POSITIVELY AWARE
HIV TREATMENT, PREVENTION, AND SUPPORT FROM **TPAN**
JULY+AUGUST 2018

SPECIAL PULL-OUT
HEPATITIS DRUG CHART

PLUS
TURNING YOUNG PEOPLE ON TO HIV PREVENTION

WHICH TREATMENT IS RIGHT FOR ME?

PATIENT ASSISTANCE PROGRAMS

WHAT YOU NEED TO KNOW ABOUT HEP A

THE 6TH ANNUAL

HEPATITIS B&C DRUG GUIDE

JANET, JOSÉ, KHAIYA, AND MATTHEW
REPRESENT SAN FRANCISCO'S TENDERLOIN DISTRICT ATOP THE GLIDE FOUNDATION'S BUILDING

What is BIKTARVY®?

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

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

IMPORTANT SAFETY INFORMATION

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

BIKTARVY may cause serious side effects:

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

Who should not take BIKTARVY?

Do not take BIKTARVY if you take:

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

What are the other possible side effects of BIKTARVY?

Serious side effects of BIKTARVY may also include:

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

The most common side effects of BIKTARVY in clinical studies were diarrhea (6%), nausea (5%), and headache (5%). Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking BIKTARVY?

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Ask your healthcare provider if BIKTARVY is right for you.

GILEAD

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

Because HIV doesn't change who you are.

BIKTARVY is a **1-pill, once-a-day complete HIV-1 treatment** for adults who are either new to treatment or whose healthcare provider determines they can replace their current HIV-1 medicines with BIKTARVY.

BIKTARVY does not cure HIV-1 or AIDS.

BIKTARVY.COM

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

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BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

(bik-TAR-vee)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT BIKTARVY

BIKTARVY may cause serious side effects, including:

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

ABOUT BIKTARVY

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

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

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

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

BEFORE TAKING BIKTARVY

Tell your healthcare provider all your medical conditions, including if you:

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

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that interact with BIKTARVY.

POSSIBLE SIDE EFFECTS OF BIKTARVY

BIKTARVY can cause serious side effects, including:

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

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

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

HOW TO TAKE BIKTARVY

Take BIKTARVY 1 time each day with or without food.

GET MORE INFORMATION

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

GILEAD

Version date: February 2018

FRONT COVER BACKSTORY

Like many other areas throughout the U.S., San Francisco's Tenderloin district has been hit hard by hepatitis. It is a community where poverty, drug use, and social justice intersect. The neighborhood is also home to the **Glide Foundation**, a non-profit organization that serves the area's poor and disenfranchised. The rooftop of the Glide Foundation's Ellis Street building served as the location of the cover photo shoot for the 2018 POSITIVELY AWARE Hepatitis B & C Drug Guide. **Paul Harkin**, Glide's Harm Reduction Program Manager, shot the cover, photographing foundation staff who themselves are a reflection of the community they serve.

Janet Ector, 60, spent most of her life not knowing that she had hepatitis C (HCV). The initial symptoms were so debilitating, Ector was unable to function. But when they eventually passed, she assumed she'd had mononucleosis and put it out of her mind. It wasn't until 1998 when Ector was diagnosed with breast cancer did she learn that a series of blood panels revealed she also had chronic HCV.

After a difficult and unsuccessful course of treatment involving interferon and ribaviran in 2007, it wasn't until 2016 that Ector's medical providers recommended her to take Harvoni. On Harvoni, Ector cleared HCV within three months.

Her years-long journey to successful HCV treatment included stigma she encountered, often from her own doctors. "I was always candid about the fact that I had contracted the virus as a result of injection drug use and sharing equipment," she says.

Today, Ector is an assistant manager of the Glide Foundation's harm reduction programs. "I grew up in a family of radical activists who were passionate about social justice, and they passed that legacy on to me from a very early age," she says. "That is why I do the work I do, in the name of the loved ones I have lost to the ravages of poverty, oppression, and stigma and in the hope that we can establish meaningful change for generations to come."

Khaiya Croom, 25, has also lost loved ones to hepatitis. "Growing up, there were a couple of deaths in my family," she says. "I was told that they both died from liver failure; I never questioned that. Later, I learned about their history of injection drug use and that they had been treated for hepatitis with interferon." Croom is now an HCV health systems navigator at Glide. "I am hyped about getting individuals linked to a better, advanced treatment. Sometimes I wish I could travel back in time to possibly save their lives, but I am motivated to spread the word about getting individuals cured of hepatitis C."

Although he doesn't have hepatitis, **José Mañuel Velázquez**, 46, has been living with HIV for 14 years. "I felt frustrated and insecure when I found out about my own status," says Velázquez, who does HIV and HCV testing at Glide. "Similarly, many people living with HIV/hepatitis C deal with stigma and guilt related to their status. This can cause feelings of isolation and can become a barrier to treatment."

Janet, José, Khaiya, and Matthew

Matthew Claveria, 32, believes allies can play an important role in the fight against hepatitis. "As an HIV/HCV testing counselor, I have learned from my clients the challenges they face in accessing culturally-aware medical treatment," he says. "If you are living with hepatitis, you don't need to feel isolated. There are treatments that can help cure you. Find an advocacy group in your community that can help link you to the right care today; you don't have to fight this alone."

—RICK GUASCO

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PHOTO Todd Rosenberg/Alice Klock

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POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

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THE 6TH ANNUAL
HEPATITIS B & C DRUG GUIDE
WRITTEN AND COMPILED BY **ANDREW REYNOLDS**, PROJECT INFORM

ON THE COVER: JANET ECTOR, JOSÉ MAÑUEL VELÁZQUEZ, KHAIYA CROOM, AND MATTHEW CLAVERIA PHOTOGRAPHED BY PAUL HARKIN ON THE ROOFTOP OF THE GLIDE FOUNDATION'S BUILDING ON ELLIS STREET IN SAN FRANCISCO'S TENDERLOIN DISTRICT.

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

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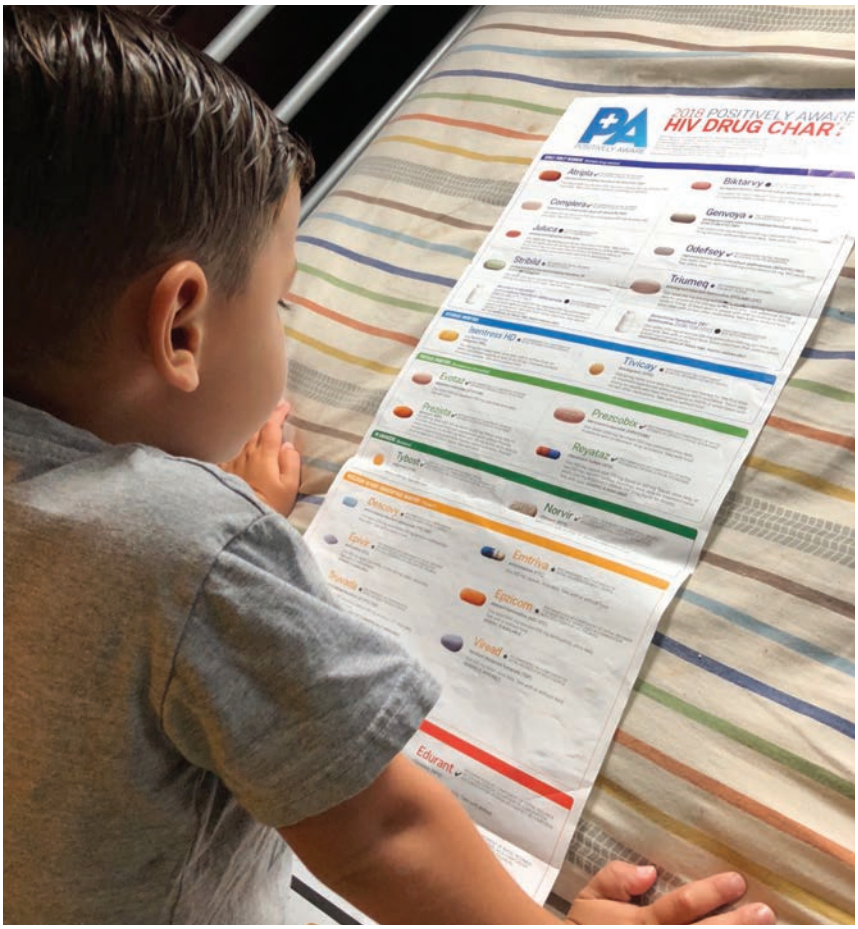
'TIME TO TAKE YOUR MEDS, GRANDPA'

Luca, my grandson whom I live with, hears me talk about HIV/AIDS and stigma all the time. Every morning Luca reminds me, "It's morning time, PaPa, time to take your meds." I share my daily life with him and his older brother Pierce, who is 6. Both boys have played a vital role in my recovery from my 2014 AIDS diagnosis. This picture came about as I was making profile picture frames for HIV Long-Term Survivors Awareness Day on the backside of the POSITIVELY AWARE HIV Drug Chart. I had been writing the names of long-term survivors and how many years they've been living with HIV. When Luca saw the colorful chart on the other side, he immediately became interested, unfolding it across his bed. He asked, "PaPa, can I look at all the meds?" As an HIV speaker I go to high schools educating our youth. A senior student once asked me what I would do differently. My response: Educate children at a much younger age. My two grandsons have lived around me since I was diagnosed. They know more about HIV than most adults.

—**MICHAEL ZALNASKY**
BROWARD COUNTY, FLORIDA



ACCESS DENIED—PRISON BANS THE HIV DRUG GUIDE

FROM ASSOCIATE EDITOR ENID VÁZQUEZ: **A reader who is a Utah inmate** had his copy of our annual HIV Drug Guide confiscated. Looking into the matter, I contacted the institution. This was their response:

Articles that describe the use, affects, or have photos, of any drugs or medication are problematic inside the prison. Inmates use information like this to determine what drugs/medications they can sell, use. We are not able to research each drug to determine if this is a possibility. We deny any publications that contain this material to ensure that we can maintain the safety and security of the institution.

If an inmate needs this kind of information they can meet with one of our medical professionals and obtain it.

To our reader—I am so sorry for what happened.

—**ENID VAZQUEZ**

GUEST EDITOR'S NOTE

ANDREW REYNOLDS

We lost a great one

Welcome to the 6th Annual POSITIVELY AWARE Hepatitis Drug Guide. In the past, I've written how this is always one of my favorite things to do each year. This year, however, I write with a heavy heart: Orlando Chávez, a dear friend and fierce hepatitis C advocate, died on Sunday, June 3, 2018. I dedicate this year's Hepatitis Drug Guide to Orlando.

