POSITIVELY AWARE
THE HIV TREATMENT JOURNAL OF TEST POSITIVE AWARE NETWORK
JULY+AUGUST 2016

PREVENTING HCV
FOR PEOPLE WHO INJECT DRUGS

AFTER THE HCV CURE
POST-TREATMENT CARE

HIV IS NOT A CRIME II
DECRIMINALIZATION CONFERENCE SEEKS TO BUILD A MOVEMENT

WE'RE STILL HERE
DOCUMENTARY FOCUSES ON YOUNG PEOPLE BORN WITH HIV

THE 4TH ANNUAL

HCV DRUG GUIDE

YOU'VE GOT OPTIONS

WHAT IS GENVOYA®?

GENVOYA is a 1-pill, once-a-day prescription medicine used to treat HIV-1 in people 12 years and older. It can either be used in people who are starting HIV-1 treatment and 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. These include having an undetectable viral load (less than 50 copies/mL) for 6 months or more on their current HIV-1 treatment. GENVOYA combines 4 medicines into 1 pill taken once a day with food. GENVOYA is a complete HIV-1 treatment and should not be used with other HIV-1 medicines.

GENVOYA does not cure HIV-1 or AIDS. To control HIV-1 infection and decrease HIV-related illnesses, you must keep taking GENVOYA. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

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

GENVOYA may cause serious side effects:

- **Build-up of an acid in your blood (lactic acidosis),** which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- **Serious liver problems.** The liver may become large and fatty. Symptoms of liver problems include your skin or the white part of your eyes turning yellow (jaundice), dark "tea-colored" urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight, or have been taking GENVOYA for a long time. In some cases, lactic acidosis and serious liver problems have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking GENVOYA, your HBV may suddenly get worse. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to monitor your health.

Who should not take GENVOYA?

Do not take GENVOYA if you take:

- **Certain prescription medicines for other conditions.** It is important to ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA. Do not start a new medicine without telling your healthcare provider.
- **The herbal supplement** St. John's wort.
- **Any other medicines to treat HIV-1 infection.**

What are the other possible side effects of GENVOYA?

Serious side effects of GENVOYA may also include:

- **Changes in body fat,** which can happen in people taking HIV-1 medicines.
- **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 GENVOYA.
- **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 GENVOYA.
- **Bone problems,** such as bone pain, softening, or thinning, which may lead to fractures. Your healthcare provider may do tests to check your bones.

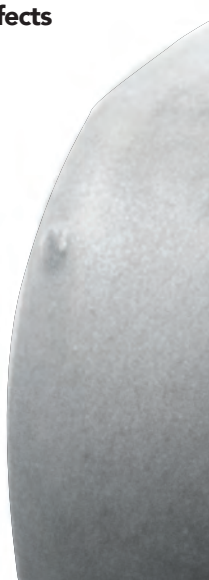
The most common side effect of GENVOYA is nausea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking GENVOYA?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how GENVOYA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Ask your healthcare provider if it is safe to take GENVOYA with all of your other medicines.
- **If you take antacids.** Take antacids at least 2 hours before or after you take GENVOYA.
- **If you are pregnant** or plan to become pregnant. It is not known if GENVOYA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking GENVOYA.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

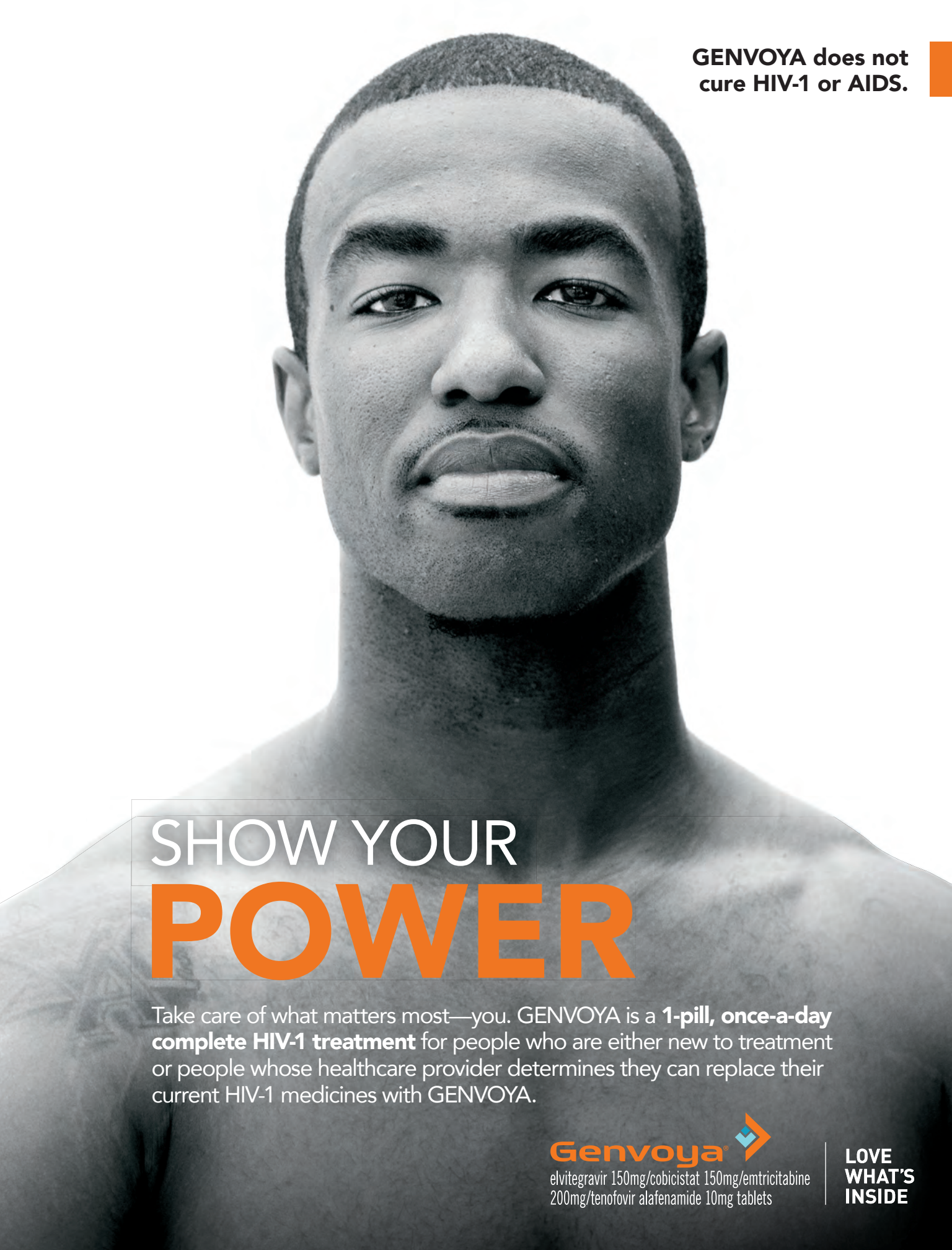
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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



Ask your healthcare provider if GENVOYA is right for you, and visit GENVOYA.com to learn more.

