay pharmacies, according to advocates.

SB 966 would create new Pharmacy Benefit Manager (PBM) regulations and curb what advocates call abusive billing practices. In introducing the bill in January, state senator Scott Wiener said, "We cannot allow these middlemen to continue charging exorbitant and unfair prices while Californians are forced to ration life-saving medication."

"The previous law said that health plans were not required to cover PrEP or PEP prescribed 'by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit,' which has been an obstacle to providing PrEP and PEP," said Dr. Clint Hopkins, owner and pharmacist at Pucci's Pharmacy in Sacramento, in an email. Hopkins testified before the legislature in favor of the previous two laws.

"We continue to run into barriers with some health plans citing that we are 'not in network' and not wanting to contract with us. All we can do is turn them in to the Department of Insurance and see if they will be able to force them to allow us in," Hopkins added.

As written, SB 966 would allow patients to get PrEP and PEP through any pharmacies, in-network or not, and prohibit "spread pricing" where PBMs charge a plan more for a drug than it pays pharmacies. It also would require the PBM to pass along drug rebates to plans or directly to patients and prohibit direct or indirect fees to the patient.

Beyond the issue of paying for PrEP and PEP, pharmacists have not been reimbursed for their time or on-site testing, if they offer it. SB 339 set no requirement that the commercial or Medicare plans pay a reasonable rate for services. For Medicaid, a compromise to get the previous legislation passed was insertion of "85% of the fee schedule for physician services" found in SB 339," according to Hopkins. "We don't get a 15% discount on purchasing HIV testing or labor costs involved in providing services," he said. "Our costs are the same as a physician's costs and we should be paid the same."

Every state regulates its pharmacists and insurers differently. Lopez said regulation of the insurance industry has been "historically weak" in California, leaving pharmacists on the hook not only for PrEP and PEP services, but for COVID work, such as testing, even when mandated to reimburse by the Emergency Federal Directive, which ended in 2023.

Other issues hampering the distribution of PrEP and PEP include stipulations that the California Board of Pharmacy makes on what a pharmacist is allowed to do, Lopez said, which sometimes override federal guidelines, such as mandating a 60-day supply of PrEP when the CDC required a 90-day supply. Mandated state education and training on PrEP and PEP protocols, which don't align with education requirements of the CDC, also present barriers to care that Lopez and Hopkins hope the new law will eliminate. PA

The language of HIV (de)

Choosing your words: **Kamaria Laffrey**, co-executive director of The SERO Project, talks about her strategy in the fight to modernize and repeal outdated laws that criminalize HIV

INTERVIEW BY **RICK GUASCO**

What's the difference between HIV *criminalization* and HIV *decriminalization*?

KAMARIA LAFFREY **Decriminalizing HIV is the goal.** We don't want people criminalized for their HIV status. But The SERO Project, specifically, when we're working with coalitions and we're talking with legislators, especially in conservative climates, we really don't use that word, *decriminalization*. We start off with talking about modernizing and aligning things with progress—we don't even use *aligning with science*. We'll say, *aligning with the progress that we've made since the '80s*. Because a lot of the conversations will start off with, *do you know anybody, or has anyone in your life passed away from HIV/AIDS?*, because there's always some relative that no one talked about, who died from something. And so we frame it to put them there—*Look how far we've come, you don't even hear about it anymore, but I'm a person living with HIV* [who was] *diagnosed in 2003*. And so we talk about, *See that progress we've made, but our laws don't align with that, and people are facing criminalization based on their health status*. And then we start breaking down the hard facts. As we talk about strategy, depending on the relationship, we'll mention that decriminalization is the ultimate goal.

We have a toolkit that helps advocates navigate language around decriminalizing: replacing, repealing and modernizing—our SERO Project Justice Institute advocates have worked to inform the legal literacy for their legislative and community engagement strategy efforts.

So, it's a matter of using the right word in the right situation or relationship.

Yeah. I have a training I do where I say, *Agree or disagree: Racial justice should be at the center point of HIV criminalization conversations*. Most people normally would say, *Yeah, racial justice is an important issue*. Yeah, I agree. But as a Black woman, I'm not going to walk into a legislator's office and start telling them hard facts about the Black community with HIV, with criminalization first. I'm not leading with race first—specifically in conservative spaces. That's just a personal choice. Because of the angry Black woman stereotype, I always try to feel the room first.

When I realize the audience I have is going to be receptive, I bring in those points—*Did you know that your district has 47% Black Americans living there? Do you know that 30% of those Black Americans are vulnerable to HIV?*—some statistics like that. I bring it around after I do the whole level setting—*Here's who I am, beyond being a Black woman, here's what I'm talking about*—because I usually have other people with me in these meetings. That's just one example—feeling the room, having the relationship, hearing how they're leaning in or not leaning in. Also, you're usually talking to a congressional staffer, and sometimes they're more clued into what you're saying—they read between the lines. Sometimes they'll start asking questions that help prompt you to say the real thing that you actually came here to say, which is we want to repeal this. And then they'll dial you back and say, well, *Representative so-and-so has supported this, this and this; let us look at your language*, and see if it's something that they align with, or see if they have any questions and then we go from there.

How is the wording or the vocabulary different when you're talking to community or with the public?

When I'm talking to a room of people who are allies and people living with HIV, the language is no sugarcoating—*Decriminalize HIV. We want it repealed. We want it gone*. Then I explain that when you are out and you're doing this education, I circle back to look at the political climate. Most states have picked up a 'modernize' strategy. Illinois, for example, started out with *modernize*. It ultimately

criminalization

RICK GUASCO

became *repeal*. So it's not impossible, it just took them a long time. When Virginia modernized their laws, they knew they had to do it that summer of 2021 because their governor was going to change. If they didn't do it, then they were going to have challenges they weren't resourced to address for the change they were seeking.

What do you tell people who say, *Oh, this is incrementalism. We need change now*?

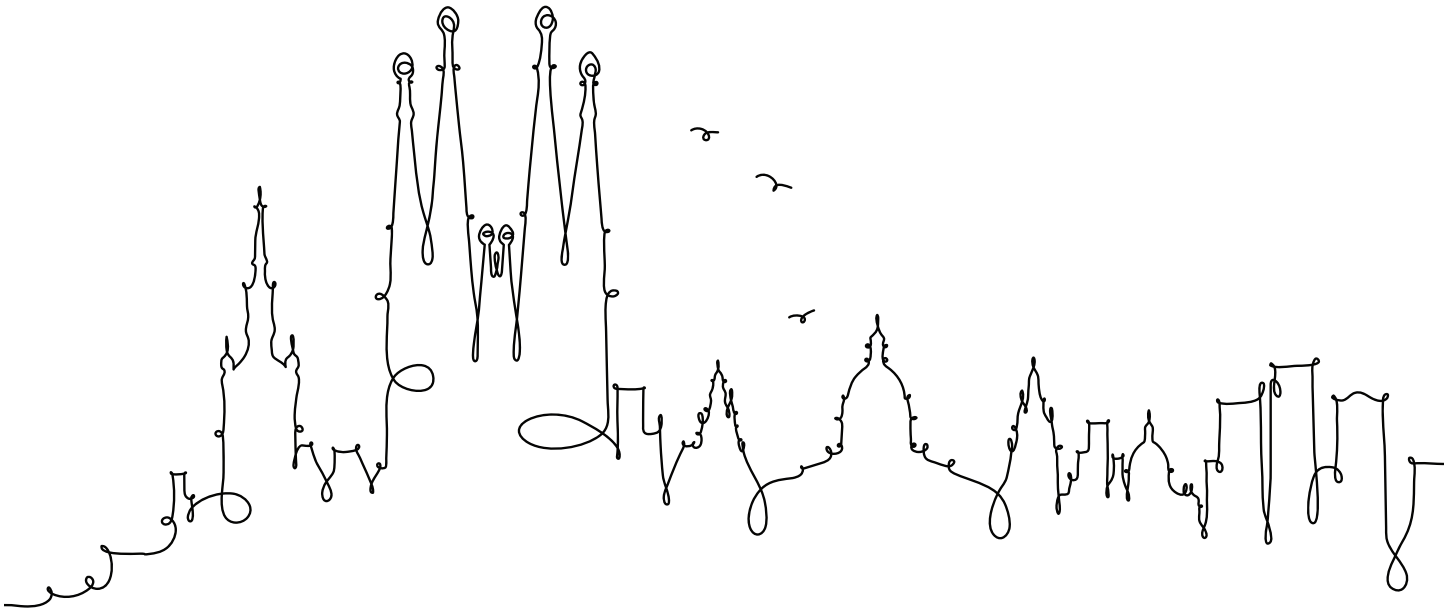
It depends on who's saying it and where they're coming from. But I get it. It's frustrating. No one wants piecemeal change, especially when you are witnessing lives being impacted. Like, somebody just got charged yesterday, or, somebody could be out right now, but their state did something crazy. I usually just ask folks to trust the community and help us amplify the work that we're doing and help us think outside the box. I'm down for innovation, because sometimes when you're in a silo and you're the only one looking at something over and over again, I need that voice of like, *I'm sick of this. Let's try something else*. And I'm like, *Okay, how do you see this? What looks different?* And if it doesn't feel realistic, then I'm like, *Okay, let's talk about that.* And if they do end up bringing in this big box idea, then I start looking, *Okay, how do we get this funded? How do we get this mobilized? Who needs to be organizing this, and what is the expected outcome from that?* So those are the things I think of when people are like, *We don't want incremental change.* I don't like it either. But also, this is the system that we're part of. I want to burn it all down, to be perfectly honest, but you also have to be building a community that will be sustained if you do decide to burn it all down. Or if something else happens and your strategy collapses, have you built community to be able to survive that? And if you haven't been doing that, then incremental changes are what you have to be doing.