Orlando was a colleague and a friend, and while I'm admittedly biased as hell towards him, I think it is fair to say that his death is a huge loss to the HCV community: Locally, nationally, and even internationally. Cured of HCV in 2004—and it's worth noting that this was with interferon and ribavirin, a nightmare concoction of medicine that one had to take for a year with very severe side effects—and based on his experience as a patient and a witness to the poor care he saw others in the community receive, he committed himself to helping others, reducing health disparities, and ending the suffering that comes with viral hepatitis.

Orlando Chávez raising a ruckus fighting for better access to hep C medications.

And, man, did he! There aren't enough pages in this issue to list all of his accomplishments, but here's a snapshot: At the Berkeley Free Clinic he brought HCV testing and education, as well as hepatitis A and B vaccinations, to the underserved. He was a living, breathing embodiment of harm reduction, bringing hepatitis education and support to syringe access programs throughout Berkeley and Oakland, California. He was awarded the Sherri Zeigler Community Service Award from the California Hepatitis Alliance (CalHEP) and as a member of the steering committee of the National Viral Hepatitis Roundtable, he help shaped national policy and awareness. Most recently, he was a Health Systems Navigator for the Glide Foundation's Health and Harm Reduction Team in San Francisco. All in all, he provided HCV results, health education and linkage to care and treatment for thousands of people living with HCV, and probably trained and developed an equal number of students, peers, and advocates.

But it was his work at OASIS, a clinic in Oakland, founded by Dr. Diana Sylvestre, where Orlando shined. From its beginning, OASIS reached out to and treated the underserved. Diana and her staff cured people who were considered incurable: Poor people, people of color, the homeless, and people who used drugs. This is where he went for care and treatment, sat in support groups, and became a peer advocate. His charm, wit, and intelligence were a hit over there, so soon he became staff: As lead health educator, Orlando shepherded hundreds (if not thousands) of people through hepatitis C treatment and helped them get into drug treatment and on methadone. In the U.S., with our problems with mass homelessness, our opioid crisis, and our HCV epidemic, OASIS is a model for providing care and services to the affected communities. There are so many people responsible for this success—and I may write about that one day in this magazine—but today is about Orlando, and he is as responsible for this success as anybody.

We can be a little more like Orlando. That would be enough.

So what can we do? It is easy to get lost in our grief over his loss or frozen in anger towards a health system that devalues and stigmatizes the communities that OASIS and Orlando cared so deeply about. The one thing we can do is to continue his fight for health equity and a cure for all those living with HCV. We can work to end the stigma surrounding people who use drugs, and fight to remove all sobriety restrictions that exist in state Medicaid programs and other insurance providers. We can expand harm reduction and provide safe injecting supplies to those living with, or at risk for, HCV. We can work to end the structural violence of a U.S. political economic system that fosters poverty, racism, and homelessness with infectious diseases and leads to so much suffering.

We can be a little more like Orlando. That would be enough.

Finally, as in years past I'm grateful to Jeff Berry and Enid Vázquez for their editorial support, and to Rick Guasco for designing the issue. This year in particular, they were all extremely supportive and made it very easy for me to work on this issue. In addition to this year's hard copy of the magazine, we will have additional articles and pieces online, from a summary of the AASLD/IDSA treatment recommendations to brief pieces on HCV testing and HCV treatment in people who use drugs. We will also feature articles from past issues that are still of use today. You can find them at positivelyaware.com.

In solidarity,

Andrew

BRIEFLY

ENID VÁZQUEZ @ENIDVAZQUEZPA

FDA APPROVES TRUVADA FOR PrEP FOR YOUTH

It's finally here. On May 15, the FDA approved Truvada for PrEP in adolescents. Thank you, Adolescent Trials Network for HIV/AIDS Interventions (ATN, for short). They helped demonstrate that Truvada PrEP was safe and well tolerated in young people.

One advantage of official approval: parental permission is no longer needed to get a prescription for the HIV prevention pill. ATN reported that "young males who could potentially benefit from PrEP and other HIV prevention strategies [such as those in the study] may be reluctant to notify their parents because of fears about disclosing their behaviors and sexual orientation."

FDA approval also gives teens access to patient assistance programs.

Although an age range was not provided with the approval, adolescents taking Truvada for PrEP must weigh at least 77 pounds (35 kg). They must test HIV-negative immediately before obtaining a prescription (the same as adults).

Grown-ups, move over.

"The FDA's decision is a milestone for HIV prevention among youth," said lead researcher Sybil Hosek, clinical psychologist at the Cook County Health and Hospital System in Chicago, in an ATN press release. "It paves the way for easier adolescent access to a highly efficacious biomedical HIV prevention product that has been approved for adults for the past six years." See page 14.

"This approval will allow adolescent minors who may be at risk of HIV to access an effective biomedical prevention medication for the first time," Bill Kapogiannis, study author and NIH program director for the ATN, said in the release. "The addition of oral PrEP to the HIV prevention toolbox for adolescents was made possible through vital research spearheaded by the ATN and is a landmark achievement for the Network and NICHD in our mission to reduce the numbers of new HIV infections among our nation's youth."

Truvada, which is also used for antiviral treatment, was first FDA approved for HIV prevention in 2012. Many medications, including life-saving HIV drugs, are not immediately approved for pediatric use when they come to market. Separate research is usually needed.

According to the CDC, Truvada for PrEP is more than 90% effective in the prevention of HIV. The once-daily pill is incredibly safe for PrEP.

However, because Truvada is known to affect the kidneys and bone mineral density, these side effects were of special concern when studying still-growing adolescents. Dr. Kapogiannis reported that the study did not show any harmful effects on bones, but that there was some evidence of minor losses in bone mass, and studies are in progress to determine the safety of the drug for this group over long periods of time.

One youth was found to have significantly decreased bone mineral density (a greater than 4% decrease) and three others had a mild decrease. The most common side effects seen (in more than 2% of participants) were headache, abdominal pain, and weight loss.

A newer version of Truvada, Descovy, is much gentler on the kidneys and bones. It is being studied for PrEP use.

Dr. Kapogiannis added that the study, also called Project PrEPare, serves as an example for future research seeking to prevent infection among adolescents who are most vulnerable to HIV (such as community statistics, as noted by the FDA).

ISTOCK

The HIV prevention pill continues to be recommended for use with other safer sex strategies such as condoms. Nevertheless, it is generally considered effective against HIV even without condoms. In fact, PrEP is recommended for people who can't or won't use condoms, among the groups that would most benefit from it, according to the drug label.

According to the FDA, when considering Truvada for HIV PrEP, those who are especially vulnerable to HIV may include those individuals who have a partner living with HIV or who engage in sexual activity within a high prevalence area or social network and have additional risk factors for HIV, such as:

- using condoms inconsistently or not at all
- a diagnosis of sexually transmitted infections (STIs)
- engaging in exchange of sex for commodities (such as money, food, shelter, or drugs)
- illicit drug use or alcohol dependency
- a history of incarceration, or partners who do
- a partner of unknown HIV status having any of the factors listed above

Truvada for PrEP is not the be-all and end-all for HIV prevention. But it's probably the greatest protection against the virus to date. HIV experts consider PrEP vital to ending the epidemic.

The NIH reported that, "HIV infection did not occur among participants who had sufficiently high blood levels of Truvada, indicating that the drug combination could be used safely by adolescents and would likely prevent HIV infection."

Study ATN113 enrolled 67 young gay and other men who have sex with men, ages 15 to 18. Side effects seen were the same as those in adults (mostly mild and temporary nausea).

After 12 weeks, there was an overall drop in taking the medicine correctly. This was after study visits were changed from monthly to quarterly, "suggesting that adolescents may benefit from more frequent visits and counseling." The study took place over 48 weeks and is ongoing.

Adherence to taking biological methods of HIV prevention has been a problem in other studies as well, including other PrEP trials.

Three youths who became HIV-positive during the study were found to have not taken their medication or taken it incorrectly (in other words, they were not adherent). The three had no drug resistance to either of the two medications found in Truvada.

In a press release from Truvada maker Gilead Sciences, Matthew Rose, Policy and Advocacy Manager at NMAC, a Washington, D.C.-based HIV treatment advocacy group, said, "We must make use of all available options when considering HIV prevention strategies, and we welcome the development that Truvada for PrEP is now available for younger people who are at risk of HIV. We will continue to build awareness and understanding of the role of Truvada for PrEP as part of a comprehensive HIV prevention plan for all who may benefit from it, particularly among communities disproportionately impacted by the disease, including young Black and Latino men in the United States."

READ MORE about Truvada for PrEP in the 2018 POSITIVELY AWARE HIV Drug Guide, March+April. Go to positivelyaware.com/drug-guides/truvada-prep.

BRIEFLY

You can't get HIV from spit

According to a meta-analysis published in *HIV Medicine*, the virus cannot be transmitted by spitting.

"Of the 742 records reviewed [both case reports, which consist of individual results, as well as studies], there were no published cases of HIV transmission attributable to spitting, which supports the conclusion that being spat on by an HIV-positive individual carries no possibility of transmitting HIV," the researchers said in their report. "Despite biting incidents being commonly reported occurrences, there were only a handful of case reports of HIV transmission secondary to a bite, suggesting that the overall risk of HIV transmission from being bitten by an HIV-positive person is negligible."

According to London-based AIDSMap, the four cases involved people living with HIV who were untreated, and therefore likely had a high viral load. The bites were deep and the person with HIV had blood in their mouth.

READ MORE in Michael Carter's article on the study at aidsmap.com/HIV-cannot-be-transmitted-by-spitting-and-risk-from-biting-is-negligible-says-detailed-case-review/page/3263982.

Lawsuit charges Gilead shelved a safer version of Truvada

AIDS Healthcare Foundation (AHF) is funding the lawyers in a lawsuit by two men claiming that Gilead Sciences kept a safer version of its HIV drug Truvada off the shelf for years longer than needed, unnecessarily harming them in terms of kidney and bone damage. There is also a similar class action lawsuit in place. AHF fought against Truvada for PrEP, or HIV prevention, for a long time before finally getting on the bandwagon with every other expert in the country and promoting the strategy. Read the *Los Angeles Times* article on the case at lat.ms/2sRNPK7.

Dolutegravir linked to birth defects

The FDA issued a safety announcement on May 18 alerting the public that serious cases of neural tube defects (NTDs) involving the brain, spine, and spinal cord have been reported in babies born to women treated with dolutegravir (DTG, brand name Tivicay, also found in Juluca and Triumeq).

