POSITIVELY AWARE
JULY+AUGUST 2025

10 THINGS TO KNOW ABOUT HEPATITIS C
From testing to treatment

A SAME-DAY APPROACH TO HEPATITIS C CARE
How a Massachusetts clinic integrated its services

BRIDGETTE PICOU
CHANGING HOW WE TALK ABOUT HIV TO CHANGE OUTCOMES

SPECIAL PULL-OUT
HEPATITIS B & C DRUG CHART

JOHN STRYKER, NP administers a rapid hepatitis C test to HIV advocate **TERRY DUDLEY**

THE HEPATITIS DRUG GUIDE

JOHN STRYKER (LEFT) WITH TERRY DUDLEY.

The ABCs of hepatitis

A care provider, a prevention specialist and a pharmacist share their experiences

BY **RICK GUASCO**

Terry Dudley and John Stryker, NP, already knew each other before the cover photo shoot for this issue, PA's annual hepatitis drug guide.

"John is my care provider, so it was actually nice to do the picture with him because we have a really good relationship," Dudley said. He and Stryker both work at Vivent Health + TPAN, the nonprofit HIV/AIDS services organization that publishes POSITIVELY AWARE. Dudley works in the prevention department and Stryker in the agency's clinic. Dudley, who was diagnosed with HIV in 2022, monitors his health, which for him includes getting tested for hepatitis C (HCV) every three to six months.

For the cover, the two demonstrated a rapid HCV test. "It's easy to do," Stryker said. "Testing can be done with a drop of blood or it can be done through a blood draw that's sent to the laboratory. The blood draw that's sent to the lab is generally more accurate because it has a higher sensitivity, but a finger stick is usually easier for most people to do, and it can be done in the field, at events, where you can screen lots of people who may not have a reason to go into their doctor and get screened."

A rapid test only detects the presence of antibodies in the blood. If a rapid test leads to a positive result, a follow-up lab test for hepatitis C viral load will be done to determine if someone has "active" HCV. There are several genotypes (a set of genes that an organism carries) of HCV. "Four or five years ago, we had to choose treatment based on what genotype somebody had," Stryker

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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.

BE GREEN. SHARE OR RECYCLE THIS MAGAZINE.

JUL+AUG 2025 THE HEPATITIS DRUG GUIDE

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THE 2025 PULL-OUT HEPATITIS DRUG CHART

Clearing the air on Trogarzo as an option for highly treatment-experienced people

TO THE EDITOR:

I read with interest the entry on Trogarzo in the 2025 HIV Drug Guide, along with the activist and doctor comments to this entry. While I appreciate POSITIVELY AWARE's recognition of Trogarzo as a key component of the treatment armamentarium for heavily treatment-experienced (HTE) people with HIV (PWH), I have concerns about the way this important medication is portrayed in the comments.

Specifically, the activist's comment that Trogarzo "hasn't really taken off" fails to account for what is, essentially, a rare disease patient population. More to the point, that comment is at odds with actual patient experience. In a survey of people living with multidrug-resistant (MDR) HIV, 87% of participants said they were very satisfied with Trogarzo, 90% reported a very positive experience with Trogarzo administration and 80% noted that having a two-week touchpoint with a healthcare professional helped them adhere to their other HIV medications. Those responses suggest that administering and adhering to Trogarzo therapy is not as laborious as the activist and physician comments imply. Notably, the survey was conducted before FDA approval of the Trogarzo IV push administration. The survey results are consistent with my own observations, as many of the HTE individuals in my practice report similar levels of satisfaction with Trogarzo.

Moreover, my peers and I believe that it's important to have a range of treatment options—including non-oral regimens—for managing MDR HIV. To that end, we're particularly interested in the real-world use of Trogarzo in combination with other injectable therapies such as Sunlenca.

With regard to the comments about the purportedly high cost of Trogarzo, a cost-effectiveness analysis presented at the Academy of Managed Care Pharmacy (ACMP) Nexus 2023 conference found that the addition of Trogarzo to an optimized background regimen (OBR) increased the time PWH spent with undetectable or suppressed virus and extended a patient's quality-adjusted life-years compared to OBR alone. The addition of Trogarzo to OBR was associated with an incremental cost-effectiveness ratio (ICER) of close to $170,000—a number that falls within the Institute for Clinical and Economic Review's Willingness to Pay (WTP) threshold for rare diseases. That determination makes Trogarzo a cost-effective treatment option that can substantially improve outcomes for its target population, according to the authors of the cost-effectiveness analysis.

Importantly, the average wholesale price of Trogarzo ($3,658.80 per box) compares favorably with that of Sunlenca ($23,400 per month), which is also indicated for use in HTE individuals whose HIV regimen is failing.

Physician comments about not prescribing Trogarzo "unless we really, really need to" imply that this is a treatment of last resort. Rather, PWH and providers can feel confident in Trogarzo's effectiveness and safety. In the clinical trial that provided the basis for Trogarzo's FDA approval, 83% of participants achieved a meaningful reduction (i.e., associated with a reduced risk of disease progression) in HIV RNA seven days after the addition of Trogarzo to a failing background regimen, compared to 3% during the trial's control period.

Furthermore, the reported adverse events in that trial were generally consistent with expected events in individuals with advanced HIV/AIDS, according to the FDA's Office of Antimicrobial Products, which described the trial's efficacy and safety data as "evidence that ibalizumab could provide benefit to extensively treated patients with MDR HIV infection and that the benefits likely outweigh the risks" for a population with "limited remaining treatment options."

Trogarzo

The demonstrated efficacy, safety and cost-effectiveness of Trogarzo fills a heretofore unmet medical need for HTE individuals with MDR HIV, a factor that prompted the FDA to designate it an Orphan Drug and to schedule it for Priority Review. Those considerations are important when PWH are faced with limited options. Questioning the value of this important medication undermines the needs of a vulnerable population and the efforts of the physicians committed to their care. I respectfully urge that all future references to Trogarzo in POSITIVELY AWARE more accurately reflect its true value and benefits for eligible people with HIV to ensure it can be appropriately considered by both patients and their healthcare providers.

—PRINCY N. KUMAR, MD, FIDSA, MACP
Professor of Medicine and Microbiology
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ASSOCIATE EDITOR ENID VÁZQUEZ REPLIES:

A concern we've heard over the years is that activist comments in the HIV drug guide—however well-intentioned—may discourage people from taking a medication that may be good for them or make them question a provider's advice. To me, the comment that a drug "hasn't taken off" says exactly what you say and what the page says: Trogarzo is a medication for a small group of people. The activist also pointed out that the cost further limits use around the globe. The doctor's comment about "last resort" to me indicates an expert's concerns about insurance coverage and clinical use (for example, fear of needles or as the doctor said, "it ends up being quite expensive to deliver from a clinical standpoint"). We do not question the value of a drug but provide its pluses and minuses. The limitations of a drug do not negate its value but provide a context for its consideration. We hope we have never allowed an overstatement or something misleading make it into the drug guide. We will be more mindful of how opinions in the HIV drug guide are expressed. This will be an ongoing discussion, especially as we prepare for the 30th annual HIV Drug Guide in 2026. We appreciate your feedback and concerns, Dr. Kumar, and invite our readers to join in The Conversation. To be continued.

EDITOR'S NOTE

Rick Guasco
@rickguasco

Heroic hearts

We are not now that strength which in old days
Moved earth and heaven, that which we are, we are;
One equal temper of heroic hearts,
Made weak by time and fate, but strong in will
To strive, to seek, to find, and not to yield.

—excerpt from the epic poem *Ulysses*, by Alfred, Lord Tennyson, and recited by Dame Judi Dench in a scene from the 2012 James Bond film, *Skyfall*

I'm a sucker for a classic poem, especially when I find personal relevance in it. In *Ulysses*, the legendary king admits that he and his friends are no longer the same young champions whose feats changed the world. But while they're older and weary, at their core, they are still who they've always been—noble, courageous and resolute. It is not in their nature to despair or surrender.

These are trying times. Sometimes it feels like a return to the bad old days, when we worried about the rising numbers of people lost to AIDS and of a presidential administration (more than one) that didn't seem to care about people with HIV.

Many of us who were around for those early battles might feel weary from the decades that have passed. We thought the victories would stay won. But the fight never really ended, even if at times it seemed to let up.

New and old battles are being fought with familiar strategies. Inciting fear, stoking division. Fear of the other has always been a useful tactic. People who are "not like us" have always been demonized and held in suspicion. In previous times there were fears of left-handed people, the Japanese, Jewish people, the Irish and Italian immigrants. Then it was gay men and people of color. Today, it's immigrants, people who "sound foreign," people of color (again, *still*) and of LGBTQ+ people with a heightened emphasis on transgender and nonbinary folk.