> "...when I'm talking to a room of people who are allies and people living with HIV, the language is no sugarcoating—***Decriminalize HIV. We want it repealed. We want it gone***."

Why should people care about HIV criminalization?

If you care about marginalized communities, if you care about housing, if you care about access to treatment, if you care about actually ending HIV and not having people prosecuted for a health status, where no other health status has this level of federal legislation attached to it, then you care about HIV criminalization. You don't have to know me to care, but you care. PA

DOWNLOAD The Sero Project Justice Institute Toolkit: seroproject.com/sero-project-justice-institute-toolkit



Notes from Barcelona

Highlights from **ESCMID Global 2024**—the European Society of Clinical Microbiology and Infectious Diseases conference in Barcelona, Spain

BY **LARRY BUHL**

CRISPR gene editing technology offers a path to a possible cure

The ability for HIV to integrate its genome into a host's DNA makes it very difficult to eliminate, leaving people with HIV reliant on lifelong antiretroviral therapy to prevent the virus from reactivating. After entering an immune cell, HIV's single-stranded RNA genome reverse-transcribes into double-stranded DNA. This lets the virus' genome establish itself in the cell's nuclear DNA, allowing constant replenishing of virus particles.

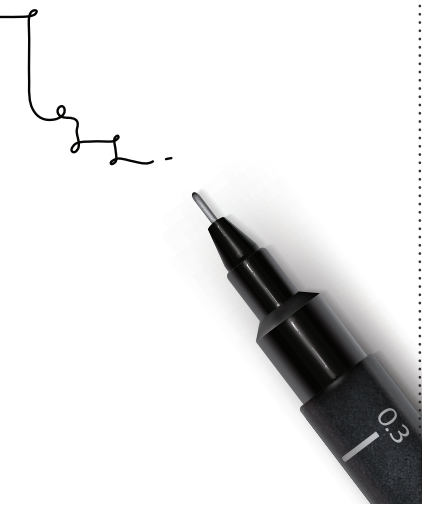
But preliminary findings presented showed how **gene editing could be used to precisely alter these genomes, which would be a significant breakthrough to eliminating HIV** from the body.

The research involves CRISPR technology, which won its inventors a Nobel Prize in 2020. CRISPR slices up genes of invading viruses and it can be directed to guide DNA to make cuts at specific genomic sequences to remove and even replace those sequences inside living cells, and it's the basis of new gene editing treatments that promise to cure sickle cell disease. A team of researchers from Amsterdam Medical University in the Netherlands and the Paul Ehrlich Institute in Germany showed how it does the same for HIV. Their results presented at ESCMID Global showed how CRISPR-Cas gene editing technology acts like molecular "scissors" to eliminate the HIV virus from infected cells in the laboratory using guide RNA (gRNA) to tell CRISPR-Cas exactly where to cut at designated spots on the virus genome.

The authors emphasize that their work represents a proof of concept rather than a cure. However, they say it could lead to a cure that would inactivate diverse HIV strains in multiple parts of the body. "The studies present a significant breakthrough in the search for an HIV cure," said lead author Elena Herrera-Carrillo, PhD, an associate professor in the Department of Medical Microbiology, Laboratory of Experimental Virology at the University of Amsterdam Medical Center.

The authors shared their evaluation of how well two CRISPR-Cas systems, saCas9 and cjCas, treated CD4+ T cells infected with HIV. SaCas9, they said, was highly effective in inactivating HIV with a single gRNA and in cutting out the viral DNA with two gRNAs. Researchers used CRISPR-Cas and two gRNAs against "conserved" HIV sequences, which are parts of the virus genome that stay the same across all known HIV strains. The idea is that by focusing on conserved sections, a broad-spectrum therapy could be developed, one that combats multiple HIV variants.

The team faced a logistical obstacle: the size of the "vehicle," or vector, that was used for transporting the cassette encoding the therapeutic CRISPR-Cas reagents into the cells was too large to be used in a clinical setting—think of stuffing a compact car full of luggage for a long journey. The researchers found a way of downsizing the "luggage" (the cassette) for easier transport. They were also able to target "hidden" HIV reservoir cells by



focusing on proteins found on the surfaces of the cells (CD4+ and CD32a+).

Researchers say their goal is targeting reservoir cells and to avoid delivering CRISPR-Cas into non-reservoir cells to make the system as safe as possible for clinical application. The team says they'll also explore how to effectively target HIV in all the different types of cells and tissues, each with unique environments and characteristics.

Obstacles to PrEP use in Europe and Central Asia

World Health Organization (WHO) guidelines recommend PrEP for key populations considered especially vulnerable to acquiring HIV, including sex workers, men who have sex with men (MSM), people who inject drugs (PWID), incarcerated people, and transgender and gender diverse people.

However, the implementation of PrEP throughout Europe and Central Asia (ECA) varies significantly by country and these key populations face significant obstacles in obtaining PrEP, according to WHO researcher Viatcheslav Grankov, who presented some disappointing PrEP uptake numbers at a symposium at ESCMID. The United Kingdom, France, Germany and Spain, he reported, account for 77% of total PrEP usage across the ECA region. In other countries, Grankov said, including Armenia, Lithuania and Tajikistan, "PrEP usage is too low to have any meaningful impact at the public health level."

Grankov pointed out some reasons why this is the case. In many countries, the law prohibits undocumented migrants, incarcerated people and PWID from being eligible for PrEP. Even in areas where a larger number of people can access PrEP, usage is poor. For example, a recent study from France, one of the higher PrEP uptake countries, concluded that less than a quarter of MSMs who could benefit from PrEP are accessing it.

In 2022, the WHO released guidelines recommending that people who may be especially vulnerable to acquiring HIV should have access to CAB-LA, stating that CAB-LA as PrEP could help close the gaps in HIV prevention in ECA. The reasoning is that CAB-LA could improve adherence and reduce stigma associated with oral PrEP. But Grankov suggested that unless countries eliminate some of the hurdles that have hampered use of oral PrEP, uptake of CAB-LA will also be minimal.

Grankov stated that across low-income and middle-income countries, long-acting injectable Cabenuva should be, but not always is, reasonably priced. But cost isn't the only obstacle facing vulnerable people in these countries. "In many countries, PrEP is still provided as a pilot project, mainly for MSM, and the number of PrEP clients is very limited. In many cases, **[prevention] services [are] highly medicalized, which creates additional barriers in a stigmatized environment**." Other issues, Grankov said, include excessive clinical monitoring, which are not in line with WHO recommendations, and even requirements to provide passport data in order to receive PrEP. "And of course, insufficient awareness and misconceptions among target populations, and even low knowledge of PrEP among providers affects retention and continuation of PrEP."

Previously incarcerated people living with HIV are highly vulnerable to dropping out of care, study says

One vulnerable population, incarcerated people, was the topic of an ESCMID presentation by Maximo Brito, MD, MPH, a professor at the University of Illinois in Chicago. **People who have been previously incarcerated, he pointed out, are especially vulnerable to being lost to care soon after being released**. Some reasons include poverty, poor mental health, lack of support, and lack of employment and housing.

"Retention remains suboptimal for many HIV programs and effective strategies to retain and re-engage patients living with HIV are urgently needed," Dr. Brito said.

He indicated how urgently such strategies are needed by sharing data from a quality improvement implementation project in which researchers estimated how many patients living with HIV dropped out of care, who they were and whether they could be re-engaged. Results were taken from six HIV primary care settings in the University of Illinois Community Clinic Network that serve PLWH in Chicago. Researchers reviewed medical records for all patients at the clinics to determine who tested positive for HIV but had not attended an HIV care appointment within the past year and were not on ART.