GILEAD


GENVOYA does not cure HIV-1 or AIDS.
SHOW YOUR
POWER
Take care of what matters most—you. GENVOYA is a **1-pill, once-a-day complete HIV-1 treatment** for people who are either new to treatment or people whose healthcare provider determines they can replace their current HIV-1 medicines with GENVOYA.
Genvoya®
elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets
LOVE WHAT'S INSIDE

Genvoya®

elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets

(jen-VOY-uh)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT GENVOYA

Genvoya® may cause serious side effects, including:

- **Build-up of lactic acid in your blood (lactic acidosis),** which is a serious medical emergency that can lead to death. Call your healthcare provider right away if you have any of these symptoms: feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- **Severe liver problems,** which in some cases can lead to death. Call your healthcare provider right away if you have any of these symptoms: your skin or the white part of your eyes turns yellow (jaundice), dark "tea-colored" urine, light-colored bowel movements (stools), loss of appetite for several days or longer, nausea, and/or stomach pain.
- **Worsening of Hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking GENVOYA. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to check your health regularly for several months.

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight, or have been taking GENVOYA for a long time.

ABOUT GENVOYA

- GENVOYA is a prescription medicine used to treat HIV-1 in people 12 years of age and older who have never taken HIV-1 medicines before. GENVOYA can also be used to replace current HIV-1 medicines for some people who have an undetectable viral load (less than 50 copies/mL of virus in their blood), and have been on the same HIV-1 medicines for at least 6 months and have never failed HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **GENVOYA does not cure HIV-1 or AIDS.** Ask your healthcare provider about how to prevent passing HIV-1 to others.

Do NOT take GENVOYA if you:

- Take a medicine that contains: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®), cisapride (Propulsid®, Propulsid Quicksolv®), dihydroergotamine (D.H.E. 45®, Migranal®), ergotamine (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), lovastatin (Advicor®, Altoprev®, Mevacor®), methylergonovine (Ergotrate®, Methergine®), midazolam (when taken by mouth), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pimozide (Orap®), rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®), sildenafil when used for lung problems (Revatio®), simvastatin (Simcor®, Vytorin®, Zocor®), or triazolam (Halcion®).
- Take the herbal supplement St. John's wort.
- Take any other HIV-1 medicines at the same time.

POSSIBLE SIDE EFFECTS OF GENVOYA

GENVOYA can cause serious side effects, including:

- Those in the "Most Important Information About GENVOYA" section.
- Changes in body fat.
- Changes in your immune system.
- New or worse kidney problems, including kidney failure.
- Bone problems.

The most common side effect of GENVOYA is nausea.

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

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

BEFORE TAKING GENVOYA

Tell your healthcare provider if you:

- Have or had any kidney, bone, or liver problems, including hepatitis infection.
- Have any other medical condition.
- 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, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA.

HOW TO TAKE GENVOYA

- GENVOYA is a complete one pill, once a day HIV-1 medicine.
- Take GENVOYA with food.

GET MORE INFORMATION

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

GILEAD

CLARIFICATION

The cover of POSITIVELY AWARE's special summer issue on aging and HIV (Our Golden Years) was photographed at the Town Hall Apartments, one of the first LGBT-friendly senior living residences in the country. The facility is co-owned by Heartland Alliance and Center on Halsted. Heartland Alliance provides property management services; Center on Halsted offers programs and on-site case management for residents.

OUR GOLDEN ISSUE

OMG! This is an amazing issue!!!! what a lineup!!!

MATHEW RODRIGUEZ

Hooray! What a fantastic lineup of voices! Many congratulations!

ROD McCULLOM

THE CARE CONTINUUM

I speak in schools from the elementary to the university level. Any chance I get, I will talk about the care continuum (Editor's Note, May+June 2016). I usually start by saying that the concept of the care continuum has been at the forefront of our knowing where we have gaps in treatment, thus leading to gaps in care and the overall state of this disease here in the U.S. The biggest eye pop, if you will, usually comes when they start to see the gaps (according to the CDC) from 82% diagnosed to 66% linked to care, then only 37% retained in care followed by the biggest gap, only 30% have reached that sought-after level of being virally suppressed. I talk about what that low level means not only for the overall health and well-being of the person but also that with that level of undetectable, this person is less infectious. You mentioned another study where some of the numbers were similar, with 55% having reached viral suppression. That's better, but still not good enough, in my opinion.

Jeff, like you, I come from a place of privilege. I receive the best of care and I have an enormous amount of support. I reached that level of viral suppression many years ago. I know for a fact we can do better. We have the knowledge and the tools so that everyone that is HIV-positive can be linked to care and be prescribed ARVs and reach undetectable, but do we have the will to do better? My dream is to live long enough to see the end of this disease.

BOB SKINNER
PRESIDENT/CEO, VALLEY AIDS INFORMATION NETWORK
CORVALLIS, OR

MEDICINES

I received your medicine issue (20th Annual HIV Drug Guide, March+April 2016) and found it very informational. As a newly diagnosed HIV-positive person, I did not know anything about it or the medicines, even the one I was taking. Finding out I had it while being incarcerated left me with very few options to get information, and I am very happy that there are magazines like yours to help people. It makes me feel that I have some support, and information is always a great form of support. I am still trying to get used to this. I do still sometimes struggle, but I refuse to let it diminish me. It has put my life in perspective. I have been diagnosed for only 10 months, but I am now considered undetectable. I do worry about having to worry about meds when I get out, but the medical staff here tells me they will help get me set up when I get released. Thank you for your magazine.

LAWRENCE ALLEN
POSEY, CAMP HILL, PA

This is one issue that I always read and take with me. I can always find something in this magazine that keeps me informed on the latest in HIV treatment and the best HIV/HCV drug guides available every year.