I think it's human nature for people to latch onto the differences. They fear what—and *who*—is different. If it's outside of their experience, then it's unknown, alien. Some people are fascinated though by what makes us different. More often than not, I'm intrigued by the differences. I want to understand what the differences are and discover that maybe they're not always so different. The people who fear us (and even hate us) want us to not only fear them, but for us to also be suspicious of each other.

"People of color have always been scapegoated as 'the other,'" says my colleague Terry Dudley, an HIV prevention specialist at Vivent Health + TPAN, publisher of POSITIVELY AWARE. "But at our core, most people are the same. We have a respect for life, we want to be treated with dignity while striving for a better life."

Terry, along with John Stryker, a nurse practitioner at Vivent Health + TPAN, appear on the cover of this issue, PA's annual hepatitis drug guide. Terry was diagnosed with HIV in 2022 and monitors his health, which for him means getting tested for hepatitis C (HCV) every three to six months. Working in our health center, John is often the one who administers the tests. Testing is fairly quick and easy, John says. So is HCV treatment, adds Jake Sepka, PharmD, one of the pharmacists here. These days, the course of hepatitis C treatment run eight to 12 weeks, usually leading to being cured. "It is a cure in a bottle," Jake said, holding up a bottle of medication in between takes during a setup of the shoot. (Read the behind-the-scenes story of the shoot, starting on page 2.)

While HCV has been curable for over a decade, the Centers for Disease Control and Prevention (CDC) estimates that of the people diagnosed with hepatitis C, 34% have been cured—among people ages 20–39 years, the rate is 24%. Among the reasons for these low rates, the CDC says, are the lack of an on-site pharmacy and team-driven patient-centric care. A clinic in Massachusetts is tackling these obstacles with its own same-day, test-to-treatment approach that integrates a number of services, reports contributing writer Larry Buhl (page 14).

The hepatitis drug guide starts on page 17 and covers hepatitis C and B (note that, unlike HCV, HBV is *not* curable). A note of appreciation to Claudia A. Hawkins, MD, MPH, a professor of medicine at the Division of Infectious Diseases of the Northwestern University Feinberg School of Medicine, who helped update the information on the drug pages.

In our personal fight against the virus, we will not yield. In the search for a cure, we will not yield. In the struggle to make HIV medications more accessible, we will not yield. Pushing back against federal cutbacks and policies, we will not yield.

We may have grown tired, but who we are—who we've always been—compels us to fight. We will not yield.

You are not alone.

We thought the victories would stay won. But the fight never really ended, even if at times it seemed to let up.

GUASCO: JOHN GRESS • HEART: ISTOCK

Briefly

ENID VÁZQUEZ @enidvazquezpa

FDA approves long-acting HIV prevention drug: Yeztugo

IAS-USA updates its PrEP recommendations to include the newest injectable

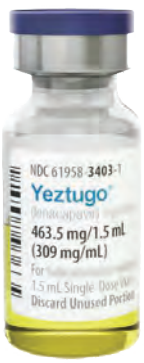
The U.S. Food and Drug Administration (FDA) in June approved **a new medication for the prevention of HIV that's given as just two injections given twice a year**.

Yeztugo (yes-TO-go), from Gilead Sciences, joins Apretude, from ViiV Healthcare, as a long-acting injectable form of HIV pre-exposure prophylaxis (PrEP). (SEE "FDA approves twice yearly injectable PrEP—will it reach the people who need it?" GO TO positivelyaware.com/six-month-prep-approved).

In quick response, recommendations for providing Yeztugo were produced by a panel of HIV treatment experts of the International AIDS Society-USA (IAS-USA). IAS-USA regularly issues recommendations on HIV treatment and PrEP.

The IAS-USA panel recommends the use of Yeztugo (generic name lenacapavir, or LEN) with an A1 rating and an AIII rating for individuals who inject drugs and have sexual exposures.

"We recommend that lenacapavir be prioritized for HIV PrEP rather than for initial or early HIV treatment, which should be reserved for multidrug-resistant HIV," the panel wrote. Lenacapavir injections are available for HIV treatment of multidrug-resistant virus under the brand name Sunlenca. According to the drug label, Yeztugo is for adults and adolescents weighing at least 77 pounds. Starting Yeztugo PrEP consists of two injections on the first day along with two 300 mg lenacapavir tablets (600 mg) and another two LEN tablets on the second day. This is followed by a maintenance dose of two Yeztugo injections six months (or 26 weeks) later and every six months thereafter.



The subcutaneous injections consist of two vials of 463.5 mg/1.5 mL lenacapavir each for a total dose of 927 mg (3 mL). The two injections, which should be administered at least 4 inches apart, can be given in the abdomen, outer thigh, upper gluteus or back of the upper arm. Injection discomfort can be reduced by icing or using topical analgesia before the injection.

According to the label, information on the time to protection against HIV is limited, but it appears that lenacapavir reaches therapeutic levels "within hours after the second oral loading dose on day 2." For people switching from oral PrEP, however, protection takes place on Day 1 with the injection initiation.

Either way, that oral LEN dose on the second day is important: without it, protection may take up to 21 days.

According to the drug label, "Risk for HIV-1 acquisition includes behavioral, biological, or epidemiologic factors including, but not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network."

For more information, including a short video, GO TO yeztugo.com. Financial assistance is also discussed.

According to the IAS-USA panel, remember to test for STIs at the time of starting PrEP, at all sites of sexual activity; look for gonorrhea and chlamydia; and do a blood test for syphilis.

The panel noted that there are no clinically significant drug interactions expected with hormonal contraceptives or gender-affirming hormone therapy with lenacapavir. While lenacapavir is recommended for prevention in pregnant persons, there is not enough data to recommend use during chest or breastfeeding. GO TO bit.ly/3JA1YXi.

Descovy for PrEP recommended for vaginal exposure to HIV

The IAS-USA panel (SEE above) now recommends the use of Descovy for PrEP to protect against vaginal exposure to HIV. This is a huge deal, because there were not enough data in cisgender women at the time of the HIV drug's approval as PrEP to have them added to the drug label. The use of Descovy to protect against vaginal exposure to HIV has been held up as a result.

"**A 2025 analysis provided evidence for an 89% reduction in risk for HIV acquisition in cisgender women** who had biomarker evidence of taking at least [an average] of 2 doses of tenofovir alafenamide/emtricitabine [Descovy] per week. Therefore, tenofovir alafenamide/emtricitabine is now recommended for prevention of HIV acquisition from vaginal exposures for those in whom tenofovir disoproxil fumarate/emtricitabine [Truvada] is contraindicated or undesirable (AIIb rating)," the panel reported. GO TO bit.ly/3JA1YXi.

TOP OF THE NEWS

➤ FDA approves long-acting HIV prevention drug: Yeztugo ➤ U.S. HIV guidelines updated ➤ New drug for anal cancer: Zynyz ➤ FDA puts clinical hold on two HIV studies ➤ AIDS United gets a new CEO ➤ Veterans with HIV and PTSD face greater rate of morbidity and mortality ➤ Good sexual health for New Yorkers ➤ *'I Kissed a Boy'* reality TV star tells his HIV story ➤ Extra! Extra! Get your Narcan here! ➤ Putting some PEP in our step

PHOTO: AFC

Extra! Extra! Get your Narcan here!

The AIDS Foundation of Chicago (AFC) in June celebrated **two years of providing free Narcan through converted newspaper vending boxes throughout the city**. The opioid antagonist medication (generic name naloxone) reverses or blocks the effects of opioids (including morphine, fentanyl and heroin). For people experiencing an overdose, Narcan restores breathing. It is available as a nasal spray.

AFC wrote that the availability of Narcan was a significant contributing factor to the "remarkable" 27% decline in overdose deaths reported by the CDC in the Spring (SEE page 8).

"However, this decrease is not equal among demographics," AFC noted. "The *Chicago Sun-Times* recently reported that Black men born between 1951 and 1970 are dying from opioid-related overdoses at rates nearly 10 times higher than Cook County's average."

The city's largest HIV service agency said that more than 2,000 Narcan kits were distributed last year from the news box across the street from its downtown office alone.

The 20 "Narcan Newstands" are sponsored by the city's Westside Heroin/Opioid Taskforce, which includes AFC, with support from Cigna Insurance.

"Anyone can and *should* [the emphasis is AFC's] carry Narcan," AFC said in a press statement. The agency noted that Narcan is available free at the city's libraries and that the Chicago Transit Authority plans to provide Narcan vending machines. Read more about it: GO TO aidschicago.org/narcan-newsstand-celebrates-its-2nd-birthday/.

New drug helps treat anal cancer: Zynyz

The U.S. Food and Drug Administration (FDA) in May approved a new drug for treating advanced anal cancer, retifanlimab-dwlr (brand name Zynyz).