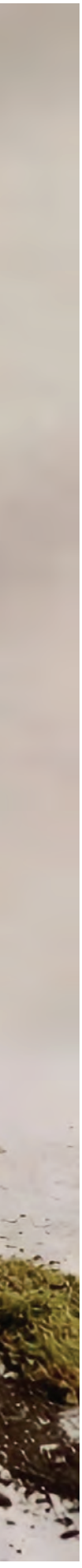
Outreach workers used phone calls, letters (mail and email), home visits and internet searches to contact this group of patients; once they located a patient—*if* they located the patient—they offered to help re-engage with treatment services and restart HIV care. Of 491 PLWH identified in the network, most were male (89%) and Black (63%) or Hispanic (19%), with an average age of 41 years. A small percentage had transferred to other clinics, been re-incarcerated, or had died. That left a small but significant number, 85 out of 491, who were likely alive but out of care, including 33 who were previously incarcerated.

Of the group lost to care, communication presented a barrier: three-quarters could not be contacted due to an invalid phone number, 16% did not answer and 2% were contacted but declined to return to care. Only five patients (6%) were successfully located, and of these, only one returned to care.

Dr. Brito said that these discouraging numbers suggest that interventions must be made prior to release from corrections.

"**We need dedicated resources to optimize people's HIV care while they are in prison and to link them to community-based care upon release**," he said. He added that case management, health insurance and treatment for addiction and mental illness—again, before release—will help incarcerated PWH remain treatment adherent, virally suppressed, and, as a side benefit, reduce recidivism.

All ESCMID Global 2024 sessions are available on the conference website until October 30, 2024. GO TO eccmid.org/online-platform.



MAGIC FINGERS PHOTOGRAPHY

Advancing the conversation

In Nigeria, an advocate uses personal storytelling to share knowledge and strength

BY **PASCAL AKAHOME**

Mohammed Awal Waju is a 23-year-old openly gay man living with HIV in Nigeria. Diagnosed at the age of 17, he says that it was difficult initially coming to terms with his new reality while dealing with the unique challenges of late adolescence. He soon discovered the U=U message, and it opened a new lease on life for him.

"To me, U=U means freedom, empowerment and hope," he says. "It means that I can live a healthy, fulfilling life without fear of transmitting HIV to the ones I love. It means that I can pursue my passions, build meaningful relationships, and contribute to my community without the weight of stigma holding me back."

I first became aware of Awal's work while scrolling through X (formerly Twitter), in November 2023. He had posted a picture of himself sporting a U=U t-shirt with the caption, "It's a virus, not a limitation. Make stigma history." As simple as this act of advocacy seemed, it drew the ire of many netizens; vitriol and unprintable homophobia overflowed in the comments. The post, which generated over 100,000 impressions at the time, went viral in Africa.

Unsettling and disturbing as the comments were, Awal was unfazed. It has become a norm for him and he is undeterred. "...I get threats every day; it is nothing new," he says. "Sometimes, I get over a hundred messages in my inbox wishing me dead." The threats and negativity have become routine. He once received a threat to his life from someone he believed knew his home address. Still, he takes it all in stride as he considers it part of the hazards of the terrain.

"For me, staying safe while advocating for LGBTQ+ rights and HIV/AIDS awareness in Nigeria is a constant balancing act," he says. "I'm always aware of the risks involved and try to be careful."

For Awal, it's the positive feedback he gets that drives him. "A lot of people hear about U=U for the first time from my posts, and I am happy about that. I typically get about 40 messages daily encouraging me and seeking to learn more about U=U. The most special I ever received was from a 17-year-old gay boy just getting diagnosed. It was significant because that was the same age I was when I received my diagnosis, and I was able to relate to the exact emotions he was passing through. I was able to take him under my wing and nurture him through the process of coming to terms with the reality of his situation." His tone is light and his face breaks into a wistful smile; it is evident that he is sharing a pleasant memory.

Moments like this remind him why he started his advocacy, he says. "I want more people living with HIV to come out and share their stories. I am inspired by the power of grassroots advocacy to raise awareness about U=U and challenge existing harmful stereotypes. More importantly, we need legislative reform. The criminalization of homosexuality in Nigeria perpetuates stigma and discrimination. Legal reform, such as repealing discriminatory laws, is essential."

More broadly, Awal believes that coming out openly to advocate for U=U as a gay man living with HIV is helping to advance conversations around the topic and, consequently, awareness. "My social media campaigns have helped to raise awareness about U=U and HIV/AIDS, particularly among young people who are more likely to engage with online content. By sharing my story, I have helped to increase the visibility of the LGBTQ+ community and people living with HIV, challenging the stigma and misinformation that surround these issues."

While Awal understands that not everyone can openly disclose their sexuality or status, he adds that other LGBTQ+ individuals living with HIV in Nigeria who may be struggling with stigma and discrimination should find a circle of support.

"Seek out friends, family or community organizations that can provide support and understanding," he says. "Practice self-care by engaging in activities that nourish your body, mind, and spirit. This can help you cope with the stress and stigma you may encounter. And also remember that you are not alone."

Asked how long he intends to continue the movement, he says there are still too many people who have not heard the U=U message. "We have to use any means necessary to get the message out there, and for me, social media is the best tool at my disposal. I will never stop advocating for U=U. This is a life journey for me and so I will continue advocating for U=U."

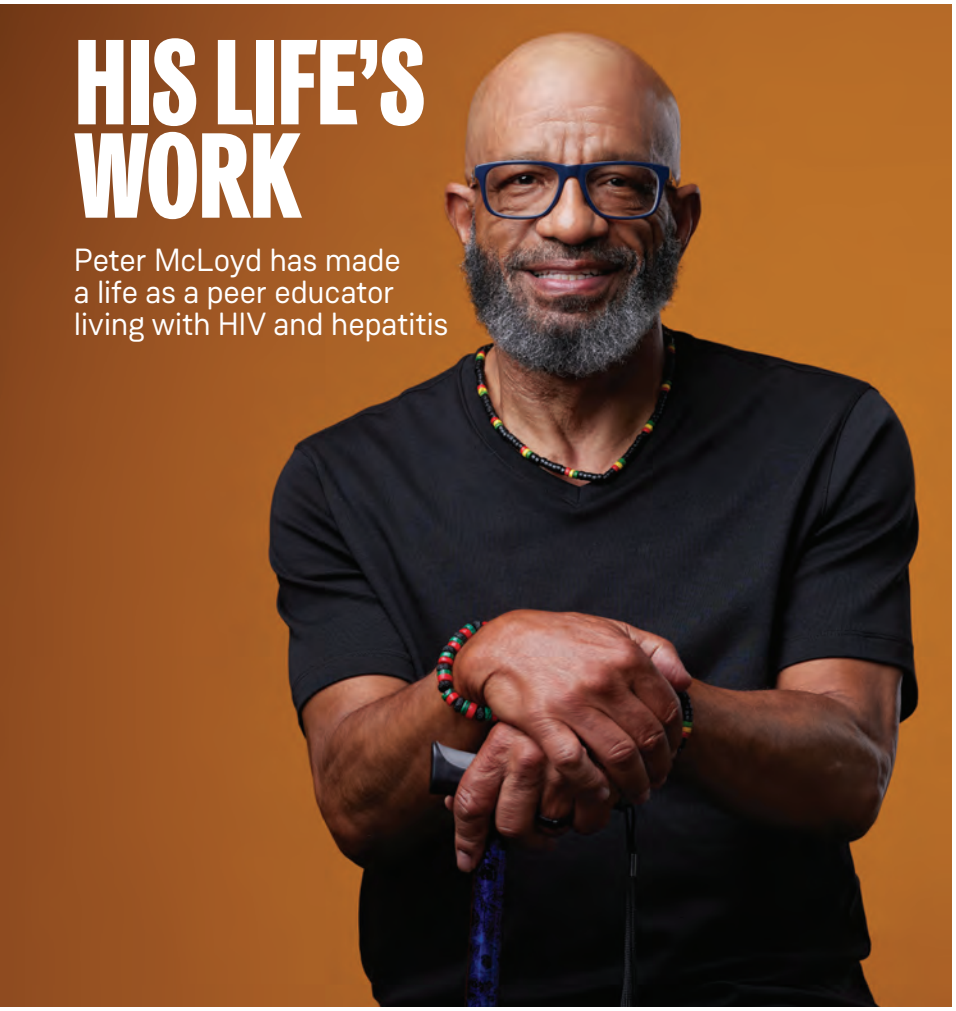
We had barely finished our call when I received a notification of a new post from Awal. It's an attention-grabbing picture; standing on a hill, his fists raised in defiance, wearing a crop top with U=U boldly emblazoned on the front and an unwavering smile on his face. PA

Awal is on X and Instagram, @awalwaju.