The agency said pregnant women who are currently taking dolutegravir should not stop taking it without speaking to their doctor. It also noted that stopping dolutegravir without switching to other HIV medications increases the risk of HIV infection for the infant.

The FDA reported that, "Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects. ... To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. We are investigating this new safety issue and will update the public when we have more information."

Drug-related birth defects most commonly occur within the first trimester of pregnancy.

The FDA did not release numbers associated with the finding, but the Department of Health and Human Services (HHS), which produces HIV treatment guidelines, reported that the birth defects were found in four infants from a study of 426 pregnant women who started dolutegravir before becoming pregnant and were still taking it at the time of conception.

HHS noted that the study also presented data on 116 women who started dolutegravir during their first trimester and no NTDs were identified in their infants.

HHS issued the following recommendations following the May 18 announcement:

- For individuals not known to be pregnant, documentation of a negative pregnancy test is recommended prior to initiating DTG.
- Those who are currently receiving DTG as a component of their ART [antiretroviral therapy] or who wish to be started on DTG should be counseled about the potential risk of NTDs when DTG is taken near the time of conception. NTDs occur within the first 28 days after conception or 6 weeks from the last menstrual period.
- Those who are pregnant, taking DTG, and within eight weeks from last menstrual period should discuss the risks and benefits of their current regimens with their health care providers. If there are other good options to replace DTG, then switching to a non-DTG ART regimen is recommended [see Table 2 at aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf].
- Those who are pregnant and 8 weeks or greater from last menstrual period may initiate or continue DTG-based regimens. Discontinuing DTG-based regimens is unlikely to confer any benefits after the neural tube has formed, and medication changes during pregnancy could increase the risk of viremia and transmission of HIV to the infant.
- Currently, it is not clear if DTG is the only integrase strand transfer inhibitor (INSTI) with the potential to cause NTDs, or if other INSTIs also carry this risk (i.e., a class effect). Although there have been no reports of NTDs associated with taking DTG or other INSTIs near the time of conception in the prospective portion of the U.S. Antiretroviral Pregnancy Registry, the Registry is based on voluntary reporting and the number of reported INSTI exposures near the time of conception is relatively small.
- The Panels encourage all providers to prospectively report the pregnancy exposures of individuals with HIV receiving ART to the Antiretroviral Pregnancy Registry.

For additional guidance, contact the Perinatal HIV/AIDS Hotline at (888) 448-8765.

Read the guidelines at aidsinfo.nih.gov.

Dolutegravir is one of the most commonly taken—and recommended—HIV medications on the market.

HIV lawsuit against the Defense Department

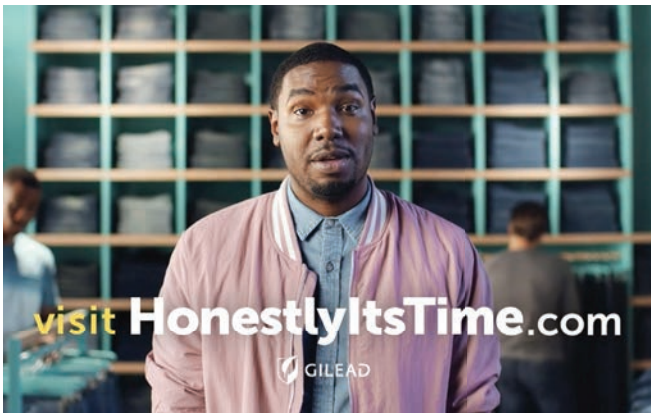
Lambda Legal and OutServe-SLDN in June filed a lawsuit challenging the Pentagon's current policies preventing

ISTOCK

enlistment, deployment, or commissioning as an officer for military personnel living with HIV. The suit was filed on behalf of Sgt. Nick Harrison, a veteran of two overseas combat zones, now serving in the D.C. Army National Guard, who was denied a position in the Judge Advocate General (JAG) Corps because Pentagon policy considers service members living with HIV non-deployable. Sgt. Harrison has made his career in the military. Under the "Deploy or Get Out" policy instituted by the Trump administration in February, people living with HIV are not allowed to enlist nor be appointed as officers. There is a separate lawsuit filed against an anonymous service member refused commission as an officer after graduating from the Air Force Academy, in spite of recommendations from medical providers. OutServe-SLDN is an organization dedicated to LGBT military personnel. Go to lambdalegal.org/in-court/cases/harrison-v-mattis.

New HIV prevention ad campaign launches

Gilead Sciences, maker of the HIV medication and PrEP drug Truvada, in June launched an HIV prevention TV campaign that takes off on its "Healthysexual" magazine ads. The campaign is intended to "encourage candid conversations around sexual health and promote public awareness of HIV prevention options," a company press release says. "When developing this campaign, it was important to us that the materials feature a diverse group of individuals who are representative of the communities disproportionately affected by HIV." The first commercial talks about testing and condoms, but future ads will also address PrEP. "Honestly, I am literally screaming!" wrote TPAN Prevention Manager Aquea Wynn. "Gilead brought the realness and diversity with this one!" HIV advocates have long complained about a lack of PrEP promotion from Gilead. Go to healthysexuals.com.



TURNING YOUNG PEOPLE ON TO HIV PREVENTION

Advocates still struggle to promote PrEP among young people of color

BY **ENID VÁZQUEZ**

The day that Christopher Balthazar stopped by TPAN for an interview for this article was the day the FDA approved Truvada for PrEP in adolescents. I kid you not. (See Briefly, page 8.)

Chris, along with psychologist Sybil Hosek and other team members, made PrEP for adolescents possible with their work on the study here in Chicago. PrEP is taking a daily pill to prevent HIV, and young men of color who have sex with other men are particularly vulnerable to infection.

But no matter how many advances are made in HIV prevention, it seems to be out of reach for those who need it the most. Like adolescents.

Hence the CDC's report at this year's CROI conference in February on how people who need PrEP the most get it the least. All the gay men had a discrepancy, but more so, as usual, the black and Latino men.

As soon as I heard Dr. Dawn Smith present the agency's estimates, I wanted to follow up on Chris's report at CROI in 2014—*four years ago*—on how to reach young black and Latino gay men with PrEP information. (Use text messages instead of phone calls. Use Facebook pages even more so, since phone numbers constantly change. Run your ads on the Facebook pages of Beyonce and Lady Gaga. See "HIV Prevention is Always in Fashion" online.)

Dr. Smith, who is African American herself, is working on PrEP at the top level. What's being reported at the ground level?

Four years ago, Chris reported hearing over and over again the words *Truvada whore*. That was the response from young gay men when someone talked to them about Truvada for PrEP. That was the image the HIV prevention pill had.

Good news: the words "Truvada whore" have lost their stranglehold on gay men's imaginations. Bad news: the concept of being "risky" remains associated with PrEP. Worse news: Myths continue to plague PrEP (see "PrEP myths").

Today, Chris says that the three greatest barriers they hear regarding PrEP for HIV prevention are: not wanting to take a pill every day; worry that people will think they have HIV (because Truvada was first an HIV medication before it was approved for HIV prevention); and fear of potential side effects. "That it could still possibly be harmful to you, even though there's evidence that suggests otherwise," said Chris.

He said stigma remains a huge blow to PrEP because people believe only promiscuous people take PrEP. Or they simply don't want to discuss their sex lives with a medical provider. Or they fear that the provider will assume that they're promiscuous and that's why they're interested in PrEP.

Ironically, the problem with PrEP's perception contains contradictions. On the one hand, some people feel that HIV infection is inevitable for them and others in their community. On the other, some people don't feel that they're at risk or understand what constitutes their vulnerability to HIV at all.

Then there's the growing acceptance of PrEP, which continues to be marred by put downs of people who take it.

I've gotten sick of writing about PrEP so that people could understand it's a good option. At one point, I was so frustrated, I thought, "Get infected with HIV. I don't care."

So when I ran into Dr. Smith in the conference hall in Boston during CROI, I asked her, "Aren't you sick of telling people PrEP is helpful?"

She looked like she was about to raise her voice, but then she calmly declared, "*No*, I want to fix the problem."

Dr. Susan P. Buchbinder, who spoke at the same session where Dr. Smith made her presentation, talked about the San Francisco program using PrEP called Getting to Zero. That's the hope—that PrEP can help us get to zero new infections.

I ran into Dr. Sharon Hilliard at the conference in the women's room. She's been a leader in the fight to bring HIV prevention methods to women around the globe. I asked her the same question, if she was sick about having to still fight for PrEP.

"We need to move on," she said. "PrEP works—now what?"

Later that day, the conference hosted a session titled, "PrEP Works. Now What?" The HIV experts get it. The community continues to struggle. PA

4 MYTHS– AND 4 TRUTHS– ABOUT PrEP

MYTH: PrEP can give you HIV.
TRUTH: Truvada PrEP is simply a medication, with no virus in it.

MYTH: There's no use in taking PrEP, because getting HIV among my group is inevitable.
TRUTH: Greater vulnerability to HIV does not make infection inevitable.

MYTH: PrEP can make you more susceptible to getting HIV when you stop using it.
TRUTH: "I have kids who come to me and say, 'Well, I heard if I take it then after I stop and start having sex, I'm going to become infected.' That is not true," said PrEP navigator Raymond McPherson. "When you stop, that protection against the virus goes away, and now you're more susceptible to HIV as a result of stopping your PrEP."

MYTH: PrEP was created to kill off gay black men, since HIV and HIV treatment didn't kill them all.
TRUTH: Truvada PrEP is medication that protects people against HIV infection.