According to the Anal Cancer Foundation, "Retifanlimab-dwlr is an immunotherapy drug that helps your immune system recognize and fight cancer cells. It targets a specific protein called programmed-death receptor 1 (PD-1), which cancer cells use to hide from the immune system. By blocking PD-1, **retifanlimab-dwlr helps your body's immune defenses attack the cancer**."

David Winterflood, the foundation's CEO, wrote that, "The approval was based on encouraging results from clinical trials. When used in combination with chemotherapy, retifanlimab-dwlr helped patients live longer without their cancer worsening, and many experienced longer overall survival compared to those receiving chemotherapy alone."

The Anal Cancer Foundation said it will follow developments of the new drug and share updates as more information and data become available.

TO READ the FDA announcement, which includes dosing information and clinical trial data, GO TO bit.ly/3HtmBnC. TO READ the Anal Cancer Foundation's report, "What You Should Know," and sign up for its peer-support program, GO TO bit.ly/45MEfe0. GO TO the National LGBT Cancer Network: cancer-network.org.

Good sexual health for New Yorkers

The New York City Department of Health kicked off a public health awareness campaign over the summer reminding residents of its low- to no-cost services for STI testing, treatment and prevention (including HIV) and reproductive health care (including medication abortion), all regardless of immigration status.

"**Our sexual health clinics have a long history of providing dignified, confidential care**, without judgment, addressing critical health needs of New Yorkers," said acting health commissioner Michelle Morse in a press statement.

Several clinics serve individuals age 12 and older, with most services provided on a walk-in basis. HIV PEP and PrEP (both to prevent acquisition of the virus), doxy-PEP (to prevent STIs) and vaccination against hepatitis A and B, HPV, mpox and meningitis are available, as are emergency contraception and birth control.

FOR MORE information, locals can GO TO nyc.gov/sexualhealthclinics, or call 311 and ask for health department clinics.

U.S. HIV guidelines updated

Several sets of HIV treatment and prevention guidelines from the U.S. Department of Health and Human Services (HHS) were updated over the spring and summer. All sets of guidelines are updated regularly by different panels of experts. TO READ more, GO TO clinicalinfo.hiv.gov.

OI guidelines

Guidelines on opportunistic infections (OIs) in adults and adolescents with HIV were updated on July 14.

For mpox:

- new data have been added that further **support the use of mpox vaccination**
- there are updated treatment recommendations reflecting **new data suggesting limited benefit of tecovirimat monotherapy**
- there's also **clarification on eligibility** for tecovirimat use under expanded-access investigational new drug research

For other immunizations there's:

- **updated dosing intervals** for meningococcal group B vaccines
- **updated pneumococcal vaccine recommendations** to include the use of the 21-pneumococcal conjugate vaccine (PCV21)
- the **addition of a second recommended** pentavalent meningococcal conjugate vaccine (MenABCWY, brand name Penbraya)

For herpes:

- **information added on diagnosing** disease
- added recommendations on the **management of epithelial keratitis and stromal keratitis** (two eye diseases)
- **added treatment recommendations for care of the central nervous system** as well as disease that is disseminated (spread throughout the body) or visceral (affecting internal organs that include the lungs, the heart, the digestive system and the circulatory system)

Other updates include drug interactions between OI medications (specifically rifamycin- and azole-related interactions) and expanded discussion of therapeutic drug monitoring, as well as new information on cytomegalovirus (CMV) disease and the fungal infection talaromycosis (formerly called penicilliosis).

Pediatric OI guidelines

OI guidelines in pediatric HIV were updated on June 5. The guidelines are for children with HIV or who were exposed to it in utero or during birth.

New information includes:

- **updated revaccination recommendations** and treatment for hepatitis B, along with screening recommendations for liver cancer
- other **vaccination schedule updates** (including added recommendations for COVID-19, dengue, mpox and respiratory syncytial virus)
- a list of **medications removed from OI treatment options for children** (plus new ones added).

CHECK OUT "What's New in the Guidelines" for the long list of updates.

HIV perinatal guidelines

Biktarvy is now recommended as a preferred HIV antiviral regimen during pregnancy. The new Biktarvy recommendation is part of the June update to the perinatal guidelines.

For people who have used Apretude and have a recent HIV acquisition, the following is recommended during conception and pregnancy: darunavir (brand name Prezista) boosted by ritonavir (brand name Norvir) plus TAF *or* TDF plus FTC *or* 3TC.

Additional new information from the update:

- When **determining the timing of repeat HIV testing in the third trimester of pregnancy**, some clinicians conduct testing at or around 28 weeks of gestation in conjunction with the recommended timing of syphilis testing.
- The panel has added a bulleted recommendation about the **care for partners in the setting of childbearing potential with HIV**.
- The panel recommends that **ART (HIV therapy) should not be avoided or withheld before conception or in early pregnancy** for the purpose of preventing preterm birth.
- The panel now recommends that ARV (antiretroviral) **management of infants with potential in utero or intrapartum exposure to HIV-2 mono-infection or HIV-1/HIV-2 co-infection** should follow recommendations for infants perinatally exposed to HIV-1 infection using drugs that are active against HIV-2.
- **When HIV RNA (viral load test) is greater than 1,000 copies/mL or is unknown near the time of birth,** scheduled cesarean birth at 38 weeks of gestation is recommended to minimize the likelihood of perinatal HIV transmission.
- The panel has updated recommendations and content about **infant safety monitoring**.

Overdose deaths dropped by more than 25%

The U.S. Centers for Disease Control and Prevention (CDC) reported in May that deaths due to drug overdose last year dropped by more than a quarter—27%—from the previous year. Deaths from drug overdose had been climbing steadily from 2015 to 2023.

States with the greatest declines—up to a 41.2% decrease—include Wisconsin, Ohio, Virginia, West Virginia, South Carolina, Tennessee and Louisiana.

The findings were provisional, not final.

The report is a confounding compilation of statistical tables. Shedding some light on its importance was Brian Mann, the first national addiction correspondent for NPR, who reported, "This is the most dramatic thing we've seen, really, since the opioid crisis began in the 1990s—a 27% drop in deaths. It's unprecedented. The researchers I talked to say it's so vast that there's a real mystery here about why it's improving so quickly. It's also continuing. **We've now seen about 16 months in a row where these dramatic improvements have continued.** And so after years of a really apocalyptic situation with fentanyl and other street drugs, we finally have some truly good news here."

Ironically, he noted that a "huge public health response" started in President Joe Biden's administration seemed to help turn the tide. Given the cuts this year to funding and programs, there are questions about continuing success.

In fact, in July, Mann reported a new story: "U.S. overdose deaths rise again after hopeful decline," following updated information from the CDC. GO TO bit.ly/46KkCE2.

TO READ the CDC report, GO TO cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

Weekly pill HIV treatment trials put on clinical hold

Development of a new weekly pill for HIV treatment has hit the brakes. Gilead Sciences reported in June that the U.S. Food and Drug Administration (FDA) put a clinical hold on two of its HIV drug studies. The studies, **WONDER-1 and WONDER-2, are examining the use of a once-weekly oral HIV treatment regimen**.

Gilead explained that, "The clinical hold is due to the identification of a *safety signal* of decreases in CD4+T-cell (CD4) and absolute lymphocyte counts in a subset of participants receiving the combination of GS-1720 and GS-4182."

The cells are part of the body's immune system. A safety signal points to a sign of trouble—there may or may not be a problem.

Both studies compare the two investigational medications against the company's bestselling Biktarvy.

'I Kissed a Boy' reality TV star tells his HIV story

"I always wanted to find a way to share my story and talk about living with HIV. I didn't think it would be on a TV show watched by millions. But looking back on my experience in the masseria [large farming complex], the way it happened just seemed right."