SCOTT DAVIS

LET'S CONNECT

TWEET:
@PosAware

EMAIL:
inbox@tpan.com

WRITE:
POSITIVELY AWARE
5050 N. Broadway, Suite 300, Chicago, IL 60640-3016

All communications (letters, email, online posts, etc.) are treated as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style, or clarity. Let us know if you prefer we not use your name and city.

POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

SINCE 1989. PUBLISHED BY
TPAN
SUITE 300
5050 N. BROADWAY
CHICAGO, IL 60640-3016
PHONE: (773) 989-9400
FAX: (773) 989-9494
EMAIL: inbox@tpan.com
positivelyaware.com
@PosAware

YOU'VE GOT OPTIONS

JUL+AUG 2016

VOLUME 28 NUMBER 5

IN EVERY ISSUE

FEATURES

ONLY ON POSITIVELYAWARE.COM

THE COVER
'YOU'VE GOT OPTIONS.'
PHOTOGRAPHY BY JOHN GRESS

THE 4TH ANNUAL HCV DRUG GUIDE
IS A COLLABORATION OF POSITIVELY AWARE AND PROJECT INFORM.

POSITIVELY AWARE

PROJECT INFORM

THE 4TH ANNUAL
HEPATITIS C DRUG GUIDE
WRITTEN AND COMPILED BY ANDREW REYNOLDS

CENTERSPREAD PULL-OUT
THE 2016 HEPATITIS C DRUG CHART

GET IN THE PICTURE.

ON THURSDAY, SEPTEMBER 22, TAKE YOUR BEST SHOT AGAINST STIGMA AS **A DAY WITH HIV** CAPTURES 24 HOURS IN THE LIVES OF PEOPLE AFFECTED BY HIV.

Grab your digital camera or smartphone and capture a moment of your day. Post the picture on social media. Include a caption—what time and where you shot your photo, and what inspired you to take it. Include the hashtag **#adaywithhiv**. Share your picture on **adaywithhiv.com** or email it to **photo@adaywithhiv.com**, and it'll become part of our gallery of images for 2016. Select images submitted to our gallery will be featured in the November+December issue of POSITIVELY AWARE.

A DAY WITH HIV **9/22/2016**

#adaywithhiv

GET AND GIVE POSITIVELY AWARE.

❑ **1-YEAR SUBSCRIPTION: $30 DONATION**
Six bi-monthly issues. Subscriptions are mailed free of charge within the U.S. to those who are HIV-positive.

❑ **ORDER BULK COPIES**
U.S. only; no overseas bulk orders. Available free of charge; however, we ask for a donation to cover shipping. Minimum order 10 copies; shipped via UPS. (No P.O. Box addresses): _____ COPIES

❑ **ORDER BACK ISSUES: $3 PER COPY**
Enclosed is my payment. Select issues below:

SUMMER 2016 ____ COPIES
MAY+APRIL 2016 ____ COPIES
MARCH+APRIL 2016 ____ COPIES
JAN+FEB 2016 ____ COPIES
NOV+DEC 2015 ____ COPIES
SEP+OCT 2015 ____ COPIES

I WISH TO DONATE:

❑ $25 ❑ $50 ❑ $100
❑ $250 ❑ $500 ❑
$_____

YOUR CONTRIBUTION HELPS
provide subscriptions to people who can't afford them. Donations are tax-deductible.

BILL TO:

NAME ON CARD

CARD NUMBER

EXPIRATION DATE SECURITY CODE

SIGNATURE (REQUIRED)

CHARGE MY: ❑ Visa ❑ MasterCard ❑ American Express
TOTAL AMOUNT: $_____
Charges will appear on your credit card statement as TPAN-PA. Test Positive Aware Network (TPAN) is a not-for-profit organization dedicated to providing support and information to all people affected by HIV.

SHIP TO:

NAME

AGENCY (AND TITLE, IF APPLICABLE)

ADDRESS

CITY STATE ZIP

PHONE E-MAIL

MAIL TO: POSITIVELY AWARE
5050 N. BROADWAY, SUITE 300
CHICAGO, IL 60640-3016

GUEST EDITOR'S NOTE
ANDREW REYNOLDS

THE BEGINNING OF THE END OF HEPATITIS C

Welcome to the 4th Annual POSITIVELY AWARE HCV Drug Guide.

We stand at the beginning of the end of hepatitis C (HCV). The only question is how fast can we end it, and so far, it's not nearly fast enough. For most people with HCV, waiting for a cure has been the norm. This made sense when the "cure" consisted of interferon and ribavirin: A year's worth of treatment with potentially debilitating side effects that maybe cured 50% of people overall was not an exciting prospect, so people waited for something better. In fact, waiting was so normal that we developed a term for it, "warehousing." Warehousing was when doctors and patients made the choice to wait for better treatment options.

And wait people did. They waited until late 2013 when the new generation of HCV direct acting antivirals (DAAs) came on the scene. Now we could talk about interferon-free regimens that were shorter, far more tolerable, easier to take, and cured 90% or more of people with HCV. It was a remarkable achievement that, in the three years since, has only gotten better with newer regimens. The wait seemed worth it and patients and their providers were ready to be cured.

As remarkable as these new treatments were, equally remarkable was their price. Media articles of $1,000 pills and sensationalistic stories of the cost burden that these new treatments would have on state and federal programs set the narrative on the access to care coverage discussion, and both public and private insurance companies set up barriers to these treatments. Some of these barriers include things like rationing access to care based on severity of liver disease (fibrosis scores), or substance use abstinence requirements before eligibility for treatment would be considered. Some coverage plans would cover treatment once, but not again if the treatment failed or the person was re-infected.

The hope for a cure was denied to most people.

In the years since, patients, providers, and advocates have fought for better access. And for all of the challenges with accessing HCV medications and the barriers patients face in getting cured, there is hope. On November 5, 2015, CMS (Centers for Medicare and Medicaid Services) released a letter to all state Medicaid programs informing them of their obligation to provide people living with HCV access to DAAs, and informing them that their restrictions were likely illegal, and setting them up for lawsuits. Indeed in recent months we've seen lawsuits or the threat of lawsuits lead to the loosening of restrictions in Washington, Florida, and Delaware. We are starting to see some private insurance carriers lift restrictions. There is much more to do to see universal access to HCV medications for all, but progress is being made.

Don't give up, and don't let perceived barriers stop you from fighting for treatment. As restrictions are lifted and more and more people are eligible for treatment and getting cured, it is our hope that this HCV Drug Guide can help you. In addition to information about the drugs themselves, we've included new material on tips for accessing treatment, resources for patient assistance, and techniques for preventing HCV. Use the resources section to learn more, and call HELP-4-HEP (I'm one of the counselors) for individualized information and support. You deserve to be cured, and we want to help.