PASCAL AKAHOME (he, him) is a pharmacist, researcher and writer who uses the power of words to advocate for improved HIV treatment and prevention services access to marginalized groups in the global south. His writings also explore the intersection between policy at a macro level and healthcare access. He is a fellow of the Advocacy for Cure Academy of the International AIDS Society (IAS) and the director of Antiretroviral Improved Access Initiative (AIAI), a local advocacy network based in Nigeria. He often speaks on HIV scientific and advocacy panels.

HIS LIFE'S WORK

Peter McLoyd has made a life as a peer educator living with HIV and hepatitis



Not long out of high school in Chicago, Peter McLoyd started using heroin and cocaine in 1972. Soon he was injecting. In the early '80s he was diagnosed with hepatitis B.

"I'm pretty sure it was from sharing a needle or works with one of my compatriots," he says.

Doctors didn't offer much help. "They told me that there was no treatment, and that that was pretty much it," he says. "They didn't give me any additional information. They told me, *don't share needles*."

On Valentine's Day 1997, McLoyd received a double diagnosis—he had tested positive for HIV and hepatitis C.

"I wasn't shocked," he says. "I was already showing symptoms. I had been to a couple emergency rooms, and they told me I had PCP pneumonia, which was indicative of having HIV, but I was thoroughly immersed in my addiction. I was basically homeless, living with friends here and there."

McLoyd's doctor gave him a referral to a local hospital, but a couple days later the doctor told him to immediately go to the emergency department of Cook County Hospital. He was soon admitted to Ward 20, County's AIDS ward.

While in the emergency department waiting room, McLoyd overheard two women seated in front of him. "It was very strange, because they were talking about HIV, and not in a stigmatizing way," he says. One of the women was waiting to be seen by a doctor. "She was like, *It's not something to be worried about or to be afraid of talking about.* She seemed pretty knowledgeable."

The woman talking about HIV was Rae Lewis-Thornton, who first shared her story in 1994, appearing on the cover of *Essence* magazine.

Hearing Lewis-Thornton, McLoyd says, "It made me very hopeful. I was taking it all in. I was like, *Whoa, this is pretty incredible*."

McLoyd was in the hospital for eight days, but not long after being discharged, he was coming back for the hospital's HIV support group.

"I went every day," he says. "It was very encouraging. There were mostly African American men and women, many of them were like me, injection drug users or former injection drug users. They had been living with HIV for a while, and so they knew the ins and outs, where to get care and how to find additional resources in the community. I just listened and learned."

Attending the support group changed his life's direction, he says. "I completely abstained from heroin, cocaine and any drugs. I was strictly focused on my health and getting an education about HIV. I never relapsed. Certainly I had moments of self-doubt, but I surrounded myself with people who were knowledgeable."

By now, McLoyd had gone from volunteering at the CORE Center, Cook County's recently built medical facility that provided services to people living with HIV, to being employed as a peer educator. In 2000, he met Kathy, a nurse who had started working at the CORE Center, and they became friends.

The two went on an HIV advocates' group trip to Kenya in 2004, marking a turning point in their relationship. They were married later that year.

Unlike HIV, there was no treatment for hepatitis C at the time other than a combination of injections of pegylated interferon and ribavirin, an oral medication. The treatment was difficult to tolerate because of its side effects, and it wasn't always successful.

"I took that for six months, and it didn't work," McLoyd says. "I agreed to go another six months, and it still didn't work. It was grueling."

A few years later, new, more effective and easier to take medications were approved in 2013 and 2014. McLoyd tried treatment again with the one of the new drugs, Sovaldi.

"I had no side effects and I soon cleared the hepatitis C," he says.

At 70, McLoyd is now retired. He had a serious stroke a few years ago; he now walks with the assistance of a cane and has some difficulties with memory. But he continues serving as a peer educator and tireless advocate.

"People who've heard me talk have told me that it was inspirational for them to have somebody who looked like them and had shared a similar experience, to be out and to be willing to talk," he said.

"I know that there's still a lot of work to do, especially in terms of normalizing HIV. It's more normalized than it was 20 years ago, but the work needs to continue." —**RICK GUASCO**

JOHN GRESS

Understanding your hepatitis C results

What do they mean? **Andrew Reynolds**, our hep C editor, explains

If you haven't tested for hepatitis C (HCV) yet, you should consider it. The American Association for the Study of Liver Disease (AASLD) recommends that everyone age 18 and older get tested for HCV at least once in their life. If you test negative and have no other ongoing factors that could lead to acquiring HCV, then you're done. If you test positive, you can work to get treated and cured.

Hepatitis C test results can be confusing as it's not just a simple matter of testing positive or testing negative. By comparison HIV tests are pretty straightforward: If you test negative for the HIV antibody test, then you do not have HIV. If you test positive for HIV antibodies, you do have HIV. There's always a risk of a false positive and there are times when a person could have so recently acquired the virus that their antibody test comes back negative, but for the most part a negative HIV antibody test means you don't have HIV, while a positive HIV antibody test means that you do.

Hepatitis C testing is a little more complicated. It's a two-step process. Step one is an antibody test. If the test comes back HCV antibody-positive, then a person will get a confirmatory test that looks directly for the hepatitis C virus. There are situations where an individual could be antibody-positive but negative for the virus. There can be situations where a person is antibody-negative but positive for the virus. And there are situations where a person is antibody-negative and viral load-negative or antibody-positive and viral load-positive.

Take this article with you when you get tested for hepatitis C and get your results. It will provide you with the various options for test results, what those results mean and what your next steps should be based on your results.

How do they test for hepatitis C?

Testing for hepatitis C is a two-step process. The first test is an antibody test. If it comes back negative, then no further testing is needed. If the antibody test does come back positive, then a second test—an HCV viral load (an RNA test)—is done to check for infection.

The most important thing to remember is this: If you test positive on the HCV antibody test, you must confirm it with a viral load test. If you are told "you are positive for HCV because you tested positive for the antibody test," then you should follow up by asking, *Are you sure? Did you confirm that antibody result with an HCV viral load?* If they didn't do a viral load test, ask for one.

Why are there two types of tests?

When you acquire HCV, your body will make antibodies in an effort to fight it off. These antibodies will be with you for the rest of your life, but it doesn't necessarily mean you actually have HCV. Some people clear the virus naturally on their own within the first 6 months of infection. This happens in about 25% (1 in 4) of people. When someone clears the virus, the HCV antibodies will remain but there's no virus damaging the liver.

Testing for HCV reinfection

If you tested positive for hepatitis C antibodies and are among the 25% of people who clear the virus, or if you were treated and cured of hepatitis C, you will always test antibody-positive. From this point forward, if you want to know if you have hepatitis C or not, you will need to get an HCV RNA (viral load) test. An antibody test alone won't tell you if you have hepatitis C or not. You need a test that looks directly for the virus (viral load).

When you go for hepatitis C testing and if you have a history of a positive antibody test, make sure you inform the clinic or testing site. They may still run an antibody test, but they'll also know to run a viral load test in order to give you an accurate result.

Conclusions

Everyone should test for HCV at least once in their life. If a person uses drugs, is sexually active while living with HIV or has other HCV risk factors, they should test at least once per year. Knowing your HCV status will allow you to know if you have it or not, and if you do, you can get treated and cured.

HCV antibody result	HCV viral load result	What it means…
NEGATIVE	NEGATIVE	**You do not have HCV.**
POSITIVE	NEGATIVE	**You do not have HCV;** you have cleared the virus either through cure or naturally cleared the virus on your own.
POSITIVE	POSITIVE	**You have chronic HCV.**
NEGATIVE	POSITIVE	**You have early HCV infection** and haven't had time (six months) to make antibodies yet.

What you need to know

HCV antibody testing:

- The HCV antibody test will come up either negative or positive (sometimes called "reactive").
- There is a rapid test for HCV antibodies. It is a finger stick (a drop of whole blood can be taken); results are ready in 20 minutes.
- If you test HCV antibody-negative, then you don't have HCV; there is no need for a viral load test.
- In rare cases, a person can have no HCV antibodies but a detectable viral load. In these situations, a person has very recently acquired HCV and their body hasn't had time to produce antibodies.
- There is a period of time, called the "window period," in which your body needs to make antibodies. The window period for HCV is 6 months. It can happen sooner, but if you're concerned about a specific event, like sharing a syringe, but you test antibody-negative 6 months afterward, you did not acquire HCV.

HCV viral load testing:

- If you test HCV antibody-positive, the next step is to get a viral load test to confirm if you have chronic HCV.
- If you are HCV antibody-positive, but viral load-negative, then you've cleared the virus.
- If you are HCV antibody-positive and HCV viral load-positive, then you have HCV until you get treated and cured.
- HCV viral load testing is done for people who cleared the virus on their own or through cure to test for reinfection.

Hepatitis C reinfection: You mean I can get this again?

Everything you ever wanted to know about hepatitis reinfection

BY **ANDREW REYNOLDS**

You can get hepatitis C (HCV) more than once. Let's start with that.