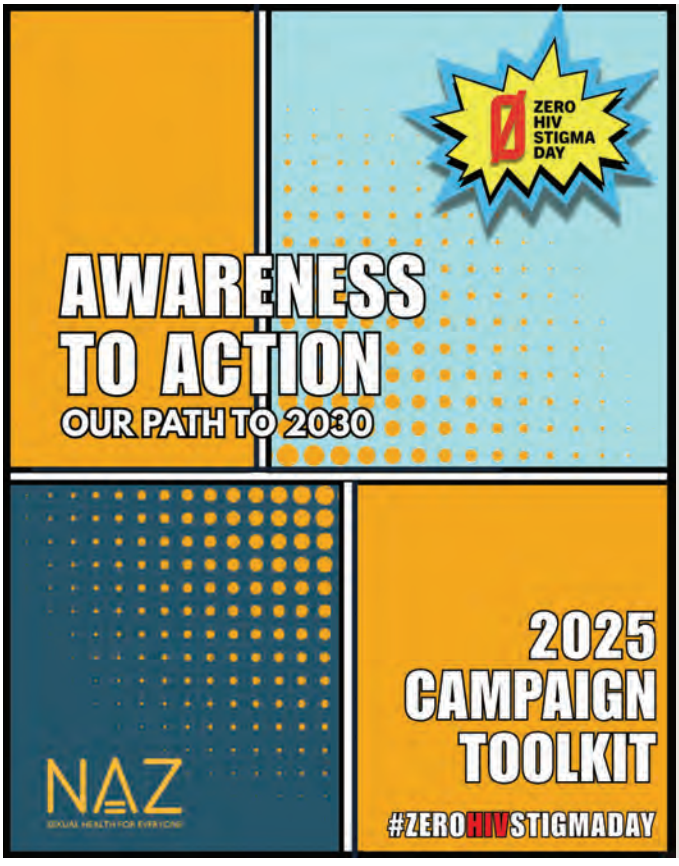
So starts Adam Williams in telling his story to Alastair James for *Pink News*, a London-based media website devoted to the LGBTQ+ community. Williams was part of *I Kissed a Boy*, the first gay dating reality show in the U.K.

"I was diagnosed when I was still pretty young. Back then, **I looked for stories of people like me. But all I could find were older voices**. Brave, yes, but not ones I could personally relate to. I felt completely alone," he said.

"That isolation stuck with me, and I knew if I ever got the chance to use my story to change that for someone else, I would."

Kudos to London's Terrence Higgins Trust and Positive East along with other organizations for helping Williams regain his health after he became sick, and to his family for their support. In *I Kissed a Boy*, Williams supports the National AIDS Trust.

TO READ his story, **GO TO** thepinknews.com/2025/06/13/ikab-adam-williams.



#ZeroHIVStigmaDay

More than 40 years since the first reported cases, HIV continues to be fueled by stigma. To combat this, a London-based nonprofit launched a campaign designating July 21 as Zero HIV Stigma Day. The social media-driven campaign urged everyone to make their voice heard using the hashtag #zeroHIVstigmaday and it released its official Zero HIV Stigma Day 2025 report, *Unmasking Stigma, Mobilizing Resilience.*

"HIV stigma discourages people from learning about their HIV status, accessing treatment and staying in care," says the anti-stigma campaign's website. "Midway through the fourth decade of the HIV epidemic, many of our young people are living in an era that feels post-epidemic with PrEP, PEP and U=U a new reality. However, **rising transmissions are indicative of misinformation and poor sexual health education**."

Zero HIV Stigma Day is produced by Naz, a nonprofit named in memory of Nazir, a gay Pakistani Muslim man. Established in the early 1990s, Naz is one of the oldest and largest sexual health nonprofits in London, providing LGBTQ+ support services, sexual health education and outreach and health interventions for communities of color and marginalized communities.

GO TO zerohivstigmaday.com.

—Rick Guasco

BRIEFLY

Maryland repeals HIV criminalization

Another state has repealed its decades-old HIV criminalization law, reports the SERO Project, the longest-running effort in the U.S. to fight these outdated and discriminatory laws.

Maryland governor Wes Moore signed into law the Carlton R. Smith Act on May 20. Smith was a Maryland advocate who worked to change HIV criminalization laws and to reduce stigma.

The SERO Project reported that the new bill was the result of efforts by "dozens of organizations, hundreds of advocates, hours of testimony and meetings and 13 years of action."

The Center for HIV Law and Policy (CHLP) reported that Black men were specifically affected—if not out and out targeted—by the HIV criminalization statute. They comprise 14% of the state's population and 44% of its individuals living with HIV, but 68% of the people accused in HIV-related criminal cases.

In the U.S., 32 states still criminalize HIV.

TO READ CHLP's press release and see photos, **GO TO** hivlawandpolicy.org/news/maryland-repeals-hiv-criminalization-law.

AIDS United gets a new CEO

AIDS United completed its leadership transition in July when **Carl Baloney, Jr., who oversaw the national agency's federal advocacy for the past 10 years**, became the advocacy organization's new president and chief executive officer. Under his leadership, the organization's Public Policy Council doubled in size to more than 60 organizations and its annual Congressional advocacy outreach, AIDSWatch, also doubled, with nearly 650 advocates addressing members of Congress this past spring. He follows Jesse Milan, Jr., JD, who retired after four decades of work in HIV, with the last nine years at AIDS United.

"As we welcome Carl into the role of president and CEO, we are confident in his deep policy expertise, strategic vision and unwavering commitment to the communities we serve," said Eugene McCray, MD, chair of AIDS United's board of trustees.

TO READ more, **GO TO** aidsunited.org/aids-united-welcomes-carl-baloney-jr-as-its-president-and-ceo.

Putting some PEP in our step

Picking up the HIV prevention pace with updated CDC recommendations

The need for HIV PEP—*post-exposure prophylaxis*—is "a medical emergency," according to the U.S. Centers for Disease Control and Prevention (CDC). Yet the **availability of PEP medication to prevent HIV is still widely unknown** by both the public and some care providers.

HIV PEP medication is supposed to be taken for 28 days following a potential exposure to the virus in order to stop infection from taking place. That's a problem, because pill bottles come with 30 pills.

"I can't tell you how many times patients called me in crisis because they were given a prescription for 28 pills and a pharmacy refused to fill it because they won't break a bottle," said Eric Farmer, PharmD, BCPS, AAHIVP, an HIV clinical pharmacist at the Indiana University Health LifeCare Clinic at Methodist Hospital, who has helped write and review the POSITIVELY AWARE annual HIV Drug Guide.

Part of the PEP medical emergency is that, currently, HIV PEP must be started within 72 hours of a potential exposure, preferably within 24 hours, in a world with still too many PEP barriers.

The first step to access, according to CDC, "is for eligible persons to know about [PEP] as an option and to seek care within 72 hours of a possible exposure."

The statement comes from the CDC's updated HIV PEP recommendations in May, the first update since 2016.

PEP is like PrEP (pre-exposure prophylaxis)—except that PEP is taken *after* possible acquisition of HIV and PrEP is taken *before*. Both HIV prevention methods use some of the same medications that are used for HIV treatment. (No, people on PrEP do not need to use PEP. The question has been asked.)

CDC notes that, "Barriers might include stigma and shame, cost of the medications, difficulty with rapid access to medications and lack of access to knowledgeable health care professionals for [PEP] initiation and follow-up care."

SEE the box on page 11 for basics from the recommendations. PEP updates include the recommendation of newer HIV medications that are easier to take and more tolerable.

"HIV prevention remains a priority, and PEP is a key component," writes HIV specialist Roy M. Gulick, MD, MPH, in an opinion piece for the *Annals of Internal Medicine*, published online May 6. "The urgency of starting PEP after a significant exposure and the streamlining of nPEP (non-occupational post-exposure prophylaxis) regimens and laboratory testing should facilitate implementation across primary care, urgent care and emergency room settings. Incorporating these guidelines will reduce new HIV infections and improve public health and should be a part of general medical practice."

That's the dream.

TO SEE the "Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—CDC Recommendations, United States, 2025," published in the CDC's May 8 *Morbidity and Mortality Weekly Report*, **GO TO** dx.doi.org/10.15585/mmwr.rr7401a1.

TO READ Dr. Gulick's article summarizing the recommendations, **GO TO** acpjournals.org/doi/10.7326/ANNALS-25-01885.

ISTOCK

Preventing HIV with PEP: CDC PEP recommendations, 2025

Recommended medications for PEP:

- **Biktarvy** (one pill once a day)
- **Tivicay in combination with either Descovy or Truvada** (or a total of two pills taken once daily)

Note: Although recommended to be taken for 28 days, bottles come with 30 pills. It might be better or easier to just get a one-month prescription. Many pharmacies will refuse to open a bottle in order to provide 28 pills.

For people with a history of taking Apretude for PrEP, it is recommended to use a darunavir-based regimen for PEP; basically, either Symtuza (one pill once daily) or Prezcobix plus either Descovy or Truvada (two pills taken once daily). Symtuza and Prezcobix should not be used during pregnancy—use darunavir boosted with ritonavir.

When to use PEP

PEP is to be started within three days (72 hours) of a "substantial" exposure to HIV, preferably within 24 hours. The recommendations also discuss considerations for starting PEP after 72 hours.

A rapid HIV test is recommended for someone seeking PEP.

PEP can be used after sharing drug equipment, not just for exposure during sex.

"Assessing the likelihood of HIV acquisition associated with an exposure requires consideration of multiple factors, including whether the source has HIV [or has unknown HIV status], the source's level of viremia [viral load, if the source is positive], the body fluid involved in the exposure, the exposure site, presence of barriers to body fluid exposure, and whether the exposed person is on PrEP [no need for PEP]," the recommendations state.