Finally, on a personal note: It's an honor and a privilege to get to write this drug guide every year for POSITIVELY AWARE. One of my first jobs in public health was as an HIV treatment advocate for homeless people who use drugs in an impoverished neighborhood in San Francisco. I would sit with patients as they were getting ready to start HIV treatment, and together we would review the POSITIVELY AWARE HIV Drug Guide pages for her/his respective medications to prepare them. I'd make photocopies of the drug pages and together we would review the side effects and drug interactions and plan for how to overcome them. I can easily say that POSITIVELY AWARE played a seminal role in my professional development, just as I can easily say it helped the patients I worked with then, just as it does for people today.

And now I get to write for them. The editorial and design team here at PA—Jeff Berry, Enid Vázquez, and Rick Guasco—are as committed to ending HCV as they are HIV. We are lucky to have them as resources for our friends and loved ones affected by these diseases. I count myself lucky to work with them, and I can only hope that this HCV Drug Guide helps people with HCV and is as impactful as their HIV Drug Guide has been for me and the people I worked with, then and now.

Be well.

Don't give up, and don't let perceived barriers stop you from fighting for treatment. As restrictions are lifted and more and more people are eligible for treatment and getting cured, it is our hope that this HCV Drug Guide can help you.

ANDREW REYNOLDS is the Hepatitis C Education Manager at Project Inform, and facilitates several HCV support groups in the San Francisco Bay Area. He's also a counselor on the HELP-4-HEP HCV phoneline listed in the resources section of this issue. Call him if you have any questions about HCV care and treatment.

Briefly

ENID VÁZQUEZ

MSM rates of HIV

"A new report in *JMIR Public Health and Surveillance*, authored by researchers at Emory University's Rollins School of Public Health, provides state, city, and county estimates of the rate of MSM [men who have sex with men] living with HIV," states a press release from the university. Overall, the HIV prevalence in MSM in 2012 was 15% (15 in 100 MSM were living with HIV), but **the rate varies drastically by geography**.

For example, the highest rate was 39.49% in the Jackson, Mississippi region. Six states with more than 15% prevalence in MSM were all in the South and 21 of the 25 metropolitan statistical areas with the highest levels of HIV-positive MSM were in southern states. Seven out of 10 new HIV diagnoses in the U.S. occur in MSM, although they represent about 2% of the population. Read the report at publichealth.jmir.org/2016/1/e22/.

Perinatal, OI guidelines

Updates to the U.S. HIV perinatal guidelines and guidelines on opportunistic infections (OIs) in people living with HIV were released in May. The section on toxicity and pharmacokinetic (PK) data on the use of HIV medications in pregnancy was updated (see Table 7 in the guidelines). In the OI guidelines, the bacterial enteric infections section was updated to include new information on "the growing issue of antibiotic resistance among enteric bacteria, as well as updated information on the treatment of enteric infections, including in pregnant women." Go to aidsinfo.nih.gov.

Updated CDC nPEP guidelines

In April, the CDC updated its guidelines for HIV non-occupational PEP (post-exposure prophylaxis, or nPEP), in which antiviral medications are used for 28 days following exposure to the virus, in order to prevent infection. All PEP should be started within 72 hours of exposure. According to the guidelines, these updates—the first since 2005—"provide additional evidence regarding use of [nPEP] from animal studies, human observational studies, and consideration of new antiretroviral medications that were approved since the 2005 guidelines, some of which have improved tolerability." "Nonoccupational" refers primarily to sexual contact, including rape.

According to expert opinion, the best HIV meds to use after an exposure to prevent infection is a triple drug combination of Truvada plus Isentress *or* Tivicay. Certain restrictions apply, and other regimens are recommended, depending on such things as a patient's age and kidney function. There are also suggestions for putting patients on PrEP (pre-exposure prophylaxis) following PEP. See cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf.

Billing codes for PrEP

A provider's guide to billing and reimbursement for HIV and STI prevention services was published in April by the National Association of State and Territorial AIDS Directors (NASTAD). See nastad.org/resource/billing-coding-guide-hiv-prevention.

Black lives and PrEP

The report "Black Lives Matter—What's PrEP Got to Do With It?" was published by the Black AIDS Institute in April. Among the key messages: "PrEP can help end the AIDS epidemic in Black America;" "Black America needs PrEP the most;" and "When it comes to PrEP, Black America is being left behind." Read the report and its recommendations at blackaids.org/reports/black-lives-matter-whats-prep-got-to-do-with-it.

Vitekta to be taken off the market

The single-tablet regimens (STRs) Genvoya and Stribild contain elvitegravir, sold separately as Vitekta. Now Gilead Sciences is taking Vitekta off the market, since the powerhouse med is rarely used outside of those two STRs. Vitekta is scheduled to come off the market in February 2017.

Less cancer care in HIV

It's known that people living with HIV are less likely to receive cancer treatment than others, reported Gita Suneja, MD, MSHP, of the University of Utah School of Medicine, and her colleagues. They looked to see whether insurance and comorbidities (other illnesses that a person has) affect this disparity. Not quite. "In the United States, HIV-infected patients with cancer appear to be less likely to receive cancer treatment regardless of insurance and comorbidities," they concluded in their study, published in *Cancer* online in May. Still, they also found that "black race and a lack of private insurance" was a predictor of non-treatment. The study looked at data from more than 10,000 people with HIV and more than two million individuals without the virus.

Addiction and recovery survey

University of Southern California researchers are conducting an anonymous, online survey of how people resolved problems with alcohol and other drugs. "We're interested in hearing about people's experiences in addiction and recovery," the researchers wrote. "If you are aged 18 or older, believe you have ever been addicted to drugs, alcohol, or another substance, and you have substantially reduced or entirely stopped use at any point, you are eligible to participate in our study." Author William L. White, a longtime leader and trainer in addiction work and recovery, promoted the study in his blog, noting that there is a "need for research on the prevalence, pathways, styles, and stages of long-term

personal and family recovery." The survey should take 10 to 20 minutes to complete. Go to usc.qualtrics.com/SE/?SID=SV_bPC9XJshl4MBatL.