THE FOLLOWING THREE PAGES have been transcribed from interviews and edited for space and clarity. >>>

HELPING YOUNG PEOPLE TALK ABOUT SEX

PrEP counselor and research coordinator
Christopher Balthazar

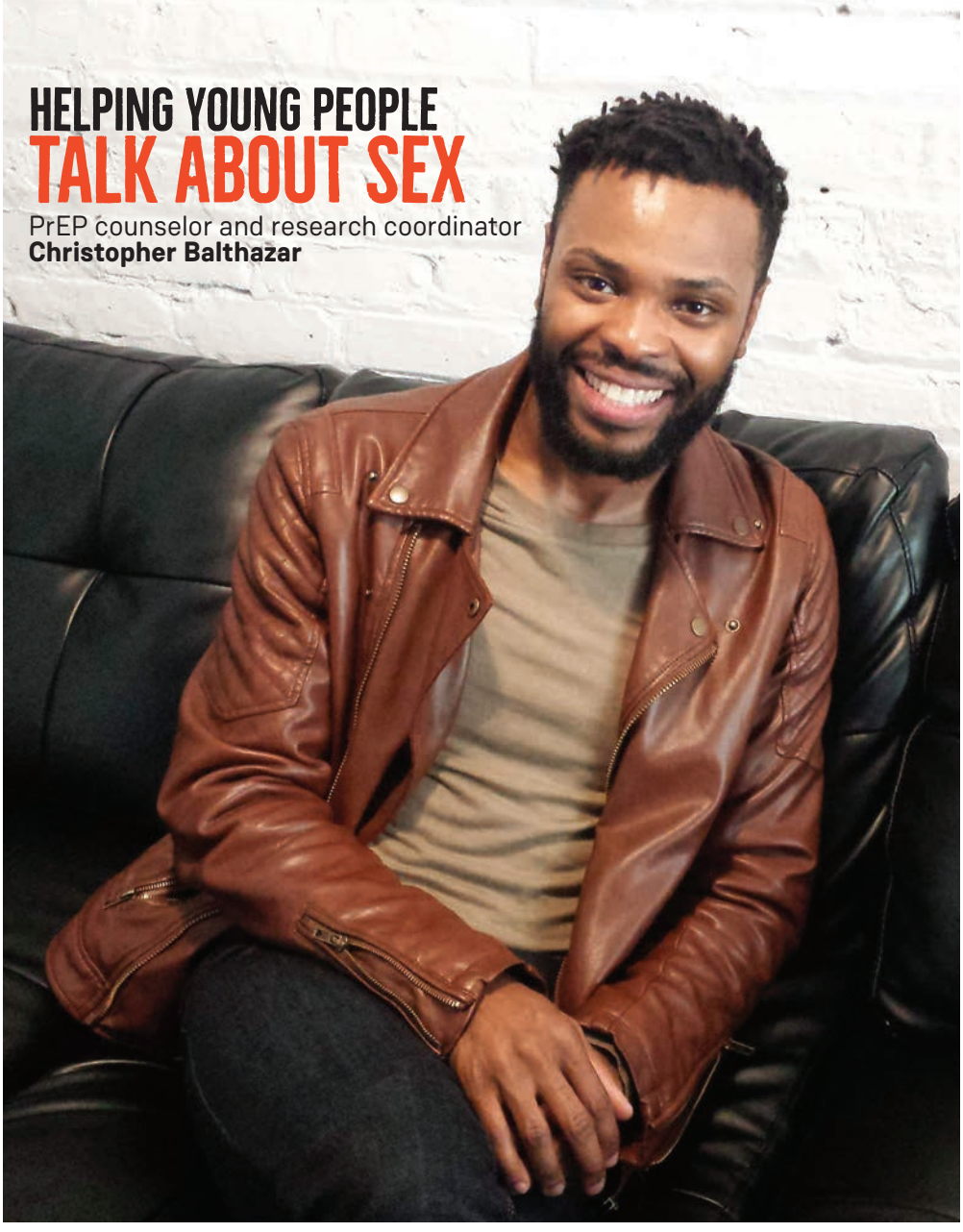


PHOTO: ENID VÁZQUEZ

It's just heartbreaking to see now that PrEP is available, we don't see as many young people taking it as we would have hoped. There's a lot more work still to be done.

We find that in our research a lot of young people are uncomfortable talking about their sexual health with *us*. It's something that takes practice and is something that could be another barrier to getting people on PrEP. They're afraid—or ashamed, even—to talk about this need.

So this idea of going to a healthcare facility and talking to someone about your sexual health is difficult for many young people.

We also have a hunch that perhaps for a lot of our participants the only health care services that they're getting is through the study, or through research. So perhaps the stigma isn't just around PrEP, but that another barrier is actually seeing a doctor.

In the back of a lot of people's minds, they think that me saying I need PrEP is me acknowledging that I'm promiscuous. Or me acknowledging that I have unsafe sex, which is taboo. I think there's that stigma that exists around PrEP, but there's also that stigma that exists around access to PrEP.

It's disheartening. We're so excited about PrEP being approved. It's widely available for anyone who goes to their doctor. But yet we're finding that that's just half the battle.

And I still think that there are a lot of people out there who don't really know what PrEP is or have a great understanding of it. So I think there's still a need for education around PrEP.

I would love to see people that feel like they can benefit from PrEP to feel comfortable enough to have access to it. My hope is much broader. I would love to see [pause] ... I would love to see people comfortable talking about their sexual health. Know that sex is normal, and that there should be no shame around that. Especially same-gender loving individuals. What we often see is shame around the fact that I'm having sex with someone of the same sex, right? And now I have to talk about it. And I think that makes it harder, because of the double shame. I'm talking about sex, and I'm talking about sex with another man.

So I would love to see that shame dissipate. Because I think then that people would be more open to getting their needs met. Maybe their need isn't PrEP. Maybe it's something else. Maybe it's education, or maybe it's just being part of a community where they can feel comfortable talking about what their needs are.

I think also a lot of people just need access to resources. I think about this drop-in center here [at TPAN, for youth, The Tea Room], and our center, and the tie between homelessness and HIV [many of the youth participants at both places are homeless]. A place where they can talk and have support. Homelessness places them at risk for HIV and other STIs.

I think about studies that are looking at creating PrEP communities using online tools to help people feel connected or supported by taking on PrEP. I think it's that sort of idea that can break these barriers of stigma and shame around just sexual health in general.

So my hope would be that people would be more comfortable with talking about their sexual health, and that people can get access to the resources that they need so they can live up to their fullest potential. Be the best self that they can be.

—ENID VÁZQUEZ

CHRISTOPHER BALTHAZAR is currently working on PrEP POSSE, a study looking at perceptions of PrEP among young gay and bisexual men, using community peers to get PrEP messages out.

YOUTH ATTITUDES ABOUT PrEP

Raymond McPherson is a PrEP navigator for the Chicago unit of the Adolescent Trials Network for HIV/AIDS Interventions

When you heard people talk about PrEP in the past, it was about Truvada whore. The only reason you're taking Truvada is because you just want to be promiscuous. Now people are talking about *I'm on PrEP* or *I'm HIV undetectable* [meaning they're HIV-positive but on medication and have viral levels so low, they are unable to transmit the virus to their partner], trying to promote that the fact that they're trying to be safe and healthy.

Some of the young people we talk to about PrEP are skeptical about it, and the reason they're skeptical is because it's new. I think with any intervention that is new, you have to be able to explain it and get the buy-in of the community.

People have to see their own perceived risk in order to even want to use PrEP. Because if I don't perceive that I'm at risk for HIV, there's no need for me to take Truvada. Some of the things that are putting them at risk are things that they themselves don't even think are putting them at risk.

One of the things that they all said to me was, "Well, Raymond, I'm not that person. I'm not promiscuous. I'm only having sex with Johnny and Steve. Those are the only two people. People who get HIV are out there having sex with 10 or 15 people, and I'm not that person."

And what they need to understand is that it does not matter how many people you are having sex with. It just takes one.

Sometimes they don't understand that we're looking at the zip code that they live in, what surveillance data is showing. That there's a high prevalence of STIs in this neighborhood, so you're more susceptible to HIV or getting an STI, and we want to make sure the interventions we have in place are able to reach you where you're at.

The other thing that we hear is young gay men always think it's an older gay man's disease. They need to understand their own perceived risk. Just because you only have sex with someone who's 16, 17, or 18 just like you, doesn't mean that those individuals are only having sex with people your same age. Younger gay men have sex with older gay men, just as younger heterosexuals have sex with older heterosexuals.

It's so much about perception.

Even though they have only two or three partners, the persons in the African American or Hispanic community are always going to be more vulnerable to the disease because there's a higher prevalence of infection in their community. It doesn't matter how many partners they're having sex with versus the white community, where persons may have eight or nine partners. The prevalence is so low in the white MSM community, and the treatment levels so high, that the chances of getting HIV are always going to be much lower than the other communities. MSM [men who have sex with men] specifically, I'm talking about. So in that respect, I completely understand it. They don't.

This neighborhood has six syphilis cases, but this other neighborhood has 25. Those are things that we see but they don't. So we try to help them understand that.

Dr. Lisa Henry Reid [a Chicago pediatrician who works in HIV] always says that you have to be at least 27 to fully understand what your true risks are, because the frontal cortex of your brain is not fully developed until then. You will not be able to rationally make some decisions before then.

Sometimes I say, "Oh, she's absolutely right." Because you can have this one kid who comes in with *10* STIs but still doesn't

learn. "Oh, it's not going to happen again." "This is the tenth time. You said that nine times ago. So how many more times is this going to happen?" They have to get to that point where they see their own risk for the infection or the disease.

You know, one thing that I would love for young Latino and African American men to understand is that they are a part of this planet. That they are a part of this world. Don't let negativity or the fact that you hear these things all the time, that you are the highest growing number of HIV infections, discourage you or make you think that you are absolutely vulnerable and going to get HIV. That is not true.

We know that even though this community has the highest growing rate of infection, we also know that there is something there to cut that rate of infection, and it's called PrEP. It's called taking your one-pill-a-day Truvada to reduce your chances of getting HIV.

I remember a parent told their kid once that just because they're gay they're going to get HIV. And a lot of times I have young gay men come to me and say, "Why should I take PrEP? I'm going to get HIV anyway because it's in my community." The reality is yeah, it's in our community, and that's the reason why we need to take PrEP. That's the reason why we need to take steps to prevent ourselves from getting an STI, because an STI increases our chances of getting HIV.

A message to young people is to understand that even if you don't think you are at risk, you are at risk. Because once you become sexually active, just one partner alone, just one incident alone, just one slip up alone can lead to HIV or lead to an STI. So you have to do what is necessary to protect yourself regardless of what people around you are saying or calling you. I will be a Truvada whore as long as I know that what I'm doing is right to take care of myself. Take my medication, to reduce my chances of getting HIV, and then condoms to reduce my chances of getting an STI. We have to understand that PrEP doesn't prevent an STI, only HIV.

So that would be my message to young people. They're the future of tomorrow. If you are not going to figure it out today, who's going to figure it out? —ENID VÁZQUEZ

RAYMOND McPHERSON helps coordinate community activities, such as the Vogue School.

PHOTO: JOHN GRESS

GETTING SCHOOLED

Known simply as Task Force, the group serves LGBTQ youth in an impoverished, black neighborhood on Chicago's West Side. The twice-weekly Vogue School brings youth together for dance practice—as well as friendship and community-building.