Stopping PEP early

PEP can be stopped if the person who may be the source of potential exposure is found to be HIV-negative. "HIV testing for the source should be provided if they are available, are unaware or unsure of their HIV status and agree to testing," the recommendations say.

Drug interactions

- Some recommended PEP medications cannot be taken with antacids or certain supplements, or must be used apart from these products.
- Metformin must be limited to 1 g a day if using Tivicay.

Note: If using metformin and Tivicay, watch for increased metformin side effects, such as bloating, diarrhea and upset stomach; metformin dose may need to be adjusted.

- The recommended medications for PEP can be taken safely with methadone, buprenorphine and hormone therapies (estrogens or testosterone) with no dose adjustment.

Where to get PEP

Any prescriber can order PEP. In some areas of the country, pharmacists are allowed to prescribe it as well. Because time is such a critical factor, PEP might need to be obtained at an emergency room or urgent care clinic. [Remember: The medication may not be on hand or the provider may not be aware of PEP.]

Note: Because some of the medications used to treat HIV are also medications used to prevent it, HIV specialists may be the best people to contact for PEP.

Lab tests

PEP should *not* be delayed while waiting for lab test results to come in. That said, people seeking PEP should be tested for HIV, pregnancy (if applicable) and hepatitis B. They should have their liver and kidney function tested.

Follow up

Close follow-up is recommended. This includes having a clinician reach out within 24 hours to see if the PEP medications have been obtained and to check if the medicines are tolerated and being taken correctly.

PEP to PrEP

For people with ongoing potential exposure to HIV, it is recommended that providers offer a smooth transition to PrEP (pre-exposure prophylaxis). PrEP medications are taken on a regular basis, *before* exposure to HIV.

PiP

For people with potential ongoing exposure to HIV who are not interested in using PrEP, it is recommended that clinics establish a PEP-in-Pocket (PiP) strategy, in which a supply of PEP medication is made available. However, the evidence for PiP at this time is limited. SEE the CDC recommendations for more information.

Costs

Clinics can help access medication assistance programs. Social workers, case managers, patient navigators and other support staff members can be included to help access medications. Check with pharmacists as well.

For providers

The National Clinician Consultation Center (NCCC) provides PEP clinical consultation for U.S. health care professionals. GO TO nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis.

More considerations

- Based on multiple studies, in cases of sexual assault, "Programs that provide the first dose at the initial evaluation and provide medication in hand before discharge with either the full course or a starter pack should be considered."
- Discuss pill boxes or smartphone reminders to improve adherence to PEP for the full course.
- Educate parents or guardians regarding PEP use in children.

GO TO dx.doi.org/10.15585/mmwr.rr7401a1.

Viral load testing should go *hasta la bye-bye* with PrEP pills

Use of viral load tests should be nixed for most people taking pills for HIV pre-exposure prophylaxis (PrEP).

A real-world study found that **just using a standard 4th generation Ag/Ab HIV test by itself was good enough for PrEP initiation and monitoring**.

Reporting on the study for *NEJM Journal Watch Infectious Diseases*, Carlos del Rio, MD, wrote, "The addition of HIV RNA for monitoring persons after initiation of oral PrEP testing adds cost and complexity without clear benefits: Ag/Ab testing seems sufficient. Indeed, the 2024 IAS-USA guideline panel (of which I am a member) does not recommend HIV RNA testing. I hope the CDC clinical guidelines will be updated soon to say the same."

Weiming Zhu, PhD, of the HIV Research Branch of the U.S. Centers for Disease Control and Prevention (CDC) and colleagues found it would take more than 8,000 viral load tests (8,226–9,900) to find one positive HIV result before an Ag/Ab test did.

TO READ more of their study summary, **GO TO** academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciaf230/8125152?redirectedFrom=fulltext#google_vignette.

Dr. del Rio is a distinguished professor of medicine in the Division of Infectious Diseases at Emory University School of Medicine and co-director of the Emory Center for AIDS Research. He is chief editor for HIV/AIDS for *NEJM Journal Watch*. **GO TO** jwatch.org/na58852/2025/06/16/does-hiv-rna-testing-monitor-prep-add-value.

THE NATIONAL COALITION FOR LGBTQ HEALTH LAUNCHED THE "MFAX" EDUCATION AND AWARENESS CAMPAIGN AT THE WORLDPRIDE STREET FESTIVAL HELD JUNE 7 AND 8 IN WASHINGTON, D.C. **GO TO** HealthLGBTQ.org/mfax TO ACCESS CAMPAIGN RESOURCES AND DOWNLOAD SHAREABLE ASSETS FOR SOCIAL MEDIA.

Veterans with HIV and PTSD face greater rate of morbidity and mortality

Veterans with HIV (VWH) who also had post-traumatic stress disorder (PTSD) were more likely to experience several illnesses and had a greater risk of mortality than positive veterans without PTSD, according to a study from the U.S. HIV Military Research Program.

"**It is recommended that providers who work with VWH consider adopting a trauma-informed model of HIV care and that providers**

screen veterans for PTSD, so that their unique trauma history can help guide medical decisions and treatment," the research team wrote in its conclusion.

Lead author Kartavya J. Vyas, PhD, of the Rollins School of Public Health at Emory University and the Atlanta Veterans Affairs Medical Center and colleagues reported that the increased risk of disease found with PTSD occurred most often in the first 10 years after its diagnosis but continued at elevated risk thereafter even as the risks later decreased.

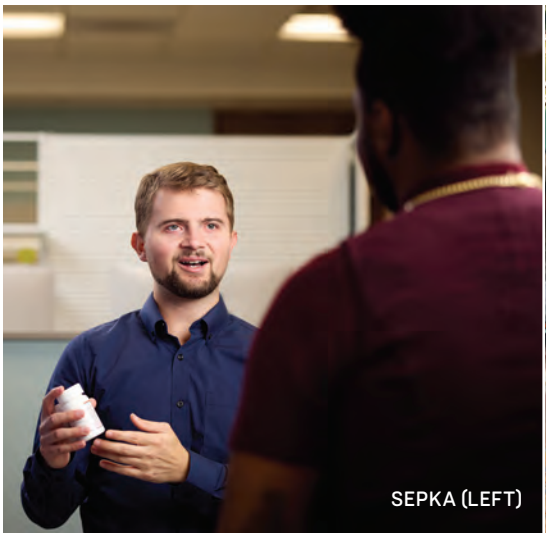
The team reported that PTSD increased the risks for:

- AIDS by 11%,
- chronic kidney disease by 21%
- chronic obstructive pulmonary disease (COPD) by 46%
- multimorbidity by 49%
- cardiovascular disease by 57%
- arthritis by two-fold (double)

PTSD was not associated with asthma, cancer, cerebrovascular disease, diabetes, liver disease or all-cause mortality.

The findings are based on 3,206 veterans who deployed to Iraq and Afghanistan, are on HIV therapy and receive care through the Veterans Administration.

The study was published May 22 in *AIDS*. **TO READ** the study summary, **GO TO** journals.lww.com/aidsonline/abstract/9900/posttraumatic_stress_disorder_and_its_associations.715.aspx. **TO READ** a summary of the study from Medscape Medical News, **GO TO** medscape.com/viewarticle/posttraumatic-stress-disorder-may-increase-morbidity-risk-2025a1000g0v.


SEPKA (LEFT)

DUDLEY

SEPKA: JOHN GRESS · DUDLEY: RICK GUASCO

The ABCs of hepatitis

>> CONTINUED FROM PAGE 2

said. "Now, most of the medications are pan-genotypic, so they treat all the different genotypes."

He added: "Approximately 20–25% of people who are exposed to hepatitis C or have hepatitis C infection will spontaneously clear it on their own and do not require treatment. They will always test positive for the antibody, it'll show that they've had exposure, but there will be no detectable viral load."

STRYKER STRESSED the importance of getting tested, and not just for hepatitis C.

"I just had friends visit from out of town, and one of them mentioned that they had had hepatitis C and cleared it, so they did not require treatment. This was after he was tested and showed the antibody. And then the other friend mentioned that he had hepatitis B. That's something that has fallen off our radar. We need to get men who have sex with men and people who inject substances to be tested and vaccinated for hepatitis B, because it's still present. Hepatitis B cannot be cured at this time, so it's important to be vaccinated for it to prevent infection."

Stryker added; "The person with hepatitis B, his body is controlling it. He has antibodies that are controlling it, but at this point in time, we don't have any treatments that can completely eradicate it from the body, so there is a potential, if he were to, say, get cancer and was to receive chemotherapy, it could reactivate. He'll always have hepatitis B, even though he's not contagious. He doesn't have to worry about passing it to anybody else, but he has to be aware that if his immune system gets suppressed, he could have a reactivation."