Medicaid and hep C treatment

In June, after negotiations to avoid a federal class action lawsuit, officials for the state of Delaware lifted some of its Medicaid restrictions on the treatment of hepatitis C virus (HCV). "It is unimaginable that an insurance provider would tell someone with cancer, 'We need to wait until you get really sick before we treat you.' But that's what patients in Delaware with HCV were being told, and what patients in other states are still being told," said Anna Haac of the law firm Tycko & Zavareei LLP in a press release. Read the press release at bit.ly/1sxDLUQ.

Declining condom use among gay men

The CDC reported that gay men's use of condoms here in the United States has been falling for a decade. This was true regardless of serosorting (having sex with men of their own HIV status), seropositioning (strategies for prevention based on HIV status; for example, where the HIV-positive partner bottoms to lessen the risk of infection to an uninfected partner), or the use of PrEP (for prevention). Read a report on the finding at aidsmap.com/American-gay-mens-use-of-condoms-has-been-falling-for-a-decade-regardless-of-sero-sorting-or-PrEP/page/3058699/.

HEPATITIS C BRIEFS

BY ANDREW REYNOLDS, PROJECT INFORM

HCV in semen of HIV-positive MSM

Researchers from the Icahn School of Medicine at Mt. Sinai in New York and the University of California, San Diego have reported on the presence of HCV in semen from some men living with HIV. Published in the journal *Open Forum Infectious Diseases*, the researchers found infectious levels of HCV in the semen of 11 of the 33 study participants (33%). There were no clear associations between HIV viral load in the blood, and the presence of HCV in semen, but men with higher levels of HCV in the blood did appear to have higher levels of HCV in their semen. It also does not appear that the presence of other STIs were needed to increase the level of HCV in semen. The authors conclude that condomless receptive anal sex with an HCV-infected partner can lead to HCV infection, and recommend the use of condoms to prevent said infection. You can read the study at bit.ly/1U9mHxw.

Harm Reduction Coalition releases report on safe injection facilities

With increased awareness of injection-related HIV and HCV outbreaks, as well as increased attention to the opioid epidemic and suffering that has resulted from overdose deaths, there has been much public discussion about new alternatives for reducing these harms. One such alternative has long been in use abroad: Safe injection facilities, or SIFs. SIFs, also called drug consumption rooms or safe injection sites, are "protected places for the hygienic consumption of pre-obtained drugs in a non-judgmental environment and under the supervision of trained staff. SIFs represent a public health intervention operating as part of a wider network of services for people who use drugs, woven into local networks of coordinated strategies to address the individual risks and community impact of drug use. These programs aim to reach underserved and marginalized populations, address health inequities, and resolve public health and safety tensions related to public injecting," according to a report from the Harm Reduction Coalition.

To further the discussion of the role of SIFs in the United States, the coalition convened a meeting of international law enforcement, substance use, and public health experts to discuss their experience and lessons learned with a group of advocates and public health officials. The report from this meeting concludes that:

- **People who use SIFs take better care of themselves,** reduce or eliminate their needle sharing, use their drugs more safely, and ultimately reduce their drug use;
- **SIF participants gain access to other medical and social services** and entry into drug treatment;
- **There has not been a single overdose death** in any of these programs over many years of operation and many thousands of supervised injections; and
- **SIFs do not increase drug use** in the area, nor do they encourage young people to initiate drug use;
- **Crime and public nuisance decrease** in the areas around these programs.

It's for these and other reasons that SIFs should be considered as a new alternative in our approach to substance use, HIV, HCV, and overdose prevention. As Daniel Raymond, Policy Director of the Harm Reduction Coalition, states: "The international experience with SIFs offers valuable insights for communities in the United States considering this strategy. Despite initial controversies, supervised injection facilities have proven their worth over and over again. While overdose rates continue to climb across the nation, we cannot afford to dismiss SIFs as a policy option. Supervised injection facilities provide an important tool to save lives and a new gateway to heath care, counseling, and treatment."

The report can be read at harmreduction.org/wp-content/uploads/2016/05/Alternatives-to-Public-Injection-report.pdf.

HEPATITIS C NOTES FROM EASL 2016 BARCELONA

BY ANDREW REYNOLDS

Experts on hepatitis C and other liver diseases from all around the world gathered in Barcelona April 13-17, 2016 for the European Association for the Study of the Liver's **International Liver Congress** (EASL 2016). There were a number of reports related to hepatitis C epidemiology, prevention, and treatment. The following is a selection of relevant presentations.

THE STATUE ATOP THE 197-FOOT TALL COLUMBUS MONUMENT IN DOWNTOWN BARCELONA.

Sofosbuvir/velpatasvir/ GS-9857: High cure rates in GT 1 treatment-experienced patients

Epclusa, the fixed-dose combination of sofosbuvir and velpatasvir, was FDA approved on June 28, 2016. The next regimen developed by Gilead will be this combination with a new protease inhibitor, GS-9857, included with it. Eric Lawitz and colleagues reported results from a Phase 2 study looking at this combination with treatment-experienced patients. This study had a treatment arm without ribavirin and one with it: 100% (24/24) of those without ribavirin and 96% (24/25) of those with it achieved an SVR12 (sustained virologic response at week 12, aka, cure), for an overall SVR12 rate of 98% (48/49). The one patient who was not cured had a viral relapse after completing therapy. The treatment was very well tolerated, with no one stopping the treatment because of them. It's worth noting the side effects were even fewer and better tolerated in the ribavirin-free group. This regimen was not impacted by the presence of drug resistance, and it's currently in a Phase 3 study to further test its effectiveness for treating and curing treatment-experienced patients who have fewer treatment options currently available.

ABT-493 and ABT-530: 100% SVR12 rates in treatment-naïve GT 3 patients with cirrhosis

Hepatitis C genotype (GT) 3 leads to a faster progression to cirrhosis, higher rates of steatosis (fatty liver), and higher rates of liver cancer. It can be challenging to cure, especially in those living with cirrhosis. In a study looking at the effectiveness of AbbVie's next generation of hepatitis C treatments—ABT-493 and ABT-530—Paul Kwo and colleagues showed 100% SVR12 among 24 treatment-naïve patients with GT3 and cirrhosis. It's worth noting that a comparison arm of ABT-493 + ABT-530 + ribavirin also achieved a 100% SVR12 among its 24 participants. Given the same cure rates, a ribavirin-free option for treating this patient population appears possible. The treatment was very well tolerated, with mild side effects reported and no one quitting the regimen as a result of them. Additionally, the regimen appears to overcome drug resistance. This is a small, Phase 2 study, and more evidence will be collected in Phase 3, but these results are very exciting and this treatment can play a key role in treating this difficult to cure patient population.