This is weird and can be a little confusing, and it is a significant concern for people who have been cured of HCV. To date we haven't done a great job of explaining this to people, and we haven't provided them with the knowledge and tools to prevent it from happening. This article will give you an overview of what HCV reinfection is, how common it is and ways to prevent it from happening.

What is hepatitis C reinfection?

Hepatitis C reinfection is when a person has a detectable virus after they have been either cured through treatment or have spontaneously cleared the virus on their own.

Background

In many cases, when you are infected by a virus, your body will create antibodies and develop immunity that will fight off any future infection. This is true for hepatitis A (HAV) and hepatitis B (HBV). In other words, if you get it once you're not going to get it again.

This is not the case with hepatitis C: With HCV you can get it and your body will clear it on its own or you can go get treated and cured, but then you can get it again.

About one in four people (25%) clear HCV in the first six months of infection. They will always have HCV antibodies, but there is no longer any virus that will damage their liver. Some people clear the virus multiple times but there's always a chance that the next time will lead to a chronic infection.

This is different from hepatitis A or B. If you get HAV, you will feel very sick for a while, eventually clear the virus and feel better, and then you will never get it again. You will have antibodies that will protect you from further HAV infection no matter how many times you may get exposed to it. The same applies with HBV: People who acquired hepatitis B and clear it will never get it again. (Note: Some people will keep HBV chronically. For more information, **SEE** "Hepatitis B: An Overview" on page 36.) These differences from HCV can lead to confusion: If antibodies can protect an individual from HAV or HBV, it's easy to think that the same is true for HCV. *It's not.*

Fortunately, HCV reinfection is not inevitable. Overall, the risk of HCV reinfection is quite low: For people who don't have any new risks for infection, especially drug use or condomless sex and HIV, the rate of reinfection is so low that there is little to nothing to be concerned about. For people with no ongoing vulnerabilities to HCV, once they are cured there is no need to retest and no need to worry about reinfection.

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Hepatitis C reinfection in people who use drugs

Hepatitis C reinfection can and does occur among people who use drugs but it's not as common as many people assume it to be. Some studies show higher rates of reinfection in areas where there are many people living with hepatitis C and have limited access to harm reduction supplies such as sterile injecting equipment; other studies have found rates of reinfection to be low. Overall reinfection rates are lower than the rates of first-time infections. So, people who get hep C once and then clear it or are cured of it are less likely to get reinfected again.

We also know that if more people are treated with curative hep C treatment they are less likely to come into contact with it if they share a syringe or other injecting equipment. We know that with U=U for HIV prevention, people with an undetectable HIV viral load *do not* transmit the virus to their sexual partners. For hepatitis C, U *absolutely equals* U: If there is no virus, there is no transmission. Thus, access to HCV treatment and cure is an essential component of HCV prevention and, by extension, means less reinfection over the long run.

Hepatitis C reinfection in MSM living with HIV

Sexual transmission of HCV is rare overall, but in people living with HIV it can be much greater. This is still not fully understood, but we know that with HIV, certain sexual practices may be associated with a greater chance of HCV transmission. This includes, but is not limited to, condomless receptive anal sex, fisting and sex toy play, group sex and drug use with sex. Similarly, certain sexually transmitted infections (STIs) may play a role in making someone more vulnerable to sexually transmitted HCV: A herpes sore or syphilis chancre can provide the opening for HCV to enter. Also, HCV has been found in the semen and non-bloody rectal fluids of men living with HIV. All these combined lead to increased risk of HCV transmission.

Research has also shown high rates of reinfection in men who have sex with men (MSM) who are living with HIV. Preventative measures like condoms, gloves for fisting and routinely testing for STIs can reduce the chances for reinfection; routinely testing for HCV is recommended. Getting at least one HCV RNA test (hepatitis viral load) a year is recommended, but feel free to test more frequently if you have concerns about reinfection. The sooner a person learns they have HCV, the sooner they can get treated and cured.

Follow-up HCV testing after a cure or spontaneous clearance

If you have been cured of HCV or are one of the 25% of people who clear it naturally and you don't have any factors that could lead to reinfection—primarily substance use or condomless sex while living with HIV—then you don't need to continue to test for reinfection.

Individuals who use drugs or are living with HIV and are sexually active should keep testing for HCV. Remember, once you are HCV antibody-positive, you'll always have HCV antibodies, so make sure to inform the test site so that they can run a hepatitis C viral load test to look for infection (**SEE** page 23). An HCV viral load test is recommended at least once per year, but you can test more frequently, especially if you believe you've had an HCV exposure. The sooner you can detect HCV acquisition, the sooner you can get treated and cured. Talk with your medical provider or an HCV test counselor to discuss how frequently you should test.

HCV treatment for people who get reinfected

The good news is that people who are reinfected with HCV can be treated and cured at the same high rates as those who get HCV the first time. The recommendations for treating HCV reinfection are the same as treating the first infection. Although there are no medical reasons to delay treatment for HCV reinfection, there may be some barriers around insurance coverage of multiple treatments for the same person. In cases like these, medical providers and benefits navigators can help work through such challenges and find alternatives to getting treatment covered.

Conclusions

Acquiring hepatitis C should not be viewed as a failure. We should accept and normalize HCV reinfection as a standard part of our lives: We are not testing and treating everyone who is vulnerable to HCV, so as a result, there are millions of people living with HCV who don't know it. Consequently, HCV transmission occurs without people knowing it. The more we test and treat, the fewer infections—both new and repeated—will happen.

SEE *Preventing HCV for People who Use Drugs*, including a step-by-step guide to handling and cleaning works, online. **GO TO** positivelyaware.com. Also check out the Harm Reduction Coalition's "Getting Off Right" booklet for more safe injecting info; **GO TO** bit.ly/4ck0kBO.

Two examples of HCV reinfection

JOE SHARED a syringe with a friend who was living with hepatitis C, and he tested positive for both the antibodies and viral load. He waited six months to see if he is chronically infected. His viral load test result is negative, meaning he is among the 25% of people who clear the virus on their own. Recently, Joe shared a cooker that had blood with hep C in it and he became infected again. Again, he waits to see if he's chronically infected; his follow-up test indicates he is positive for the virus. Joe was reinfected with hepatitis C and will only be able to clear the virus now through treatment and cure.

A YEAR AGO, Amy shared a cooker with a friend living with HCV, and acquired the virus. She waits six months to see if she is chronically infected and her test results tell her that she is. She goes on treatment and gets cured. One year later she shares a syringe with a friend, and her HCV viral load test is positive. She waits six months to see if she's chronically infected again, and when she tests her viral load test comes back negative. Amy was reinfected with hepatitis C but cleared the virus on her own without the need for treatment.

Preventing HCV reinfection for people who use drugs

Although it might seem that substance use and HCV go hand in hand, HCV can be prevented and so too can reinfection. The key is having access to the tools to stay HCV-negative—new and unused injection equipment, new pipes and smoking equipment—and the knowledge of certain practices that can help a person stay negative.

The first and most effective way to prevent both primary HCV infection and reinfection is to not use drugs. This is easier said than done and quitting is not always easy. For people who use opioids, exploring medications like burprenorphine or methadone to prevent painful withdrawal symptoms can be an option. Drug treatment programs, therapy and other behavioral interventions may also be effective. It can sometimes be hard to get into a treatment program; there may not be one that is a good fit for you, or you may not be ready to stop right now.

In the absence of stopping using drugs, there are harm reduction interventions that can be used to reduce or eliminate a chance of reinfection. Accessing new injecting and smoking equipment and never sharing these items is essential to preventing HCV.

Hepatitis C treatment for people who have both HIV and HCV

BY **ANDREW REYNOLDS**

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 coinfected 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 coinfected.

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 coinfected

Everyone with HCV should get treated, regardless of the amount of liver damage; persons who are coinfected with HCV and HIV are no exception. In fact, AASLD/IDSA Guidance states that people who are coinfected 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 coinfected 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 coinfected persons

As soon as possible. Coinfected 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 reinfection 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 reinfection.

After you've been cured, and if you have ongoing risk that could lead to reinfection, 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 coinfection. 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.