ALTHOUGH MUCH less common in the U.S., he also suggested protecting against hepatitis A.

"When I was like 23 or 24, I had hepatitis A," Stryker said. "It's almost always self-cleared by everybody. It happened before there was a vaccine, I got it from an ex during sex. There are parts of the world where it's endemic, and in those places, many children who are exposed to it have a mild diarrheal disease. It's usually not a big deal, but it can be more severe in adults. I was very sick for about three weeks. The most common groups of people exposed to hepatitis A tend to be people who travel to different parts of the world, or men who have sex with men. These days, it can be avoided with a vaccine."

In addition to Stryker, Dudley looks to other colleagues, such as the pharmacists at the in-house pharmacy. "I often spend the last 30 minutes of my day talking to them, Dudley said. "If I ever have questions about the medications, they're the first people I go to, and they usually have the answers."

JAKE SEPKA, PharmD is a staff pharmacist at Vivent Health + TPAN. "When patients come to me, I want to make sure my information aligns exactly with what the doctor says, so that we're on the same page," Sepka says. "My responsibilities include the where, what and why of the drugs. A lot of the times, for newly diagnosed patients, I like to explain how the drug works."

In another set of photographs from the shoot, Sepka posed with Dudley, enacting a typical pharmacy consultation.

"I really enjoyed it, and it was a pretty accurate representation of what we do," Sepka said. "What I was doing with Terry was talking about how you should take the drug, what the administration of the drug looks like, what other dietary stuff to take into consideration, foods and drinks to avoid. Any sort of food or drink interaction is a big one. A lot of people don't consider that. A lot of drugs can be affected by what you eat. That's really my wheelhouse, the details of the medication."

Added Sepka: "The key thing to remember is to stay adherent to your medication. With hepatitis C, if you take your medication as prescribed, within 8–12 weeks, depending on your regimen, you're going to be free and clear of hepatitis C."

A same-day approach to hepatitis C care

How one clinic integrated its services

BY **LARRY BUHL**

Hepatitis C (HCV) has been curable now for more than a decade, since development of the first direct-acting antiviral medications, but in the U.S. HCV can still go undetected and untreated. The Centers for Disease Control and Prevention (CDC) estimates that of the people diagnosed with HCV, 34% have been cured (achieving "viral clearance")—among people age 20–39 years, the rate is 24%. Among the challenges to improve these numbers, the CDC says, are expansion of testing, removal of prior authorizations and the lack of on-site pharmacies or team-driven patient-centric care.

One clinic in Massachusetts took on these challenges by implementing same-day, low-barrier, integrated HCV care initiation. At the 2025 NaLa conference (National Latinx Conference on HIV/HCV/SUD) in Las Vegas, Katrina Baumgartner, MD, AAHIVS, director of HIV/HCV at the Greater Lawrence Family Health Center (GLFHC) in Lawrence, explained how, by "meeting patients wherever they are," the clinic finds more people with HCV who don't easily or routinely access healthcare. She emphasized that this hard-to-reach population takes dedication, teamwork and patience, though not necessarily at great expense.

Baumgartner and her team drew upon examples in the U.S. and Australia where rapid initiation models of care overcame multiple barriers in the care cascade. Patients with a known history of HCV (who test RNA-positive) are offered same-day treatment initiation at a usual place of care—brick-and-mortar sites, a mobile health unit or a local hospital. Each patient is evaluated by a member of a multidisciplinary team that includes a community health worker and/or a nurse, either in-person or through telehealth. GLFHC offers same-day nurse intake, FibroScan (if indicated, a non-invasive test of liver health) and additional labs if needed. Medication is provided at, or delivered from, the on-site pharmacy.

She acknowledged that not every clinic has the immediate capacity to provide all these services (FibroScan machines can be pricey) but streamlining the processes and bringing all points of care in-house can help address the growing need for HCV testing and treatment in any region.

A great need in northern Massachusetts

The CDC estimates that one percent of the U.S. population has HCV, and that includes nearly one in five people who inject drugs. HCV is considered a silent killer, slowly doing damage over time, often without symptoms. If left untreated, HCV can lead to long-term liver damage including scarring (fibrosis), cirrhosis and liver failure as well as an increased risk of liver cancer.

Baumgartner noted that HCV exacerbates health inequities, and people experiencing poverty and homelessness, or who are incarcerated or medically underserved, are historically vulnerable to the virus. "And now we are seeing a larger distribution of HCV in younger individuals who are newly acquiring HCV as a result of the opioid epidemic," Baumgartner told the audience.

Of concern, Hispanic people saw a 10-fold increase in acute HCV diagnoses in 2022 over the last 15 years, and they are 13% more likely to die from HCV.

Tucked in the Merrimack Valley 50 miles north of Boston, Lawrence's population of about 89,000 is 82% Hispanic; more than half are Dominican. More than 40 percent of residents were born outside the U.S. and have the lowest per capita income in the state. Baumgartner pointed out the region's high prevalence of HIV, plus hepatitis B and C, all exacerbated by opioid needle sharing, has created a syndemic of HIV and hepatitis.

A dedicated team and streamlined processes

A Ryan White-funded clinic, GLFHC serves approximately 65,000 people. Early in the COVID-19 pandemic the clinic started a mobile health program, part of a multi-pronged effort to engage people with known HCV who have not been successful in traditional HCV care pathways. The goal was completion of pre-treatment evaluation and initiation of treatment on the same day of HCV diagnosis, as well as engagement or reengagement in health care for any reason.

Before 2020, the multi-step HCV treatment process was cumbersome, with many points for patients to disengage. After a diagnosis, a primary care doctor would refer a patient to a viral hepatitis clinic. There, an RN would do a pre-visit evaluation, intake and order labs. Next, the clinic would schedule a drug-drug interaction review and exam from a specialist and counsel the patient and a FibroScan or biopsy would be conducted, if indicated. Finally, medication would be ordered and the RN would call the patient when the meds were ready. If there's low risk for cirrhosis, all these steps can be done by telehealth, Baumgartner said. She noted that the more steps in the care cascade, the less likely a patient is to follow through to be cured.

"We always had a nurse care manager who would follow the patient, get them in from a referral and get them into a hepatitis clinic. But we found that we lost [patients] all the time." This was due not only to patients getting frustrated with so many steps, but to hurdles clinicians faced at every step, like prior authorizations.

Now, with the same-day treatment model, the clinic still relies on its regular brick-and-mortar site as well as its mobile

health units and telehealth. "For those who are hospitalized [the team] consists of a community health worker, a nurse like myself and a clinician. The same day, a nurse would run over to a hospital or run to the Mobile Health Unit and get a FibroScan completed." She added that the Department of Public Health helped with funding for the FibroScan machine, but emphasized that clinics can still move to a same-day model without the equipment. "You can have the lab work done and still start treatment. We have done that."

The results: out of 30 HCV patients seen July 2022–March 2025, 77% completed treatment, which is a huge increase, Baumgartner said. The only "failure" was one person who didn't complete treatment.

"With these medications, if you finish your treatment, 99% of the time you are cured." She admitted that there was a high rate (23%) of patients lost to follow-up.

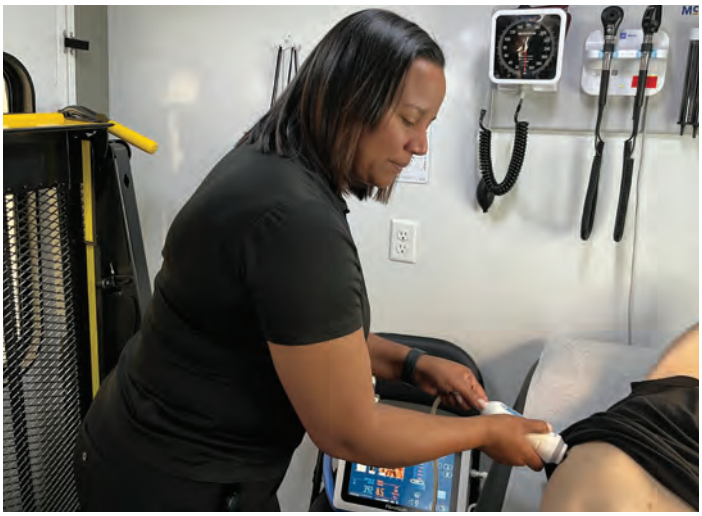
But given that patients lost to follow-up wouldn't have gotten diagnosed and into treatment in the past, it's still a success, added Jennifer Bergeron, an addiction nurse manager at GLFHC.

The doctor can do addiction consults at the hospital, and the doctor can also find new HCV patients at emergency departments.