ABT-493 and ABT-530: 96% SVR12 rates in GT 1 patients with cirrhosis

Ed Gane and colleagues presented results from the SURVEYOR-I Study, a Phase 2 study looking at treating GT 1 patients with compensated cirrhosis given ABT-493 and ABT-530. In the study, 26 of 27, or 96%, of participants achieved an SVR12. Side effects included headaches and fatigue, but all were considered mild to moderate, and no one stopped treatment because of them. Drug resistance did not appear to impact SVR rates. This treatment will be further studied in a Phase 3 study, but these early results look very promising for the treatment of GT 1 in patients with cirrhosis with or without drug resistance.

High cure rates for GT 1 and 2 patients with 8 weeks of ABT-493 and ABT-530

Over the past five years we've seen hepatitiss C (HCV) treatment duration shorten from as many as 48 weeks down to 12 weeks, with very effective and well-tolerated medications. The next step in the development of HCV treatments is to further shorten the length of treatment. Fred Poordad and colleagues reported results from a study that looked at curing HCV GT1 and GT2 with 8 weeks of ABT-493 and ABT-530. Among the participants of this study, 97% (33/34) GT1 and 98% (53/54) GT2 achieved a cure. The cure rates were not impacted by viral load, treatment experience, or presence of drug resistance. The treatments were very well-tolerated with only one person stopping treatment due to side effects. Most significantly, there were no virologic failures among the participants. Further research with larger numbers of patients is needed, but this is a promising start for a shorter treatment to cure hepatitis C.

HIV IS NOT A CRIME: BUILDING A MOVEMENT

Biennial reflections on creating cultural change

BY OLIVIA G. FORD

In 2014, at the first HIV Is Not a Crime National Training Academy, in Iowa, participants hailed advocates in the state for successfully modernizing its outdated, stigmatizing HIV criminalization laws. When a presenter at the closing session asked "Which state will be next?" Positive Women's Network - USA (PWN-USA) Colorado advocate Kari Hartel raised her hand on behalf of their state. "I remember seeing her hand go up," Barb Cardell, also of PWN-USA Colorado, recalled, "and thinking, 'Well, damn! Now we have to figure out how to pull this off.'"

Thus the Colorado Mod Squad ("mod" stands for "modernization" of the law), a diverse task force led by women living with HIV, was born. By the time advocates from 34 states and four countries came together for the second HIV Is Not a Crime gathering in Huntsville, Alabama, from May 17-20, 2016, they were celebrating the Mod Squad's victory in the Colorado legislature—the second such win in the nation. As the new bill awaits the governor's pen, there are 44 U.S. states where such stalwart advocacy is needed: where HIV stigma is still codified into laws, or sentence enhancements, that criminalize people for living with a health condition, and have terrible effects on public health.

"The lesson we have learned from the successes in Iowa and Colorado is that people living with HIV must be meaningfully involved in the decision-making processes," said Tami Haught, who led Iowa's modernization efforts and was a key organizer of both training academies. People living with HIV made up more than two-thirds of the advocates that came to Huntsville to learn how to fight HIV criminalization in their states. There were nearly 300 attendees overall—almost double the number in 2014.

A biennial event provides a critical benchmark for observing the development of a project, a community, or a movement. "[Since 2014], the effort to combat HIV criminalization has become linked in important ways with related movements addressing racial justice, sex work organizing, drug policy, and penal system reform," said Sean Strub, executive director of the Sero Project, which, along with PWN-USA, co-convened the gathering. "It is increasingly becoming an interwoven quilt of advocacy for profound change in how we understand, pursue, and embrace justice."

POSITIVELY AWARE asked presenters and participants at the Huntsville training academy to reflect on the progress they wish to see in this epic human rights endeavor in the next two years.

The growth and (hopeful) success of more statewide campaigns. "It took Iowa five years," Strub explained to activist and blogger Mark S. King in a video interview at the training academy. "Colorado did it in two years." (Watch the video at youtube.com/watch?v=Dpw7d0AuJ80.) Though a number of states, including Michigan, Georgia, Idaho, and Florida, are now home to nascent campaigns (in part thanks to the 2014 training), predicting the next success story is challenging. "Each state is different, from different laws to different legislative makeup," said Haught. "We were able to provide basic advocacy strategies for everyone; it is then up to state advocates to adapt to fit their specific needs."

Nina Martinez, who engages in HIV decriminalization advocacy in Georgia, would like to see advocates look beyond state legislatures. "Why aren't there more constitutional (judicial) challenges to HIV criminalization laws? Why aren't we appealing to heads of state (executive branch)?" she asked. "Criminalization is the most stigmatized of all advocacy issues, and we're going to have to get creative."

More available data on the realities and impacts of HIV criminalization. To make their case, advocates need data supporting their messages. Legal and social science research on HIV-related criminal cases is sorely lacking. But committed investigators like Trevor Hoppe of the State University of New York at Albany and others, as well as institutions like the Center for HIV Law and Policy and the Williams Institute at UCLA Law School, have contributed to this pipeline of research.

"We need more data on the public health harms of HIV criminalization in the US context," stated Edwin Bernard, one of the world's foremost anti-criminalization advocates and the coordinator of HIV Justice Worldwide. "Rights-based arguments—convincing as they are for advocates and our intersectional allies, and the reason many of us do this work—may not be enough to change the hearts and minds of policymakers."

Embracing linkages with intersecting communities and movements. "Many of the communities impacted by HIV criminalization are generally at risk for being targeted by law enforcement, may regularly face police brutality, and are unlikely to have good representation in a court of law," said Naina Khanna, executive

director of PWN-USA. "We can't fight HIV criminalization as a single battle, without looking at these other issues impacting our community."

According to Ashton Woods—a Houston-based activist in many intersectional communities, including HIV, LGBT, and the Movement for Black Lives—the HIV decriminalization movement needs "partnerships with groups, organizations, and persons that are already doing the work around [other forms of] criminalization. That provides a foundation and infrastructure to build a real-time system for information sharing, response to incidents, and a cohesive way to speak with legislators."

Derek Demeri, a sex worker rights advocate in New Jersey, looks forward to the strengthening of these alliances. "Given how these laws are overwhelmingly applied to sex workers across the country," Demeri said, "it is time the sex work community deepens our involvement in these strategic meetings."