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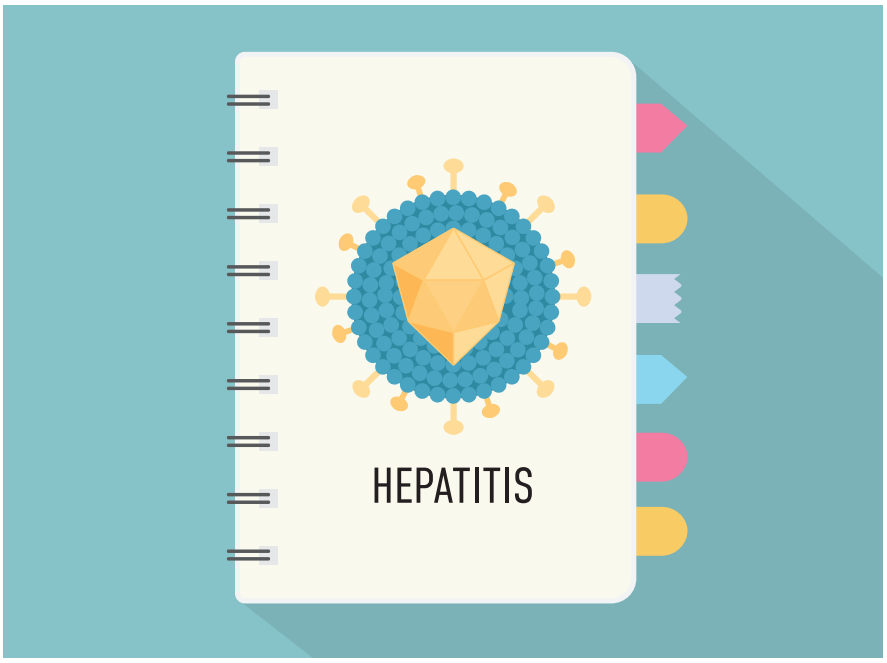

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HOW TO USE THIS GUIDE

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 36**.

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

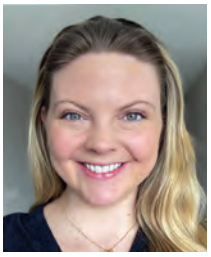
This section provides information about the variety of known and potential drug interactions. Again, it's not an exhaustive list. You can find a complete list in the package insert, but you should also talk with your medical provider and/or pharmacist about any medications (including over-the-counter 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 38** for more information.



SPECIAL THANKS TO KAITLYN RUEVE, PHARMD, BCPS, AAHIVP, for reviewing the 2024 POSITIVELY AWARE Hepatitis Drug Guide.
Dr. Rueve is an HIV clinical pharmacist at the LifeCare Clinic at Methodist Hospital and IU Health Physicians Infectious Disease Clinic at University Hospital in Indianapolis, IN. Dr. Rueve graduated from the University of Mississippi (Ole Miss) in 2018. After pharmacy school, she completed a two-year residency at IU Health, with her second year specializing in pharmacy administration. In addition to her clinical role, she is a preceptor for pharmacy students and residents, and serves on the "hub team" for IUPUI's HCV 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, as well as other diseases and 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 enters 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 by blood—**when blood containing HCV gets into you**. The main way it is transmitted today is through the sharing of injection equipment: syringes, cookers, cotton, and water. If blood containing HCV 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 a person has an ongoing vulnerability to HCV, such as injection drug use, they should test for HCV more routinely, at least once a 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 a positive 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 HCV, 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 are exposed again and re-acquire the virus.

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 as 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

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against all types of HCV tough. There have been attempts in the past to come up 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 PrEP or PEP for hepatitis C?

There is PrEP and PEP for HIV, where people who do not have HIV can take medications before (pre-exposure prophylaxis or "PrEP") or after (post-exposure prophylaxis or "PEP") to prevent acquisition of the virus. There is even a PEP for hepatitis B. Unfortunately, **there is no PrEP or PEP for HCV**. If you do not have HCV and are concerned about a potential exposure to HCV, you should get tested to see whether you have acquired HCV. 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. **Establish open, clear and honest lines of communication between you and your physician.**

Here are a few tips to help 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 is free

According to the Hepatitis Plan, "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

400 mg sofosbuvir/100 mg velpatasvir (SOF/VEL)

DRUG CLASS

sofosbuvir: NS5B polymerase inhibitor
velpatasvir: NS5A inhibitor

GENOTYPE

1 2 3 4 5 6

MANUFACTURER

Brand: **Gilead Sciences**
Authorized generic:
Asegua Therapeutics LLC

AWP

Epclusa (all available doses):
$32,040 / month
Authorized generic (400/100 mg tablets):
$10,286 / month

DOSE

One tablet once daily with or without food for adults and adolescents weighing 66 pounds or greater (≥30 kg). Lower-dose tablets and pellets are available for pediatric patients age 3 and older (≥3 years of age) and weighing less than 66 pounds (30 kg). Treatment is usually 12 weeks, but recommendations vary depending on genotype, treatment history, cirrhosis status, and presence of NS5A polymorphisms (genetic mutations that make Epclusa less effective). For some people, treatment may require the addition of ribavirin and/or a longer treatment duration (24 weeks). See treatment duration recommendations at hcvguidelines.org**.**

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

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. Pediatric formulations are currently only available as brand name.

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. People who are pregnant or 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 recreational. 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 (both of which are rarely used today). If taking tenofovir disoproxil fumarate (TDF) with an HIV protease inhibitor, ritonavir, or cobicistat, closely monitor for toxicities, 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. Sofosbuvir-based HCV regimens should be avoided if taking 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.

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 38 for more information and consult your medical provider.

Harvoni

ledipasvir/sofosbuvir (LDV/SOF)

DRUG CLASS

ledipasvir: NS5A inhibitor
sofosbuvir: NS5B polymerase inhibitor

GENOTYPE

1 4 5 6

MANUFACTURER

Brand: **Gilead Sciences**
Authorized generic:
Asegua Therapeutics LLC

AWP

Harvoni (all available doses):
$40,500 / month
Authorized generic (400/90 mg tablets):
$15,429 / month

DOSE

One tablet once daily with or without food for adults and adolescents weighing 77 pounds or more (≥35 kg). Lower-dose tablets and pellets are available for pediatric patients aged 3 years and older and weighing less than 77 pounds. Treatment is usually 12 weeks, but recommendations vary depending on genotype, treatment history, cirrhosis status, and baseline HCV RNA or viral load. For some people, treatment may require the addition of ribavirin and/or a longer duration of therapy (24 weeks). In some cases, an 8-week treatment duration is possible. See treatment duration recommendations at hcvguidelines.org**.**

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

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. Pediatric formulations are currently only available as brand name.

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 recreational. 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. If taking tenofovir disoproxil fumarate (TDF) with an HIV protease inhibitor, ritonavir, or cobicistat, closely monitor for toxicities, 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. Sofosbuvir-based HCV regimens should be avoided if taking 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 prescribed.

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.

For more information, GO TO hcvguidelines.org.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Harvoni, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could 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 38** for more information and consult your medical provider.

Zepatier

50 mg elbasvir/100 mg grazoprevir (EBR/GZR)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP
elbasvir: NS5A inhibitor **grazoprevir:** NS3/4A protease inhibitor	1 4	**Merck**	Zepatier 50/100 mg tablets: **$9,360 / month**

DOSE

One tablet once daily with or without food for adults and children aged 12 and older and weighing 66 pounds or more (≥30 kg). The typical duration of therapy is 12 weeks, but recommendations vary depending on genotype, treatment history, cirrhosis status, presence of HIV coinfection, and presence of NS5A polymorphisms (genetic mutations that may make Zepatier less effective). See treatment duration recommendations at hcvguidelines.org**.**

Take missed dose as soon as possible unless it is less than 12 hours before 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 or without cirrhosis. Nausea, insomnia, and diarrhea have also been reported. Zepatier has not been studied in people who are pregnant or nursing, so its impact on fetal development or nursing babies is unknown.

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 recreational. 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 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 when it was released, but it is no longer used as much as the other newer treatments are preferred due to potential need for an additional lab test 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 should be prescribed an alternate regimen. 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 (cannot be taken) 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 Zepatier, 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 38** **for more information and consult your medical provider.**

Mavyret

glecaprevir/pibrentasvir (GLE/PIB)

DRUG CLASS

glecaprevir: NS3/4A protease inhibitor
pibrentasvir: NS5A inhibitor

GENOTYPE

1 2 3 4 5 6

MANUFACTURER

AbbVie

AWP

Mavyret 100/40 mg tablets:
$15,840 / month
Mavyret pack 50/20 mg pellets (pediatric):
$10,184–$20,367 / month based on dose required

DOSE

Three tablets once daily with food for adults and adolescents aged 12 years and up and weighing 99 pounds or more (≥45 kg). It is important to take all three tablets at the same time—do not separate throughout the day. Each tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir for a total daily dose of 300 mg/120 mg. Lower-dose pellets are available for pediatric patients aged 3 and up and weighing less than 99 pounds. Treatment is usually 8 weeks, but recommendations vary depending on genotype, treatment history, cirrhosis status, and presence of HIV coinfection. See treatment duration recommendations at hcvguidelines.org.