There are 13 staff members on the HCV team, with 7 AAHIVM-certified clinicians and prescribers, including 4 exclusively on homeless care. One of the team members, Christina Jerez, an infectious disease community health worker, shared the story of Mr. E., a 63-year-old Latino man with diabetes and a history of alcohol and drug use as well as hepatitis C, who reengaged in care when a GLFHC mobile unit literally met him where he was at. "We'd been trying to get him into treatment for more than 10 years," Jerez said. "He never showed up to appointments and never wanted anything to do with us."

In 2024, the mobile unit showed up at a shelter where the man was staying, and team members encouraged him to engage in treatment by emphasizing the ease and simplicity. They drove him to get his labs done and completed a FibroScan to see if he had advanced liver disease (he didn't). "The team fought with insurance and got him medication, and this time brought the meds every week to the shelter," she said. Mr. E is now cured.

Like Mr. E, an estimated 40% of HCV patients in northern Massachusetts are unhoused.



Eighty percent have substance use disorders and nearly two-thirds deal with psychiatric illness. By removing barriers to care, this model significantly improved HCV outcomes for underserved and vulnerable populations. Jerez said this demonstrates the potential for similar initiatives to address health disparities in high-risk communities anywhere in the country.

Bergeron explained how decentralized treatment and the ongoing efforts of a team working together find more people with HCV. While about half were still treated through the GLFHC brick-and-mortar clinical site, mainly walk-ins, the rest are treated through two mobile health clinics, telehealth visits and at regional hospitals.

Zoom, which the team started using at the start of the COVID-19 pandemic, has been essential in streamlining care, Bergeron said. "That's how we communicate back and forth between our teams. We have a hep-HIV channel that providers—anyone in the clinic—can use to communicate with us all day at any time, ask us questions, get the provider's feedback. If they are seeing a patient that they want to treat and they may not be a hep care provider, they just ask a question and they get an answer immediately, and they can start treatment if the patient's ready."

There was another hurdle to care: prior authorizations. For that, the in-house pharmacy streamlined that procedure. "If you check all the boxes—you've never had a prescription on file for hepatitis C treatment, if you're not on any medications that are known to interact with this medication, if you're not on any medications like rifaximin—that might indicate you have decompensated services, they'll approve it without us having to do an authorization request," Bergeron said. "And that can all happen within 20 minutes."

Baumgartner said that the team is still refining its approach and is planning its next steps, including working with its pharmacy to provide meds for a short duration while awaiting RNA results, adding rapid testing and making testing in the field more acceptable to patients (like adding a lawn chair for a patient to sit in while getting a FibroScan).

Responding to an audience question, Baumgartner admitted that the same-day HCV care model was not unlike the clinic's same-day HIV care model, which has been in place for years. "We have teams for both [HIV and HCV] and they're very similar," she said, noting that, thanks to the state's AIDS drug assistance program, prior authorizations and wait times are less of a hurdle for HIV treatment.

Addressing a major issue, funding, Baumgartner said the key to covering new HCV services is partnerships. "One of our health center-funded clinicians who also works on the mobile unit is an addiction certified doc, and so we have grant funding that we got for addiction care." That means the doctor can do addiction consults at the hospital, and the doctor can also find new HCV patients at emergency departments. "[The ER] is contacting the addiction care doc, and that addiction care doc is either treating hepatitis C through our team or communicating with us to treat them." PA

ISTOCK

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 drug classes in one pill. In certain situations, some regimens may add 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 28**.

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 30** for more information.

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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, multiple partners or condomless sex, 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 reinfection.

A viral load test confirms a positive antibody test. If it comes back detectable, 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. Some individuals (those without prior treatment or cirrhosis) can be cured with very minimal monitoring throughout the course of treatment. 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, other medical conditions you might have and insurance. 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 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

ISTOCK

in the HCV world, as a vaccine would play an essential role in preventing new infections and helping us achieve hepatitis elimination. That said, HCV has proven tricky for vaccine development for a number of reasons, including limited options for animal models in early research and the fact that it has a lot of genetic diversity which makes finding a vaccine candidate that protects against all types of HCV tough. There have been attempts in the past to come 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 6 months after the exposure, you didn't get it. If you test positive for antibodies and have detectable 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** on 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 age 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	✘	✔	✘

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):
$29,904 for a package of 28 tablets
Authorized generic (400/100 mg tablets):
$9,600 for a package of 28 tablets

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 side effects 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 individuals 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. Rapid reduction in hepatitis C viral load during direct-acting antiviral therapy (DAA) may lead to improvement in glucose metabolism in people with diabetes, potentially resulting in symptomatic hypoglycemia if anti-diabetic medications are continued at the same dose. People with diabetes should be monitored for changes in glucose tolerance, particularly within the first three months. Modification of antidiabetic therapy may be necessary 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 27).

See "Black Box Warning" on hepatitis B testing and treatment on page 30.

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 kidney 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; 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 age 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.

Harvoni

90 mg ledipasvir / 400 mg 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):
$37,800 for a 28-day supply
Authorized generic (400/90 mg tablets):
$14,400 for a 28-day supply

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 age 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 discontinue treatment due to side effects. The most commonly reported side effects are fatigue, headache, nausea, diarrhea and insomnia, all considered to be mild. 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. Rapid reduction in hepatitis C viral load during direct-acting antiviral therapy (DAA) may lead to improvement in glucose metabolism in people with diabetes, potentially resulting in symptomatic hypoglycemia if anti-diabetic medications are continued at the same dose. People with diabetes should be monitored for changes in glucose tolerance, particularly within the first three months. Modification of antidiabetic therapy may be necessary. Hepatic decompensation and hepatic failure (including fatal cases) have been reported, typically occurring within the first four weeks of starting treatment. Most people with severe outcomes had either advanced liver disease with moderate or severe hepatic impairment prior to treatment initiation or compensated cirrhosis with mild liver impairment at baseline but with a prior decompensation event (e.g., history of ascites, variceal bleeding or encephalopathy). Additionally, rare cases have been reported in people without cirrhosis or with compensated cirrhosis (often with evidence of portal hypertension) with concomitant use of medications that are not recommended, or in individuals with other confounding factors (such as serious liver-related medical or surgical comorbidities). In individuals with compensated cirrhosis (Child-Pugh class A), transient elevations in bilirubin (<2 ULN) without concurrent elevations in liver enzymes (ALT/AST) may occur early in treatment (generally within the first two weeks); this usually resolves with continued treatment. Liver function test results should be monitored as clinically indicated in individuals with compensated cirrhosis (Child Pugh class A) or with evidence of advanced liver disease (e.g., portal hypertension). Treatment will be discontinued in people who develop signs or symptoms of hepatic decompensation/failure. 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).

See "Black Box Warning" on hepatitis B testing and treatment on page 30.

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. 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 liver 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.

Harvoni can be used in several special populations, including people on dialysis and after liver or kidney transplant.

For more information, GO TO hcvguidelines.org.

Mavyret

100 mg glecaprevir / 40 mg 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:
$13,200 for a 28-day supply
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 age 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 age 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 co-infection. 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 co-infection, history of kidney transplant or adolescence. There are no serious lab abnormalities expected. Rapid reduction in hepatitis C viral load during direct-acting antiviral therapy (DAA) may lead to improvement in glucose metabolism in people with diabetes, potentially resulting in symptomatic hypoglycemia if anti-diabetic agents are continued at the same dose. People with diabetes should be monitored for changes in glucose tolerance, particularly within the first three months. Modification of antidiabetic therapy may be necessary. Hepatic decompensation and hepatic failure (including fatal cases) have been reported, typically occurring within the first four weeks of starting treatment. Most patients with severe outcomes had either advanced liver disease with moderate or severe hepatic impairment prior to treatment initiation or compensated cirrhosis with mild liver impairment at baseline but with a prior decompensation event (e.g., history of ascites, variceal bleeding or encephalopathy). Additionally, rare cases have been reported in people without cirrhosis or with compensated cirrhosis (often with evidence of portal hypertension), with concomitant use of medications that are not recommended, or in individuals with other confounding factors (such as serious liver-related medical or surgical comorbidities). In individuals with compensated cirrhosis (Child-Pugh class A), transient elevations in bilirubin (<2 ULN) without concurrent elevations in liver enzymes (ALT/AST), may occur early in treatment (generally within the first two weeks); this usually resolves with continued treatment. Liver function test results should be monitored as clinically indicated in individuals with compensated cirrhosis (Child Pugh class A) or with evidence of advanced liver disease (e.g., portal hypertension). Treatment should be discontinued in people who develop signs or symptoms of hepatic decompensation/failure. Mavyret has not been studied in people who are pregnant or nursing, so its impact on fetal development or nursing babies is unknown.

See "Black Box Warning" on hepatitis B testing and treatment on page 30.

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 people who are post-liver or kidney transplant. It is also approved for children age 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.

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: **$8,736 / month**

DOSE

One tablet once daily with or without food for adults and children age 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 co-infection 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.