ALLANTE NYLA, PrEP LIASION, PROJECT HEAT: More Latinos and blacks are more receptive to PrEP now that they know what it is. Also, more young people are now interested because no parental approval is needed because of the FDA approval. They may ask about the side effects. Nausea, upset stomach, diarrhea. Depends on your body. Maybe no side effects at all. *So it doesn't have a bad rep?* ALLANTE: Not anymore.

TYE: I'm actually taking PrEP. It's a good med to be on. It has a good reputation and I would recommend it. [Tye, who's 26, had been taking Truvada for PrEP for three months. In the first two days, he experienced tightness in his chest that went away. His doctor told him different people have different side effects.]

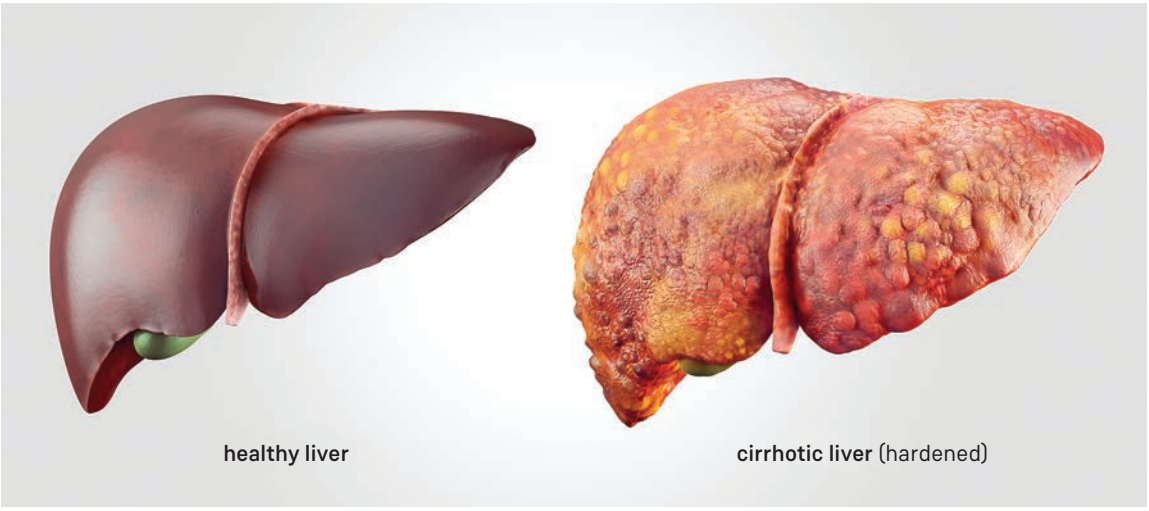
REYNA ORTIZ, TASK FORCE TESTING AND PROGRAM SERVICES COORDINATOR: If it's talked about [out in the community], it's not talked about in a way that's helpful to people. One thing I heard that was so mind blowing to me was that PrEP was like the flu vaccine, it puts the virus in your body. So we have to put more education in the community. Make sure they understand it's beneficial. Use it correctly. Take it consistently. Be really aware of the window period. Probably a couple of kids went to their doctor frantic and got PrEP, and a month later came up reactive [HIV-positive]. [Meaning that they tested HIV-negative at the time they got PrEP, but their bodies were still in the process of seroconverting to HIV-positive.]

RHONDA JOHNSON, PREVENTION WITH POSITIVES (PWP) COORDINATOR: PrEP was promoted wrong, for high-risk instead of everyone.

KARMA: People aren't afraid of PrEP. Because people don't let anyone know what they like [to do sexually].

GIA: Some people, it makes them throw up and get nauseated. Different strokes for different folks. *Do people still say 'Truvada whore'?* Gia: No, not necessarily.

YOUR LIVER AND HEPATITIS—A PRIMER



healthy liver

cirrhotic liver (hardened)

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

OTHER FUNCTIONS of the liver include:

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

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

Fibrosis and cirrhosis

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

Fibrosis

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

FACTORS THAT INFLUENCE the rate of fibrosis progression:

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

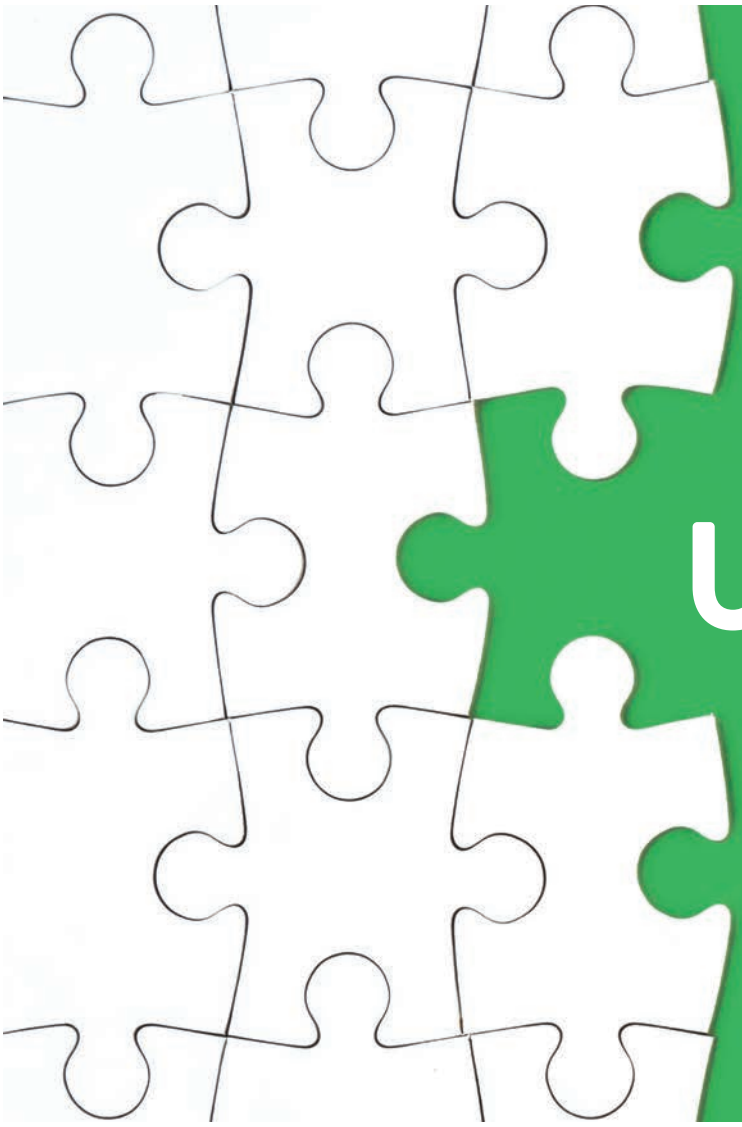
Cirrhosis

AS THE FIBROSIS PROGRESSES and the scarring covers more and more of the liver, it literally changes shape. This is called cirrhosis. Early cirrhosis, called compensated cirrhosis, can also be asymptomatic while the liver is still able to perform its functions. As the scarring gets more severe, the shape of the liver changes and it gets increasing stiffer, reducing the blood flow and leading to a series of symptoms and complications. This is called decompensated cirrhosis, and it can be life-threatening without access to specialist health care.

SIGNS AND SYMPTOMS of decompensated cirrhosis:

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

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



HOW TO USE THIS GUIDE

The POSITIVELY AWARE/Project Inform Viral Hepatitis Drug Guide includes medications for the treatment of hepatitis B (HBV) and hepatitis C (HCV) that are FDA approved. Currently, there are no HBV or HCV treatments that are close enough for FDA approval to be included this year. The guide lists FDA-recommended treatment regimens, as well as "off-label" recommendations (that is, treatment options that may not yet be FDA approved, but which are acceptable according to medical providers and other experts). The information provided on the FDA-approved drugs comes from the package labels, as well as other sources such as the AASLD/IDSA Recommendations for Testing, Managing and Treating Hepatitis C (HCV Guidance), AASLD Hepatitis B Guidance, conference presentations, medical journals and other sources.

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

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

What's new in 2018?

In short, not much. Since last year's publication, two new HCV drugs—Vosevi and Mavyret—received FDA approval, so we updated those to include their brand names and other information from their package insert. We have removed several drugs from the hard copy version of the guide: Viekira XR, Technivie, Daklinza, and Olysio. None of these drugs are recommended as first-line choices by the AASLD/IDSA HCV Guidance panel,

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and they are not prescribed very much (if at all) when compared to other, more preferred treatments. In fact, AbbVie recently announced that they will stop the production of Viekira XR and Technivie at the end of 2018. We will keep these drugs available in our electronic version of the guide, found at positivelyaware.com.

Each drug page will include, where applicable:

DRUG NAMES

Drug names can be confusing. We include the brand name, the generic name, and an abbreviation. For example, Sovaldi is the brand name of sofosbuvir. Sovaldi can be abbreviated as SOV, and sofosbuvir is abbreviated as SOF. For these FDA-approved drugs, the brand name will appear first, at the top of the page, followed by the common name(s).

FDA STATUS

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

DRUG CLASS

The "direct-acting antiviral" or DAA era of HCV treatment has seen the development of several different classes of hepatitis medications. Currently, there are five classes of HCV drugs, and six multi-class fixed-dose combinations:

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

GENOTYPE (HCV ONLY)

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

APPROVED FOR HIV/HCV CO-INFECTION

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

DOSAGE

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

MANUFACTURER

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

AVERAGE WHOLESALE PRICE (AWP)

The AWP is the measure used by insurance companies—both private and public—to determine the average cost of prescription drugs. HCV drugs can be expensive, and there is much concern over the burden these high costs are going to place on programs like Medicaid and Medicare, as well as the Veterans Administration and private insurance carriers. Patients should never have to pay for medications at this price, but it's still important to know these costs when shopping for health insurance coverage. Each of the pharmaceutical companies has a Patient Assistance Program (PAP) to help uninsured and underinsured people cover all or part of the costs. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. A list of HCV drug patient assistance and co-pay programs appears on page 29; HBV drug patient assistance programs are listed on page 40.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

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

A note on the risk of hepatitis B reactivation in some patients treated with Direct-Acting Antivirals (DAAs) for hepatitis C

On October 4, 2016 the FDA made a safety announcement, also known as a "Boxed Warning," about the potential risk of HBV reactivation in some patients taking **all hepatitis C DAAs**. A **Boxed Warning** is the most important warning the FDA can issue. In this case, there were a number of unexpected cases of hepatitis B reactivation in people who were cured of HCV using the DAAs, leading to hepatic flares, liver failure (requiring transplant), or, in some cases, death. See page 33 for more information on this warning.