Diane Burkholder, an anti-oppression consultant and co-founder of One Struggle KC, which does Movement for Black Lives work in Kansas City, worked in HIV service organizations for many years. She is wary of what she sees as the directive in HIV decriminalization advocacy to "play nice" with lawmakers. "I find this very interesting, considering the momentum of those involved in the Movement for Black Lives," said Burkholder. "If Black folks are disproportionately affected by HIV, especially Black youth … why aren't we taking their lead?

"This movement against HIV criminalization laws must be made palpable for folks who don't want to engage in conversations about HIV."

On the HIV community side, urged Maxx Boykin, manager of the HIV Prevention Justice Alliance and a leader in the Black Youth Project 100's Chicago chapter: "We have to start having conversations about: What *is* anti-Blackness? What is the war on drugs? How do many of our laws already affect us in racist ways?

"When we talk about this in the overall context of the war on drugs, and the criminalization of Black bodies," he added, "that is where HIV decriminalization, to me, comes in. … I don't think that a lot of people who have had wins in this arena are ready for [those conversations]."

Marco Castro-Bojorquez—a California-based filmmaker and a community educator at Lambda Legal, points out the importance of defining and outlining what *intersectionality* (the idea that multiple aspects of a person's identity simultaneously impact their life and outcomes) means for advocacy work. He suggests that, "advocates, lawmakers, and the community in general can have a common understanding … to address the fear of the unknown that people have when they hear terms like 'intersectionality' or 'interlocking oppressions.'"

"Greater attention to the nuances and complexities of modernizing versus repealing laws" is another of Bernard's expectations for the movement to end HIV criminalization in the coming years. Boykin agrees: "There needs to be more education on what is true decriminalization," he said. "In mobilizing the communities that are most impacted by HIV, I don't believe you will get large amounts of our communities coming out [against HIV criminalization] when we talk about simply modernizing laws that can still harm us—that can still be used to criminalize young Black people."

Demeri has similar concerns about the compromise inherent in talking about modernizing laws, rather than working to get rid of them altogether. "Until these laws are repealed … the language will still be manipulated and distorted as a means to arrest people who are looked upon as 'vectors of disease'." He warned: "If you want to include the sex work community, then do not expect our involvement, only to throw us under the bus later, as some advocates have done."

Greater attention to *how* advocacy work is done. At the training academy, conversations emerged regarding models for engaging in advocacy in ways that are just, growthful, and creative, that resist interpersonal violence and support building connections within and across communities, as part of a strategy for ending HIV criminalization.

Randall Jenson, director of the LGBTQ media company SocialScope Productions, presented on the anti-oppression, trauma-informed, and harm reduction frameworks that have been central to his years of work with LGBTQ and HIV-positive survivors of violence—and all LGBTQ people, Jenson asserts, are survivors of the traumas of homophobia and transphobia. These frameworks open up space to address the fact that even people in the same community can potentially perpetrate harm with respect to one another, and can have different experiences of the dynamics of privilege, structural power, and oppression. Community members can also mobilize to support and help one another heal.

"Harm reduction would say: How to reduce the harm and the trauma that this

TOP: Maximillian Mathis Boykin discusses intersectionality; panel on anti-blackness with Akil Patterson, Tyrone Hanley, and Isaiah Wilson. **MIDDLE:** Workshop on the impact of criminalization on the transgender community; with NASA space exhibits as a backdrop, Sean Strub addresses the closing reception held at the U.S. Space and Rocket Center. **BOTTOM:** Members of the Colorado Mod Squad celebrate their victory with keynote speaker and Colorado state senator Pat Steadman (center). PHOTOS COURTESY OF PWN-USA.

person is going through? How to meet them where they are at?" Jenson envisions communities, and movements, where these approaches are incorporated at all levels of work, with firm commitments from leaders—and attention to explaining to members what these approaches mean. "We cannot assume all are coming in with the same level of understanding," Jenson said; "there has to be room for ground work."

Woods also supports "anti-oppression models that have embedded education on privilege, life chances, and other factors that vary by race and gender.

"Many good people out there want to do this work," he said, "but they often drown out the voices of those most affected by current issues surrounding HIV."

Castro-Bojorquez would like to hear more advocates expound on the language around "cultural factors" that negatively impact HIV outcomes—and use culture as an organizing tool and a positive force. "Why don't we look at infrastructure and access," he said, "and the cultural capacity of those folks that have no problem diminishing the only thing that keeps us going?"

Micky Bradford, regional organizer for Transgender Law Center and Southerners on New Ground, summed up HIV criminalization in this way: "The problem is both legislative and cultural. It will take a movement of radicals, artists, and 'angelic troublemakers,' as Bayard Rustin coined, to end state violence against all our people—but especially transgender and gender-nonconforming folks living with HIV in the South.

"What is a law," Bradford said, "but the culture of the time crystallized and executed?" PA

OLIVIA G. FORD has been engaged with HIV-related media since 2007. She currently works as a freelance editor and writer, and is based in New Orleans.

WE'RE STILL HERE

DOCUMENTARY TELLS THE STORIES OF YOUNG PEOPLE BORN WITH HIV

BY ENID VÁZQUEZ

"WE WERE TRYING to make sense of it all before we could even fully develop into who we were as people … and these experiences have shaped our lives for better or for worse," says filmmaker Grissel Granados in a voiceover for *We're Still Here*, a short documentary that tells the stories of five young adults who were born with HIV back in the '80s.

"This community has really been forgotten," said her co-producer, John Thompson, a social worker and activist who works with Granados at Children's Hospital in Los Angeles. "One of the first things people say when you talk to them about perinatally infected youth is, 'Didn't all those babies die in the '80s?' This film was created to raise the awareness that this community is still here."

Born in Mexico City, Granados was not diagnosed until she moved to Los Angeles at the age of five with her mother and sister, following the death of her father from HIV-related complications. Her mother, Silvia Valerio, traced her infection to a blood transfusion; she remains active as an advocate for people living with HIV, as well as working as a peer navigator at Bienestar in Los Angeles, where she focuses on transgender women.

Granados has talked publicly since she was 12 about growing up as a child who was born with HIV. In her journey—including her appointment as one of the youngest members of the Presidential Advisory Council on HIV/AIDS (PACHA)—she realized there was little awareness about this chapter of the epidemic, the children born with the virus who survive to this day. She also felt a need to reach out to others who shared her experience.

"The way we were told [about having the virus] also impacted our relationship with our own HIV and how open we were about it," Granados noted in the film. "Those of us who received positive messaging grew up embracing our status at a young age, while those who grew up receiving stigmatizing messages grew up with more fear … shame."