See "Black Box Warning" on hepatitis B testing and treatment on page 30.

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 (ritonavir or cobicistat), such as atazanavir and darunavir, to increase drug levels. Zepatier should 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 people 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.

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:
$29,904 for a 28-day supply

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. This regimen is usually reserved for people who are treatment experienced or who have experienced treatment failure. 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 or nursing people, 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 27).

See "Black Box Warning" on hepatitis B testing and treatment on page 30.

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 kidney 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 co-infection, 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.

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 tablest: **$1,390 for a 28-day supply** Generic 200 mg capsules: $1,600 for a 28-day supply

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 kidney 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 $10,000 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. 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 approximately 900 public and private patient assistance programs, including around 200 offered by the drug companies themselves. They also have a directory of 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 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.

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.

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.

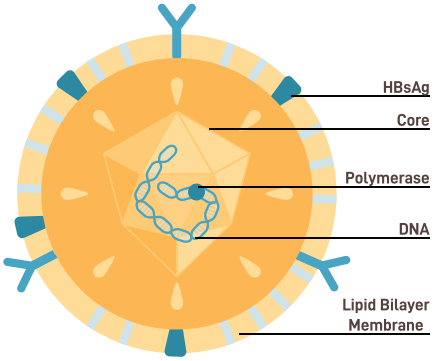
National AIDS Treatment Advocacy Project
natap.org
Easily the best website for scientific results from HIV and HCV conferences and academic articles.

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 (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 infants during exposure in pregnancy and birth (known as vertical transmission) in the U.S., directly related to the opioid crisis. Screening, vaccination, prevention and HBV treatment are essential tools for addressing this public health issue.



Hepatitis B

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 a partner with HBV
- sharing syringes and other drug-injection equipment (cookers, cotton, water, etc.)
- sharing household items such as razors or toothbrushes with a person who has HBV
- 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 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" mean: Your provider will explain it 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
- Men who have sex with men
- Household contact or former household contacts of people with known HBV positive status
- Needle-sharing or sexual contacts of people with HBV
- 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 age 19 to 59 years and adults > 60 years with risk factors for hepatitis B. Adults age >60 years without known risk factors for hepatitis B may also receive HepB vaccines. Infants and all other persons age <19 years are already recommended to receive HepB vaccines."

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

ISTOCK

>> 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 age 19–59 years (at the discretion of clinicians for people with diabetes age 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 co-infected with HCV/HBV while they were either on or shortly after HCV Direct-Acting Antiviral therapy, resulting in hepatic flares, and in some cases a liver transplant or death. This reactivation does not happen to everyone—there were 24 cases reported to the FDA over approximately 2.5 years—but it's a serious enough risk that several precautions should be taken:

People should be screened for HBV with both an HBsAg and an anti-HBc test before starting any HCV DAA (for more details on testing, SEE page 20).

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 them 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 age 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 co-infected persons.

If you are dually diagnosed with HBV/HIV, you should not treat HBV without also treating your HIV. You should be checked for resistance to Epivir (lamivudine) before starting Baraclude. Epivir resistance decreases the effectiveness of Baraclude at the 0.5 mg dose, and it must be increased to 1 mg daily. For individuals with HBV/HCV co-infection or people at risk of HBV reactivation while undergoing HCV DAA treatment, Baraclude may be one of the medications you could be prescribed to prevent it from happening and is safe to use while being treated for HCV. SEE **HBV Reactivation on page 30** 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	MANUFACTURER	AWP
Nucleoside reverse transcriptase inhibitor (NRTI)	**Gilead Sciences**	$1,831.98 for a 30-tablet pack

DOSE

One tablet once per day with food for adults and children age 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, creatinine clearance (CrCl) should be 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 build-up 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, an HIV medication.

Before starting Vemlidy, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent the development of HIV drug resistance. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. If you have HBV/HIV and need to switch from any tenofovir-containing regimen—such as Vemlidy—there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. Abrupt discontinuation of Vemlidy may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Vemlidy is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first. SEE **HBV Reactivation on page 30** for more information and consult your medical provider. For individuals with HBV/HCV co-infection, or who are at risk of HBV reactivation while undergoing HCV DAA treatment, Vemlidy is one of the medications that can be prescribed to prevent this from happening and is safe to use while being treated for HCV.

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

300 mg tenofovir disoproxil fumarate (TDF)

DRUG CLASS

Nucleoside reverse transcriptase inhibitor (NRTI)

MANUFACTURER

Gilead Sciences

AWP

Viread:
300 mg tablets: $1,368.26 (30-tablet pack)
250 mg, 200 mg and 150 mg pediatric tablets: $1,142.66 (30 tablets)
40 mg/g powder (pediatric): **$820–$3,076 / month based on dose required**
Generic: 300 mg tablets: $167.18–$1,215.94 **/ 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 age 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 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, creatinine clearance (CrCl) should be 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 is also an HIV medication. Before starting Viread, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent the development of HIV drug resistance. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. If you have HBV/HIV and need to switch from any tenofovir-containing regimen—such as Viread—there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. Abrupt discontinuation of Viread may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Viread is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first. SEE **HBV Reactivation on page 30** for more information and consult your medical provider. For individuals with HBV/HCV co-infection, or who are at risk of HBV reactivation while undergoing HCV DAA treatment, 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 age 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 approximately 900 public and private patient assistance programs, including some offered by the drug companies themselves. They also have a directory of 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

Talk to me

I have never met a man who asked me about my HIV status or volunteered his before I told him about mine. That's a problem.

I *have* met a (heterosexual) man who likely would not have told me about his HIV-positive status if I hadn't brought up mine. I know grown, strong, sensible men *and* women who get flustered and very uncomfortable if I try to discuss my HIV status, testing, prevention or the very real possibility of individual HIV acquisition with them. I would call that challenging. Which is just an alternate term for a problem, lol.

Adolescent girls and young women are rarely taught how to have empowered conversations about sex. We are taught to keep our mouth shut (and our legs closed even tighter) because there is no need to talk about something you shouldn't be doing, and you better not bring babies into your parents' house. As a result, we end up learning lessons the hard way. I am not just referring to the act of sex in this context. I mean learning the hard way through stumbling embarrassing talk with each other, learned from books or movies, acquiring an STI and having to have the conversation that starts with "why didn't you tell me?" Black girls and women are oversexualized early and judged for being such. Jezebel and Sapphire tropes are persistent labels, even when people don't know those terms.

Most young Black men don't fare much better. They get the toxic masculinity lessons of "conquer in numbers" to prove your "manhood." Dirty magazines, exaggerated bragging, porn and under the bleacher conversations amount to noxious end lessons—manliness is having a high body count (number of partners); admonished to use a condom or ask if she's "clean;" pull out if you must, but definitely, do not bring babies into the house.

That's an oversimplification but doesn't feel like an exaggeration to me. Feel free to disagree, but at the end of the day, neither gender is fully prepared to talk about sex, pleasure, boundaries or shared decision making around negotiating sex. More broadly speaking, and more to my point, honest empowerment is missing for both because it never gets instilled. Say it with me, *this is a problem.*

Heterosexual-identifying men, specifically Black men, are hyper-masculine (read: homophobic), hypersexualized and taught anything else is weird or a weakness. There are systemic, cultural and institutional reasons for this based in history and race, but that is not my focus. The focus and point are that because HIV is so rooted in homophobia, a lightweight discussion about it is impossible and becomes the "keep your mouth shut" conversation from adolescence all over again because to talk about it as a man means you must be engaging in *those activities* because *why else* would you need to worry about HIV. This is painfully ignorant, a byproduct of both cultural bias and shame and—you guessed it—problematic. None of this even begins to touch on the separate stigma of intravenous drug use. For hetero-identifying women, social norms still box them in to discomfort about talking about HIV because, multiple partners and bad decisions, right? Wrong, but these hetero-normative constraints are part of the reason Black women acquire HIV at disturbing rates and reasons the (debunked and untrue) myths about down-low men persist, and why, for me, conversations about disclosure sometimes feel like I am carrying cultural stigma, cultural ignorance and the weight of misconceptions on my tongue.

Folks encourage open, empowered conversations, but very few feel empowering until after the fact. After the fact is often too late and people are then shamed into silence. The ignorance of what HIV is, the ways it is acquired and what it means to live with it cannot continue to exist behind stigma and half-truth. We must change how we talk about it to change the impacts and outcomes. I want to be able to talk about my HIV status the way I talk about other health issues impacting my community. Without making others feel uncomfortable or them feeling the need to try to shame me to make themselves feel safe. I won't be shamed by it, so can we just talk about it?

> We must change how we talk about [HIV] to **change the impacts and outcomes.**

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.

PICOU: CHAD SAIN · ISTOCK