Potential drug interactions

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

MORE INFORMATION

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

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WHICH HCV TREATMENT IS RIGHT FOR ME?

A look at hepatitis C treatment options in 2018—and beyond

Five years ago, the list of hepatitis C (HCV) treatment options would have been very short and no one would have been excited to take them! Today, we have 10 FDA-approved direct-acting antivirals (DAAs), as well as ribavirin, for treating all HCV genotypes in nearly all patients. With so many options, there can be confusion over what treatment to take.

A Patient's Guide to the Professional Guidance: AASLD/IDSA HCV treatment guidelines

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

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

If you've talked to someone who took the earlier HCV treatments, you likely heard nightmare stories of a yearlong treatment with terrible side effects that didn't always cure people. As you will see in this section, treatments are now shorter—8 or 12 weeks for everyone—and the cure rates are around 95-100%. The treatments have the added benefit of being better tolerated with fewer side effects. For information on possible side effects, check out the individual drug pages found in this year's guide.

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

Who should be treated?

In short, everyone! Current HCV treatment guidelines recommend treatment for everyone, regardless of severity of liver disease, co-morbidities (what other diseases one might have, including HIV or kidney disease), or current (or past) substance using history. The only patients who should not consider treatment are those with less than 6 months to live who would not benefit from HCV treatment or a liver transplant.

That said, sometimes treatment gets denied. Medical providers might not think someone who uses drugs should be treated because they fear the patient won't take the medications consistently or will re-infect themselves. Some insurance companies also have "sobriety" restrictions, requiring a varying period of abstinence from drugs or alcohol before treatment. These restrictions are unnecessary barriers, as research and real-world experience shows that people who use drugs or drink alcohol can and do take their HCV medications properly, get cured at similar rates as their non-drug using counterparts, and do not re-infect themselves at high rates. People who use drugs are part of the "everyone" we reference above!

Additionally, some insurance companies, including state Medicaid programs, may have restrictions for treatment based on severity of disease: That is, if you have hep C, but it has yet to do much damage to your liver, you have to wait for the cure until it does! For example, if you are infected with HCV, but only have a fibrosis score of F1, you may not be eligible, but when the disease progresses to F3, you can get treated and cured. If this sounds ridiculous to you, that's because it is. Again, everyone should be cured!

If you find you get denied treatment, call HELP-4-HEP (see below for details) and they can help you with the appeals process to make treatment happen. Sometimes this is as easy as having your medical provider write a letter, while other times it can be more complex. Regardless, don't do it alone. Don't let "No" stop you from getting cured. Get the support to get treated. You deserve it!

What about HIV/HCV co-infection?

Just as everyone living with HCV alone should be treated for their disease, this is equally true of people co-infected with HIV/HCV, according to U.S. guidelines for both diseases. Fortunately, the same hep C treatment options are available for people co-infected with both viruses.

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

Patients living with co-infection may have to adjust their HIV regimen to avoid drug-drug interactions, but no one should ever stop their HIV medications to accommodate their HCV ones. Switching HIV medications can be a very traumatic experience for someone, and if this is an issue for you, do not hesitate to talk to your medical provider about this.

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

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

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

Conclusions

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

Hepatitis C medications

BY CLASS: 2018-2019

CLASS	BRAND NAME	GENERIC/ COMMON NAME	STATUS	GENOTYPE (FDA AND OFF-LABEL)	APPROVED FOR HIV/HCV CO-INFECTION?	MANUFACTURER	FIND IT ON PAGE
Nucleoside analog	Moderiba	**ribavirin** (RBV)	APPROVED	1 2 3 4 5 6	YES	AbbVie	28
	Ribasphere	**ribavirin** (RBV)	APPROVED	1 2 3 4 5 6	YES	Kadmon	28
NS3/4A protease inhibitor	Olysio	**simeprevir,** (SIM)	APPROVED	1	NO	Janssen	ONLINE
	Viekira XR; Technivie	**paritaprevir,** (P)	APPROVED	Viekira XR: 1 Technivie: 4	YES	AbbVie	ONLINE
	Zepatier	**Grazoprevir,** (GZR)	APPROVED	1 4	YES	Merck	25
	Vosevi	**Voxilaprevir,** (VOX)	APPROVED	1 2 3 4 5 6	NO, but off-label use is OK	Gilead Sciences	27
	Mavyret	**glecaprevir,** (G)	APPROVED	1 2 3 4 5 6	YES	AbbVie	26
Nucleoside and Nucleotide NS5B polymerase inhibitor	Sovaldi; Harvoni; Epclusa	**sofosbuvir,** (SOF)	APPROVED	1 2 3 4 5 6	YES	Gilead Sciences	24 23 22
NS5A inhibitorx	Harvoni	**ledipasvir,** (LDV)	APPROVED	1 4 5 6	YES	Gilead Sciences	23
	Daklinza	**daclatasvir,** (DCV)	APPROVED	1 3	YES	Bristol-Myers Squibb	ONLINE
	Viekira XR; Technivie	**ombitasvir,** (OMB)	APPROVED	Viekira XR: 1 Technivie: 4	YES	AbbVie	ONLINE
	Zepatier	**elbasvir,** (EBR)	APPROVED	1 4	YES	Merck	25
	Epclusa	**velpatasvir,** (VEL)	APPROVED	1 2 3 4 5 6	YES	Gilead Sciences	22
	Mavyret	**pibrentasvir,** (P)	APPROVED	1 2 3 4 5 6	YES	AbbVie	26
Non-nucleoside NS5B polymerase inhibitors	Viekira XR	**dasabuvir,** (DAS)	APPROVED	1	YES	AbbVie	ONLINE

Epclusa sofosbuvir/velpatasvir, SOF/VEL

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

GENOTYPE 1 2 3 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Gilead Sciences

AWP
$29,904 / month

DOSAGE

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

BLACK BOX WARNING

Before starting treatment with any DAA, including Epclusa, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 33 for more information and consult your medical provider.

What are the potential side effects and adverse events?

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

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

What are the potential drug interactions?

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

More information

Epclusa marks an exciting development for treating HCV: One pill, once per day taken without ribavirin for 12 weeks for all genotypes with minimal side effects and high cure rates is an extraordinary achievement when one considers that the first DAA came on the scene less than 5 years ago. It is an effective and highly tolerable treatment option for people with GT3, with SVR12 rates as high as 98% for treatment-naïve patients without cirrhosis. The presence of cirrhosis looks to lower the SVR12 rates a bit (93%), but this is still an interferon- and ribavirin-free option for this hard-to-treat patient group. The ASTRAL-4 Study, which looked at patients with decompensated liver disease resulted in an SVR12 of 83% of people taking Epclusa alone, but it increased to 94% when ribavirin was added. This is also an excellent choice for HIV/HCV co-infected persons: The ASTRAL-5 Study, which looked at treating HIV/HCV co-infected persons with SOF/VEL, had an overall 95% SVR12, including 100% in people with cirrhosis and 97% in treatment-experienced people.

Recommended treatment regimen and duration

in HIV-mono-infected persons with genotype 1 2 3 4 5 6*

Patients without cirrhosis and patients with compensated cirrhosis (Child-Pugh A): **Epclusa for 12 weeks**

Patients with decompensated cirrhosis (Child-Pugh B and C): **Take Epclusa + ribavirin for 12 weeks.**

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

Harvoni ledipasvir/sofosbuvir, or LDV/SOF

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

GENOTYPE
1 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Gilead Sciences

AWP
$37,800 / month

DOSAGE

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

BLACK BOX WARNING

Before starting any DAA treatment, including LDV/SOF, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 33 for more information; consult your medical provider.

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit. Sofosbuvir should not be used with amiodarone. Cases of symptomatic bradycardia and fatal heart attack, and cases requiring a pacemaker, have occurred. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. See your doctor.

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

More information

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

Recommended treatment regimen and duration

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

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

Sovaldi sofosbuvir, SOF, or SOV

DRUG CLASS
Nucleotide analog NS5B polymerase inhibitor

GENOTYPE
1 2 3 4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Gilead Sciences

AWP
$33,600 / month

DOSAGE

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

BLACK BOX WARNING

Before starting treatment with any DAA, including Sovaldi, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See box on page 33 for more information; consult your medical provider.

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

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

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

More information

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

Recommended adult and pediatric treatment regimens and durations

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

Zepatier grazoprevir/elbasvir, or GZR/EBR

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

GENOTYPE 1 4

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
Merck

AWP
$21,840 / month

DOSAGE

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

BLACK BOX WARNING

Before starting treatment with any DAA, including Zepatier, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 33; consult your medical provider.

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

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

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

More information

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

Recommended adult and pediatric treatment regimens and durations

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

Mavyret glecaprevir/pibrentasvir, or G/P

DRUG CLASS
glecaprevir: NS3/4A protease inhibitor; **pibrentasvir:** NS5A inhibitor

GENOTYPE 1 2 3 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

MANUFACTURER
AbbVie

AWP
$16,332 / month

DOSAGE
Take three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily for a total of 300 mg/120 mg. Take it with food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING
Before starting treatment with any DAA, including Mavyret, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 33; consult your medical provider.

What are the potential side effects and adverse events?

Mavyret is a very well-tolerated medication with minimal side effects. Only headaches and fatigue were reported by clinical trial participants at rates higher than 10% (16 and 11% respectively), with even fewer reporting nausea or diarrhea. There were no serious lab abnormalities, and very few people stopped treatment because of side effects.

What are the potential drug interactions?

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. It cannot be taken with St. John's wort. It is not recommended to take Mavyret with the HIV antivirals atazanavir, darunavir, lopinavir, ritonavir, or efavirenz. There are no dose adjustments needed when taken with the following HIV antivirals: elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide, abacavir, dolutegravir, or lamivudine.

More information

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

Treatment-naïve patients

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

GENOTYPE	NO CIRRHOSIS	COMPENSATED CIRRHOSIS (CHILD-PUGH A)
1 2 3 4 5 6	**8 weeks**	**12 weeks**

Treatment-experienced patients

If you have taken HCV treatment before, you'll take it as follows:

GENOTYPE	PREVIOUS TREATMENT REGIMEN	NO CIRRHOSIS	COMPENSATED CIRRHOSIS (CHILD-PUGH A)
1	An NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor	**16 weeks**	**16 weeks**
1	An NS3/4A protease inhibitor without prior treatment with an NSA5 inhibitor	**12 weeks**	**12 weeks**
1 2 4 5 6	Prior treatment interferon, ribavirin and/or sofosbuvir but no other HCV treatment	**8 weeks**	**8 weeks**
3	Prior treatment interferon, ribavirin and/or sofosbuvir but no other HCV treatment	**16 weeks**	**16 weeks**

Vosevi sofosbuvir/velpatasvir/voxilaprevir, or SOF/VEL/VOX

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

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
Not approved for use in co-infection, but off-label use is okay

MANUFACTURER
Gilead Sciences

AWP
$29,906 / month

DOSAGE
Take one fixed-dose combination SOF/VEL/VOX 400 mg/100 mg/100 mg tablet once per day with food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

BLACK BOX WARNING
Before starting treatment with any DAA, including Vosevi, take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse or reactivate again during or after DAA treatment, potentially leading to serious liver problems including liver failure or death. Patients with HBV or some with past infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. For more information, see box on page 33; consult your medical provider.