Take missed dose as soon as possible unless it is less than 12 hours before 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 coinfection, history of kidney transplant, or adolescence. There are no serious lab abnormalities expected. Mavyret has not been studied in in people who are pregnant or nursing, 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 recreational. 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 a booster (ritonavir or cobicistat), 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 (specifically doses greater than 20 mcg per day) 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 pangenotypic (active against all 6 genotypes) regimen that cures most people in as few as 8 weeks of treatment. Some people may need to take Mavyret for 12 or 16 weeks, depending on HIV status, previous treatment experience, and presence of cirrhosis. The overall cure rate (sustained virologic response, or SVR) across all genotypes was 97.5%.

Mavyret can be used in several special populations. 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. It is also approved for children aged 3 and older.

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 Mavyret, 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 38** **for more information and consult your medical provider.**

Vosevi

400 mg sofosbuvir/100 mg velpatasvir/100 mg voxilaprevir (SOF/VEL/VOX)

DRUG CLASS

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

GENOTYPE

1 2 3 4 5 6

MANUFACTURER

Gilead Sciences

AWP

Vosevi 400/100/100 mg tablets:
$32,040 / month

DOSE

For adults: one tablet once daily with food. Treatment is usually 12 weeks, but recommendations vary depending on genotype, treatment history, and cirrhosis status. For some patients, treatment may require the addition of ribavirin and/or a longer duration of therapy (24 weeks). See treatment duration recommendations at hcvguidelines.org.

Take missed dose as soon as possible unless it is less than 12 hours before 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. 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 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 recreational. 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; 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. Sofosbuvir-based HCV regimens should be avoided if taking 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

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 coinfection, it may be considered if drug interactions are also assessed. Vosevi is currently only approved for use in adults.

For more information, GO TO hcvguidelines.org.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Vosevi, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could 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 38 for more information and consult your medical provider.

ribavirin

ribavirin (RBV)

DRUG CLASS	GENOTYPE	MANUFACTURER	AWP (BASED ON 600 – 1,200 MG / DAY DOSING)
Nucleoside analog	1 2 3 4 5 6	Generic capsules/tablets: **Manufacturers vary**	Generic 200 mg tablet: **$744–$1,489 / month** Generic 200 mg capsule: **$858–$1,715 / 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 and may be adjusted based on renal function. Ribavirin is now only available as a generic tablet or capsule; other products have been discontinued. It must be taken with food. The capsules should not be opened, crushed, chewed, or broken. 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.

Take missed dose as soon as possible unless it is less than 6 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

There are very serious potential side effects associated with ribavirin: anemia and birth defects, miscarriage and 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 people. People who are pregnant or trying to become pregnant, and males whose partners are pregnant, should not take ribavirin. People of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. It is unknown if ribavirin passes through breast milk or the impact it could have on breast- or chestfeeding 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 or drug resistance. 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.

DOSAGE INTERVAL ADJUSTMENT for adults with altered creatinine clearance (mL/min)

Creatinine clearance (mL/min)	Dose adjustment (capsules)	Dose adjustment (tablets)
50 or greater	No dosage adjustment necessary	No dosage adjustment necessary
30 to 50	Contraindicated	Alternate 200 mg and 400 mg every other day
Less than 30	Contraindicated	200 mg once daily
ESRD on HD*	Contraindicated	200 mg once daily

*End stage renal disease on hemodialysis

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 to 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 $3,800 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
caringambassadors.org/hepatitis-c/
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
help4hep.org
National hepatitis C support line staffed by peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9 am–9pm ET.

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 magazine
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.

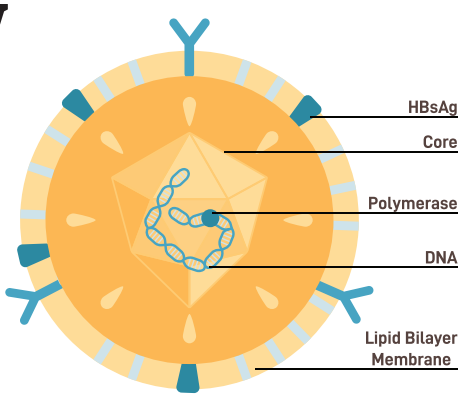
infohep
infohep.org
Based in the U.K., this is an excellent resource for viral hepatitis news and education.

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 B—An overview

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



Hepatitis B

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:

We have now moved into a universal HBV screening guideline recommendation. This is a very simple way to ensure that everyone is tested and offered a vaccine as indicated. The CDC offers a summary of the 2023 HBV screening and testing recommendations:

Summary of 2023 HBV screening and testing recommendations

- Screen all adults aged 18 years and older at least once in their lifetime using a triple panel test
- Screen pregnant people for hepatitis B surface antigen (HBsAg) during each pregnancy regardless of vaccination status and history of testing
- Expand periodic risk-based testing to include people incarcerated, people with a history of sexually transmitted infections or multiple sex partners, and people with hepatitis C virus infection
- Test anyone who requests HBV testing regardless of disclosure of risk

For our purposes here, don't worry about understanding what "triple panel test" or "hepatitis B surface antigen" means: Your provider will explain to you when you get the test. The most important thing is to make sure you get tested; ask for a test to make sure.

In addition to these universal recommendations, the CDC recommends testing people at risk of infection, regardless of age and testing history:

- People with a history of sexually transmitted infections or multiple sex partners
- People with hepatitis C infection or a history of hepatitis C virus infection
- People incarcerated or formerly incarcerated in a jail, prison, or other detention setting
- Infants born to HBsAg-positive people
- People born in regions with HBV infection prevalence of ≥2%
- U.S.-born people not vaccinated as infants whose parents were born in geographic regions with HBsAg prevalence of >8%
- People who inject drugs or have a history of injection drug use
- People with HIV infection
- Men who have sex with men
- Household contact or former household contacts of people with known HBV infection
- Needle-sharing or sexual contacts of people with known HBV infection
- People on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis
- People with elevated liver enzymes

SOURCE: CENTERS FOR DISEASE CONTROL AND PREVENTION (cdc.gov/hepatitis)

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:

As with their testing and screening recommendations, the CDC is keeping it simple:

"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. >>

ISTOCK

>> 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

Additional 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.

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 coinfected 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 37).

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

Nucleoside reverse transcriptase inhibitor (NRTI)

MANUFACTURER

Bristol-Myers Squibb

AWP

Baraclude:
0.5 mg and 1 mg tablets: **$1,647 / month**
0.05 mg/mL solution (equivalent of 0.5–1 mg daily): **$1,647–$3,294 / month**
Generic: 0.5 mg and 1 mg tablets: **$1,332–1,800 / month**

DOSE

For adults (age 16 years and older) who are treatment-naïve (no previous hepatitis B therapy) with no drug resistance, take one 0.5 mg tablet once daily. If there is drug resistance to lamivudine (Epivir) or telbivudine (Tyzeka, discontinued since December 2016), take 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 Baraclude).

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 recreational, 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 coinfected 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 coinfection 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 38** 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 INTERVAL ADJUSTMENT for adults with altered creatinine clearance (mL/min)

Creatinine clearance (mL/min)	Dose adjustment (Treatment-naive)	Dose adjustment (Lamivudine-refractory, lamivudine/telbivudine resistant, or decompensated cirrhosis)
50 or greater	No dosage adjustment necessary	No dosage adjustment necessary
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

25 mg tenofovir alafenamide (TAF)

DRUG CLASS
Nucleoside reverse transcriptase inhibitor (NRTI)

MANUFACTURER
Gilead Sciences

AWP
Vemlidy 25 mg tablets: **$1,730 / month**

DOSE

One tablet once per day with food for adults and children aged 6 years and older weighing at least 55 pounds (25 kg).

Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Never double your dose.

No dose adjustment required for those with a creatinine clearance (CrCl) of at least 15 mL/min (measurement of kidney function), as well as those below 15 mL/min who are receiving chronic hemodialysis (HD). For people on chronic hemodialysis, take tablet once daily and administer after completion of hemodialysis on days of HD treatment.

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, weakness, nausea and back pain. Other, more rarely reported, side effects include rash, excessive gas, and generalized pain and achiness. Vemlidy may lead to decreases in bone mineral density (BMD); patients should be monitored for osteoporosis or osteopenia. 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 recreational, before starting this regimen. Report any changes in your medications as they happen. Because Vemlidy (TAF) 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, Temixys 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. Vemildy and Viread are also HIV medications.

Before starting Vemlidy, you should be tested for HIV. If you are coinfected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent the development of HIV resistance mutations. In people with HBV/HIV coinfection, 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 38** for more information and consult your medical provider. For individuals with HBV/HCV coinfection, 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.

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).

Viread

tenofovir disoproxil fumarate (TDF)

DRUG CLASS

Nucleoside reverse transcriptase inhibitor (NRTI)

MANUFACTURER

Gilead Sciences

AWP

Viread:
300 mg tablets: **$1,504 / month**
250 mg, 200 mg and 150 mg pediatric tablets: **$1,394 / month**
40 mg/g powder (pediatric): **$820–$3,076 / month based on dose required**
Generic: 300 mg tablets: **$110–1,216 / month**

DOSE

For adults, one tablet once per day, with or without food. Also available as an oral powder and as smaller pediatric tablets for children aged 2 years 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.