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit. Refer to the package insert for more details. SOF/VEL/VOX should not be taken within 4 hours before or after you take antacids. Take at the same time with H2-receptor antagonists, otherwise wait 12 hours to take at a dose that does not exceed doses comparable to famotidine 40 mg twice daily. May use proton pump inhibitors comparable to omeprazole 20 mg or lower, but on an empty stomach. Do not take with the HIV antivirals atazanavir, lopinavir, efavirenz, or tipranavir/ritonavir. Do not take with the antimycobacterials rifabutin, rifampin, or rifapentine; the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine; the anti-cancer drug topotecan; or the herb St. John's wort.

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

More information

SOF/VEL/VOX marks the next generation of Gilead drugs, and will provide people who have been considered difficult to treat—treatment-experienced patients for whom prior treatments did not cure them—with a new option to get cured. Of particular importance is this medication's effectiveness in people with cirrhosis and/or HIV drug resistance: This is a wonderful achievement and offers hope to people living with HCV-associated compensated cirrhosis. See the chart below for treatment recommendations.

Recommended treatment regimen and duration

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

Copegus, Moderiba, Ribasphere ribavirin, RBV

DRUG CLASS
Nucleoside analog

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
APPROVED USE

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

AWP
$1,390 / month for generic, based on 1,200 mg/day
Copegus: $5,589/month

DOSAGE

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

Generic available.

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

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

More information

It's not entirely understood how ribavirin works against HCV, but along with interferon, it's been a major part of HCV treatment for years, and while interferon is no longer used, ribavirin continues to play a role in some treatments and patient populations. That said, we are in the ribavirin-free era with many of the current HCV DAAs.

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

HEPATITIS C CO-PAY AND PATIENT ASSISTANCE PROGRAMS

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

Harbor Path
harborpath.org
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 $15,000 to eligible patients who are insured and have an annual household income of up to 500% of the federal poverty level.

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

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

Patient Access Network Foundation
(866) 316-7263
panfoundation.org
Has an HCV-specific program, and can offer up to $7,000 in financial assistance for eligible individuals.

Patient Advocate Foundation
(800) 532-5274
copays.org/diseases/hepatitis-c
Has an HCV-specific program, and can offer up to $7,500 in co-pay assistance for eligible individuals. They also assist patients with insurance denials and access to care issues.

Additional financial assistance and access advocacy programs

DRUG	MANUFACTURER	PHONE NUMBER	WEBSITE
Moderiba	AbbVie	(844) MODERIBA (844) 663-3742	moderiba.com/patient-support/financial
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
Ribasphere	Kadmon	(888) 668-3393	ribapak.com/hcp/resources.html
Zepatier	Merck	(866) 251-6013	merckhelps.com/ZEPATIER
Vosevi	Gilead	(855-) 7-MYPATH (855) 769-7284)	mysupportpath.com
Mavyret	Abbvie	1-877-628-9738	www.mavyret.com/hcp/patient-support

ISTOCKPHOTO

TREATMENT IN HIV/HCV CO-INFECTION

It wasn't that long ago that treating hepatitis C was limited to two drugs: pegylated interferon and ribavirin. These medications were very challenging: People had to take them for a year, inject one of them, suffer severe side effects and, worst of all, they were not very effective at curing people. They also weren't very good for people living with HIV.

Today, HCV treatment is easier than ever: For most people it can be completed in 12 weeks (some people may need 24 weeks), with few pills (and no injections!), and manageable side effects that are usually quite mild. Best of all, they cure people at very high rates, between 90 to 100% of the time. They work very well in people living with HIV. HIV infection might complicate treatment, but it's nothing that can't be managed and you can still be cured of HCV.

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

Managing HIV in co-infected persons

Managing and treating your HIV makes sense for your immune system and keeping your HIV viral load undetectable, but it's good for your HCV, too. HIV treatment slows down liver damage and reduces the risk of liver-related problems for co-infected people.

There could be drug interactions between your HIV and HCV medications. In these cases, there may be a need to switch your HIV regimen to accommodate the HCV ones. If you can't (or don't want) to switch them, you may be able to try an HCV treatment that doesn't interact with your HIV medications. Make sure you HIV provider and your HCV one know about all the medications you're taking so they can help you manage any potential interactions.

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

HCV treatment in co-infected persons

Everyone with HCV should be treated for it regardless of the amount of liver damage one might have, and HIV/HCV co-infected persons are no exception. In fact, the AASLD/IDSA Guidance states that people who are co-infected can be treated and re-treated with the same DAAs as those who are not. There may be some drug interactions between HIV and HCV meds, so make sure all of your medical providers know what you're taking.

The cure rates for HIV/HCV co-infected people are extremely good—more than 90%, the same as in HIV-negative folks, and the medications have few side effects. There's never been a better time to treat HCV.

When to begin HCV treatment for co-infected persons

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

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

Maximizing treatment effectiveness

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

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

Preventing reinfection after treatment

You can get hepatitis C more than once. After you've been cured, it will still be important to prevent reinfection with HCV. If you inject drugs, use new syringes and injecting equipment and avoid sharing them. HIV-positive people are more vulnerable to sexual transmission of HCV, so minimizing your risk of exposure to HCV through safer sex practices (condoms for anal sex, gloves for fisting, and so on) can offer you protection from re-infection.

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

Closing

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

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

RESOURCES, SERVICES, AND INFORMATION

PA's annual Hepatitis Drug Guide is a handy resource for reliable treatment information and what you should know about HIV/HCV co-infection—in print and online at positivelyaware.com—but here are other useful resources, too

HEPATITIS B

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 provide an excellent section on liver cancer via their Liver Cancer Connect program. Information is offered in a variety of languages.

Hep B 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.

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

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

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

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

HEPATITIS C

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

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

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

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

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

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

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

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

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

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

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

AIDSVu.org, whose interactive website offers a visualization of HIV statistics from national to local levels, also offers a similar site for a state-by-state view of hepatitis across the U.S. HepVu.org provides basic information about hepatitis A, B, and C, along with a list of resources.

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

Hepatitis B transmission

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

- Vertical (mother to child) transmission;
- Condomless sex with an infected partner;
- Sharing syringes and other drug-injection equipment (cookers, cotton, water, etc.);
- Sharing household items such as razors or toothbrushes with an infected person;
- Other blood-to-blood contact;
- Occupational exposure from needlesticks or other risks of blood-to-blood contact.

Testing for hepatitis B

Most people who become infected with HBV don't know it because it rarely leads to signs or symptoms in the acute or chronic stages of infection. Over time, as the liver is damaged, noticeable symptoms may arise, but screening (testing) for the virus is the only way to determine if you have HBV.

Here's who should get tested for HBV:

Persons from endemic regions of the world:

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

Persons with certain medical situations or conditions:

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

Risk-based

- People who inject drugs
- Men who have sex with men
- People living with HIV
- Household, needle-sharing (including injection equipment), or sex partners of people with chronic HBV
- People who are the sources of blood or body fluids resulting in a potential HBV exposure (such as an occupational needle stick or blood splash or sexual assault) where post exposure prophylaxis may be necessary

SOURCE: Centers for Disease Control and Prevention (cdc.gov/hepatitis)

Vaccination for hepatitis B

Hepatitis B is vaccine preventable. It is safe and highly effective in preventing HBV, successful over 95% of the time. After the first dose, the vaccine is administered one month and six months later. The vaccine remains effective the rest of your life with no need for a booster shot ever.

The following should be vaccinated against HBV:

- All infants, beginning at birth
- All children under the age of 19 years who have not been vaccinated previously
- Susceptible sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., more than one sex partner during the previous 6 months)
- Anyone seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men
- Injection drug users
- Susceptible household contacts of HBsAg-positive persons
- Health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids
- Anyone with end-stage renal disease, including pre-dialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to regions with intermediate or high rates of endemic HBV infection
- Anyone with chronic liver disease
- Anyone living with HIV
- Unvaccinated adults with diabetes mellitus ages 19–59 years (at the discretion of clinicians for unvaccinated adults with diabetes mellitus who are aged 60 years and older)
- Anyone seeking protection from HBV infection—acknowledgment of a specific risk factor is not a requirement for vaccination

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

FOR MORE INFORMATION about HBV, including more details on HBV testing, vertical transmission, and treatment, go to positivelyaware.com.

Hepatitis B medications

BY CLASS

CLASS	BRAND NAME	GENERIC/COMMON NAME	STATUS	MANUFACTURER	SEE PAGE
Nucleoside reverse transcriptase inhibitor; NRTI	Epivir-HBV	lamivudine, 3TC	APPROVED	GlaxoSmithKline	34
	Hepsera	adefovir, ADV	APPROVED	Gilead Sciences	35
	Baraclude	entecavir, ETV	APPROVED	Bristol-Myers Squibb	36
	Vemlidy	tenofovir alafenamide, TAF	APPROVED	Gilead Sciences	37
	Viread	tenofovir disoproxil fumarate, TDF	APPROVED	Gilead Sciences	38
Interferon-alfa	Intron A	interferon alfa-2b	APPROVED	Merck	39

BLACK BOX WARNING

HEPATITIS B REACTIVATION

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

PATIENTS SHOULD BE SCREENED for HBV with both an HBsAg and an anti-HBc test before starting any HCV DAA (for more details on testing, see page 32);

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

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

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

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

In addition to these clinical measures taken by a medical provider, patients should watch for any signs or symptoms of HBV reactivation, including the following: A yellowing of the eyes or skin (jaundice), loss of appetite, nausea or vomiting, lighter colored stools, pain in the liver (right side of the belly, below the ribs), weakness, or fatigue. If you experience any of these symptoms, call your medical provider and let her/him know.

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

Epivir-HBV lamivudine, or 3TC

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

MANUFACTURER
GlaxoSmithKline

AWP
$578.00 / month; generic: $359.00 / month

DOSAGE

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

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

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

Generic available.

What are the potential side effects and adverse events?

Overall, Epivir-HBV is a very well-tolerated medication with minimal side effects. When side effects do occur, they include headache, nausea, fatigue, and diarrhea. Nasal symptoms and cough can occur, too. Insomnia, dizziness and muscular pain may also occur. There are two potential serious side effects when taking Epivir-HBV: (1) Lactic acidosis: The buildup of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately; (2) Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

What are the potential drug interactions?

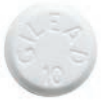
Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Epivir-HBV has no significant drug interactions. Epivir-HBV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

More information

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

Dosage of Epivir-HBV in adult patients with renal impairment

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



Hepsera adefovir dipivoxil, adefovir, or ADV

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

MANUFACTURER
Gilead Sciences

AWP
$1,991.00 / month

DOSAGE
One 10 mg tablet once daily, with or without food.

What are the potential side effects and adverse events?

Hepsera is a well-tolerated medication, with the following side effects: asthenia (weakness), headaches, abdominal pain, nausea, excessive gas, diarrhea, and dyspepsia (indigestion). These tend to be mild and manageable. As Hepsera is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine, and of serum phosphorus should be standard of care, too. There are two potential serious side effects when taking Hepsera: (1) Lactic acidosis: The buildup of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and lightheadedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately; (2) Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness, or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

What are the potential drug interactions?

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

More information

Hepsera was the second medication approved for treating HBV. Hepsera will not cure you of HBV (no HBV medication will cure you), but it can decrease your risk of long-term complications like cirrhosis or liver cancer. Although Hepsera is not an HIV medication, it does have some activity against HIV and should not be taken by itself if you are HIV-positive. If your HBV is resistant to Epivir HBV (lamivudine), use Hepsera with Epivir HBV. If your HBV viral load does not fall below 1000 copies/ml with this combination, you and your medical provider should consider alternative treatments. Hepsera is not to be used in people with decompensated cirrhosis.

If you have kidney disease and/or are on hemodialysis,

Hepsera can be taken safely, but with the following dose adjustments:

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

Baraclude entecavir, or ETV

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

MANUFACTURER
Bristol-Myers Squibb

AWP
$1,728 / month, generic $977 / month, prices for both 0.5 mg and 1 mg tablets

DOSAGE

ADULT (AGE 16 AND OLDER):
Treatment-naïve with no resistance, one 0.5 mg tablet once daily on an empty stomach (no food 2 hours before or 2 hours after taking pill); if lamivudine or telbivudine (brand name Tyzeka, discontinued for use since December 2016) resistant, 1 mg once daily on an empty stomach. Adult with decompensated liver disease: 1 mg once per day. Dose adjustments needed for individuals with kidney disease. See drug page and consult a medical provider for more detail.

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

What are the potential side effects and adverse events?

Baraclude is a very well-tolerated medication with minimal side effects. When side effects do occur, they include headache, fatigue, dizziness, and nausea. There are two potential serious side effects when taking Baraclude: (1) Lactic acidosis: The build-up of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately; (2) Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

What are the potential drug interactions?

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

More information

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

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

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

Vemlidy tenofovir alafenamide, or TAF

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

MANUFACTURER
Gilead Sciences

AWP
$1,281.00 / month

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

What are the potential side effects and adverse events?

Vemlidy is a very well-tolerated medication with minimal side effects. The most commonly reported side effects were headache, abdominal pain, fatigue, cough, nausea, and back pain. Not everyone experiences side effects, and among those who did, approximately 1% had to stop taking Vemlidy. As Vemlidy is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine, and of serum phosphorus should be standard of care, too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain, or fractures with or without muscular pain, consult your medical provider immediately. Vemlidy may lead to lactic acidosis: The buildup of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. 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).

What are the potential drug interactions?

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

More information

Vemlidy was approved for HIV in 2015 and then for HBV in 2016. It's related to Viread (see page 38), using a smaller dose that is more efficiently delivered so the risks of kidney disease and loss of bone density appear to be less. If you are co-infected with HBV/HIV, you should not treat HBV without also treating HIV. If you have HBV/HIV, and need to switch from any tenofovir-containing regimens, there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those at risk of HBV reactivation while undergoing HCV DAA treatment, Vemlidy is one of the medications you could be prescribed to prevent it from happening. Vemlidy should not be used in patients with severe kidney disease who have a creatinine clearance below 15 mL per minute. Vemlidy should not be used in patients with decompensated cirrhosis (Child-Pugh B or C).

Viread tenofovir disoproxil fumarate, or TDF

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

MANUFACTURER
Gilead Sciences

AWP
$1, 571.00 / month

DOSAGE
One 300 mg tablet once per day, with or without food. Take your missed dose as soon as possible, unless it is closer to the time of your next dose. Never double your dose.

What are the potential side effects and adverse events?

Viread is a very well-tolerated medication with minimal side effects. The most commonly reported side effects are diarrhea, nausea, asthenia (muscle weakness), headache, depression, and abdominal pain. Other, more rarely reported side effects include rash, excessive gas, and generalized pain and achiness, including back pain. Nervous system side effects include depression, insomnia, peripheral neuropathy, and dizziness. Viread may lead to decreases in bone mineral density (BMD), and patients should be monitored for osteoporosis or osteopenia. As Viread is processed by the kidneys, there is some risk of kidney toxicity. Before starting it, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine, and of serum phosphorus should be standard of care, too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain, or fractures with or without muscular pain, consult your medical provider immediately. There are two potential serious side effects when taking Viread: (1) Lactic acidosis: The buildup of lactic acid in the blood that could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately; (2) Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

What are the potential drug interactions?

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

More information

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

Intron A; Pegasys

Alfa-PEG-IFN; pegylated interferon; interferon

DRUG CLASS
Interferon-alpha

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

AWP
Pegasys: $5,580 / month

DOSAGE

Pegasys

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

Intron A

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

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

What are the potential side effects and adverse events?

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

What are the potential drug interactions?

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

More information

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

HEPATITIS B

CO-PAY AND PATIENT ASSISTANCE PROGRAMS

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

MEDICATION	MANUFACTURER	PHONE NUMBER	WEBSITE
Epivir HBV (lamivudine)	Glaxo Smith Kline	866-728-4368	gskforyou.com/eligibility
Entecavir (baraclude)	Bristol Myers Squibb	855-898-0267	bms.com/patient-and-caregiver/get-help-paying-for-your-medications.html (PAGE UNAVAILABLE)
Hepsera (adefovir)	Gilead	800-226-2056	gileadadvancingaccess.com
Viread (tenofovir disoproxil)	Gilead	800-226-2056	gileadadvancingaccess.com
Vemlidy (tenofovir alafenamide)	Gilead	800-226-2056	gileadadvancingaccess.com
Intron A (interferon alpha)	Merck	855-257-3932	merckaccessprogram.com/hcp/intron-a/
Pegasys (pegylated interferon)	Genentech	888-422-2377	genentech-access.com/patient/brands/pegasys/how-we-help-you.html

Additional financial assistance and access advocacy programs

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

HealthWell Foundation
(800) 675-8416
HealthWellFoundation.org
Offers a 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 400% of the federal poverty level.

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

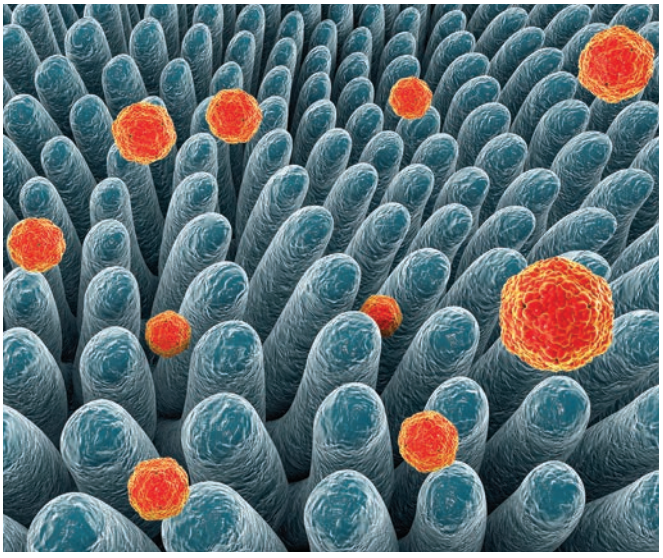
Partnership for Prescription Assistance
pparx.org
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop shopping site for over 475 public and private patient assistance programs, including around 200 offered by the drug companies themselves. They also have a directory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

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

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

HEPATITIS A: WHAT YOU NEED TO KNOW

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



HEPATITIS A VIRUS INFECTING INTESTINE.

ISTOCKPHOTO

Throughout the United States, there have been multiple outbreaks of hepatitis A (HAV), especially among people who inject drugs (PWID) and those who are homeless. Hepatitis A is not normally fatal, but for individuals with pre-existing liver disease, it can lead to death. Consequently, these recent outbreaks have led to a significant number of deaths. This box is designed to give you very basic information about HAV, including ways to prevent it so we can avoid this unnecessary loss of life from a vaccine-preventable disease.

What is hepatitis A?

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

Hepatitis A is transmitted from fecal to oral contact: When poop is inadvertently eaten. It is commonly a food-borne illness, where someone eats something that has not been properly cleaned or cooked, but it can be sexually transmitted as well through oral to anal contact.

What are the symptoms of hepatitis A?

Once infected with HAV, it usually takes about 4 weeks for the symptoms to arise. Whereas hepatitis B and C are usually asymptomatic (no symptoms), hepatitis A almost always has symptoms, some that can feel quite severe:

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

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

How is hepatitis A prevented?

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

The HAV vaccine is a safe and effective way to prevent infection. The vaccine is a two shot sequence: You get the first one and then follow up with the second one 6 months later. Depending upon the brand of vaccine used, the second dose can happen as long as 12–18 months later. There are also vaccines that have both HAV and HBV in them. If a person misses the vaccination within the allotted time period, its safe to start over as extra doses are not harmful. The HAV vaccine is safe for people with HIV, as well as those with HBV or HCV. Indeed, people living with any of these infections should be vaccinated against HAV.

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

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

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

Who should be vaccinated?

In the U.S., all children have been vaccinated since 2005. Some states started earlier. The following people should be vaccinated against HAV:

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

Hepatitis A is a preventable disease. Talk with a medical provider to see if you need to be vaccinated.

FOR MORE INFORMATION, check out the CDC's website on hepatitis A: cdc.gov/hepatitis/hav/afaq.htm.

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This ad is not intended to imply that the models pictured have HIV.

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