Vemlidy should be avoided in individuals with existing chronic kidney disease, but if use cannot be avoided, dose adjustments are needed (SEE chart below).

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Viread is a well-tolerated with minimal side effects. Side effects may include diarrhea, nausea, weakness, headache, depression, abdominal pain, rash, excessive gas, and generalized pain and achiness. 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; its use may lead to 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. Enlarged liver or fatty liver may occur. Signs and symptoms 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 recreational, 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, the two medications cannot be taken together. Similarly, Viread cannot be taken with any of the following HIV combination medications: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Genvoya, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, Temixys 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 is related to Vemlidy. Viread and Vemlidy are also HIV medications. Before starting Viread, you should be tested for HIV. If you are coinfected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent the development of HIV resistance mutations in the HIV. In people with HBV/HIV coinfection, 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 38** for more information and consult your medical provider. For individuals with HBV/HCV coinfection, 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 does not require dose adjustment for hepatic (liver) impairment.

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	No dosage adjustment necessary	Every 48 hours or 150 mg once daily	Every 72–96 hours (twice weekly)	Every 7 days or after approximately 12 hours of dialysis; doses are to be taken after dialysis

*Has not been studied; avoid use if alternatives are available

Pegasys

peginterferon alfa-2a (PEG-IFN)

DRUG CLASS
Interferon-alfa

MANUFACTURER
Genentech

AWP
Pegasys:
180 mcg/mL solution: **$1,336 / week**
180 mcg/0.5 mL prefilled syringe: **$1,336 / week**

DOSE

For adults: 180 mcg injected subcutaneously once per week for 48 weeks. Dose should be given in the abdomen or thigh. Injection sites should be rotated. There are no food restrictions.

Dose should be given on the same day and at approximately the same time each week. 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.

Dose adjustments are needed for individuals with kidney disease (SEE chart below) and those with significant side effects. Pegasys is also available for pediatric patients aged 3 years and older; dosing is individualized based on body surface area.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Interferon has many potential and possibly serious side effects including: fatigue, headaches, nausea, chills, insomnia, anemia, pyrexia (fever), loss of appetite, rash, myalgia (muscle pain), neutropenia, 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 (low white blood cell count) and thrombocytopenia (low platelet count). Psychiatric/emotional side effects are possible. Interferon has been associated with irritability, 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 recreational, 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, and is currently the only effective treatment for individuals co-infected with Hepatitis D (HDV). That said, it is rarely used for HBV mono-infection, 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 oral medications are easier to take 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.

DOSAGE INTERVAL ADJUSTMENT for adults with altered creatinine clearance (mL/min)

Creatinine clearance (mL/min)	Dose adjustment
Greater than 30	No dosage adjustment necessary
Less than 30 (<30) mL/min	135 mcg once weekly
End stage renal disease requiring hemodialysis	135 mcg once weekly*

NOTES: Monitor for toxicity. If severe reactions or laboratory abnormalities occur, may reduce dose to 90 mcg once weekly until side effects resolve; if intolerance persists, discontinue.

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.

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.org
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.

Medicine Assistance Tool
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-b
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.

Centers for Disease Control and Prevention
cdc.gov/hepatitis-b/
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

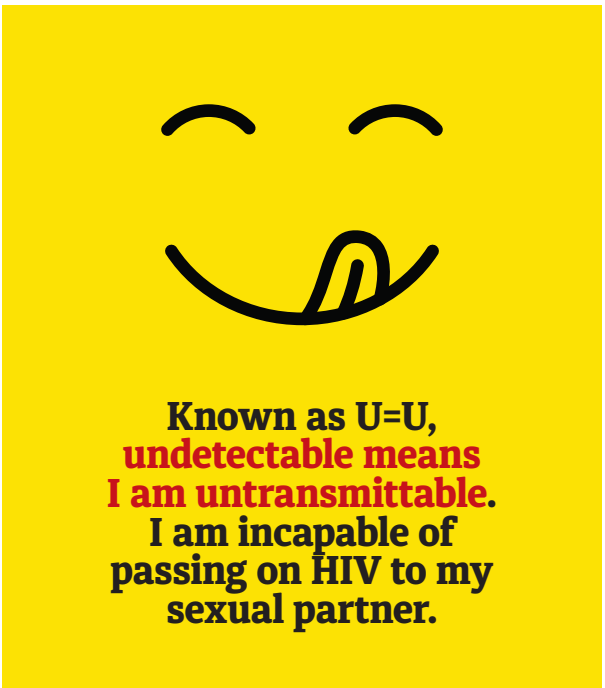
What's a girl gotta do to get some?

Sexual health. Wait, don't run away yet. You probably read that and immediately thought about sexually transmitted infections and having to get tested. The intrusiveness of the questions about "partners and practices." The invasiveness of swabs and urine specimen cups. Stay with me though. What if I told you the idea of sexual health could be more? That it should in fact be *more*?

By most accounts, I am at a disadvantage when it comes to sexual health. If I listened to online comments and conversations from peers and strangers alike, one would think I am "toxic" and should wear a sign on my body somewhere that I am a walking "risk factor" and rendered asexual. Supposedly, HIV makes me "dirty," whatever the hell that means. Sadly, bias among health care providers means they don't ask me sexual health questions because they assume I'm just not doing it. In actuality, my decision to live well with my diagnosis means none of this is true.

Adherence to my HIV medication means my virus is suppressed and my HIV is controlled to an undetectable state, so if I were to be sexually active, I can't pass the virus on to partners. If I wanted to get pregnant and have a baby, undetectable status means my baby can be born free from HIV. Known as U=U, *undetectable* means I am *untransmittable*. I am incapable of passing on HIV to my sexual partner. Regular health care appointments to make sure my HIV is managed mean that I can get tested more frequently for other STIs. All of this means if I am in care and stay in care, all my parts and pieces work and are overall healthy. So, what's a girl got to do to get some? And by some, I mean comprehensive sexual health care—of course.

That's where the *more* I was talking about comes in. All too often we view sexual health through the limited lens of sexually transmitted infections, treatment of STIs or unplanned pregnancy. Health care isn't helped by this narrow view. When people show up for care, clinics often treat them for the STI, but they don't have the interventional—and intentional—conversation that's needed for it to not happen again in six months. When women present for gynecological care, it tends to be only in the context of pregnancy and prevention, or the health of the vaginal microbiome or changes related to menopause. For men, outside of STI testing, it's usually prostate health and erectile function. The 5P's approach—partners, practices, protection from STIs, past history of STIs and pregnancy intention—that is the trained approach. So, what's missing?



Conversations about pleasure and mental health considerations for a healthy sex life are missing. Healthy sex doesn't only mean free from infections, it also means being mentally free from shame, knowledgeable enough to be able to safely negotiate sex, and feeling empowered to have the type of sex you want to have. The *why* of sex and the *fun* of sex are often missing from conversations with clinicians. Lest we overlook it, transactional sex—or sex for basic needs like shelter, food, or housing—is a part of some folks' sex lives, and that should be acknowledged and addressed as part of staying healthy, too. Education about all the things I've talked about has to become the new normal.

A shift in thinking and education for both clinicians and for the public needs to happen—inclusive of talking to people living with HIV about reducing the *internal* stigma that contributes to shame and loss of connection to others. By shifting the paradigm around what sex and HIV positivity is, we can start to take the pressure and onus from people living with HIV to *always* having to be the one who initiates these conversations. That's exhausting, and frankly, mentally detrimental.

Every person deserves connection and affection. I am not toxic and I'm certainly not dirty. I am a healthy, attractive fifty-something-year-old single woman. My heart didn't stop beating and my hormones didn't cease to hormone when I got HIV. I enjoy life. I want a boyfriend/partner/husband. I want a loving, full relationship with affection and physical closeness. *I want to have to sex.* I know—it's shocking. I often want to tell people to calm their moral panic—*Hey, lady. Calm your tits!*—when I say that out loud and see the judgment take over their face and body language. Not only do I want these things, I deserve them. So does everyone else living with HIV. Shift the paradigm. Let's talk about pleasure.

Be well. You matter.

BRIDGETTE PICOU, LVN, ACLPN, is a licensed vocational and certified AIDS Care Nurse in Palm Springs, California. She works for The Well Project-HIV and Women as their stakeholder liaison. Bridgette is a director at large for ANAC (the Association of Nurses in AIDS Care), and a sitting member of the board of directors for HIV & Aging Research Project-Palm Springs (HARP-PS). Bridgette's goal is to remind people that there are lives being lived behind a three- or four-letter acronym.

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