In *We're Still Here*, poet and musician Mary Bowman reads her poem "Dandelions," in which she first publicly revealed her positive status, and which also shows her strength.

Playing guitar in a punk rock band helps Nestor Rogel survive not just the virus, but the many demons of his past. "When I was younger, I thought it didn't matter what I did, I was going to die. I didn't really see a future for myself," says Rogel in the film. Taking his cue from one sister's advice, he says, "I can choose to live a happy and normal life, or I can choose to let the weight of the world sink in and swallow me up."

Alison Luker is now a wife and the mother of three small children. She talks about how as a child, she only felt open and free while at Camp Laurel, where she met other children living with the virus. "I felt safe and secure at camp, but I knew that when I went back home I would have to… face realities. I was back to the world of stigma, where I was the outcast again." Granados met both Luker and her brother Jimmy, who passed away in 2013, at camp. The documentary is dedicated to him.

Artist and dancer Kia Michelle Benbow, aka Kia Lebeija, talks about bringing "Disney" colors to her photographs relating to HIV loss, including the death of her mother. She talks about taking medicine, disclosure in school, and her own mortality after the

PHOTOS COURTESY OF JOHN THOMPSON AND GRISSEL GRANADOS

FROM LEFT, TOP TO BOTTOM: Grissel Granados; Nestor Rogel; Mary Bowman; Midnight Urge rehearses.

death of her "super woman" mom.

"In the '80s and '90s," Granados says in *We're Still Here*, "while people were watching their friends, family, and lovers die *en masse*, we were there too. The friends we lost were other kids, and the family we lost were our parents and siblings."

In her interviews and in the art produced by the young people in the film, there's a range of themes such as being ostracized and the death of their parents. Granados, however, wanted to show their strength and triumphs as well. She said stories about living with HIV too often get stuck in tales of trauma. "For me," said Granados, "one of the important parts about the film is focusing more on the resilience that people have." It provides, she added, "a different narrative" for talking about people living with HIV, and "the characteristics that we have, which is more than all of the challenges and all of the trauma that we have faced."

Granados found that they all used creativity as an important part of their life, "whether it was art, music, poetry, or family."

Another similarity was that everyone talked about the death of their mother, except for Granados, because it was her father who had died. "As children, it was our parents telling our stories," said Granados, "but in this situation, it is our opportunity to tell the stories of our parents. So I think the film demonstrates not just how HIV impacted children since the beginning of the epidemic, but also women and people of color."

"It comes out through the stories, a division between different members of the HIV community," said John Thompson. "These aren't just the stories of people born with HIV, but they're the stories of women living with HIV, of communities of color, the stories of how HIV is connected to poverty and to other kinds of social problems. It's really a way to talk about those intersections and to build bridges rather than maintain those divisions."

Thompson and Granados each earned a master's of social work from the University of Southern California; at Children's Hospital Los Angeles, Thompson is a clinical social worker working with youth and young adults living with HIV, while Granados works as a program coordinator in prevention. Part of her work is to oversee a prevention project aimed at gay and bisexual young men of color, as well as transgender youth of color. In their work, both have noted a misunderstanding among medical providers about the existence of adults who were born with HIV, and as a result, a diminished ability to address the needs of this population, such as addressing sexuality and childbearing. They hope that *We're Still Here* can serve as an educational tool for both providers and advocates.

They also felt the need to connect the members of this neglected group, whose stories are rarely heard.

"We hoped to create a sense of community in this population," said Thompson. "Grissel needed a way to connect with other people that were also born with HIV in the 1980s."

It appears that others born with HIV needed her too. "People have reached out to us after seeing the film," she said, "to ask whether there are any resources or any spaces for them to connect. There really isn't anything." She said they see that as another goal, how to support a digital space for people born with HIV to connect with each other and resources for providers who want to know more about this population and how to work with them. PA

FOR MORE INFORMATION or to schedule a screening, go to werestillherefilm.com.

Chicago Dancers United *presents*

dance for life CHICAGO 25

PHOTOGRAPHY **Sandro** | DANCER **Tom Mattingly**

August 20, 2016

5pm
Hilton Chicago's
Grand Ballroom

7:30pm
Auditorium Theatre
of Roosevelt University

PERFORMANCES BY
Giordano Dance Chicago
Hubbard Street Dance Chicago
Joffrey Ballet
Chicago Dance Crash
Visceral Dance Chicago

WORLD PREMIERES BY
Randy Duncan
Harrison McEldowney

EMCEES
Carisa Barreca and Tim Mason
of The Second City

BENEFICIARIES
The Dancers' Fund
AIDS Foundation of Chicago

$15 – $75 *Performance Only*

$250 – $600 *Includes admission to the 5:00p.m. gala reception and premiere seating at the performance*

SPONSORS

ALPHAWOOD FOUNDATION CHICAGO · ATHLETICO PHYSICAL THERAPY · AUDITORIUM THEATRE of ROOSEVELT UNIVERSITY · BELLLITHO, inc. · CENTER ON 3656 N. HALSTED · JEWELL EVENTS · CATERING

J&L CATERING · Hilton CHICAGO · HMS MEDIA · BARBARA LEVY KIPPER · mb financial bank · N·I·B FOUNDATION · PaternoGroup PRINT & eMEDIA DESIGN

MEDIA PARTNERS

a&u Magazine | 4Dancers.org | Best Gay Chicago | ChicagoPride.com | GC Magazine
GRAB Magazine | Positively Aware Magazine | SDC Chicago
SeeChicagoDance.com | Windy City Media Group

ChicagoDancersUnited.org | 312-922-5812

/DanceForLifeChicago · @danceforlifechi · /DanceForLifeChicago

HOW TO USE THIS GUIDE

THE HCV DRUG GUIDE INCLUDES medications that are FDA approved, expected to be approved this year, or are likely to be approved through June 2017. 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), conference presentations and medical journals. For the non-FDA-approved drugs, the information comes from conference presentations, and medical journals.

Treatment for HCV will comprise two or more medications taken together, and some of these may be two (or more) separate pills (for example Daklinza with Sovaldi), or a fixed-dose combination (FDC) pill which contains medications from two (or more) different classes (for example Viekira Pak).

Each drug page will include:

Drug names

DRUG NAMES CAN BE very confusing. We include the brand name, the generic name, and often an abbreviation. For example, Sovaldi is the brand name of sofosbuvir. Sovaldi can be abbreviated as SOV, and sofosbuvir is abbreviated as SOF. Drugs that have been FDA-approved will have a brand name, while those that have not yet reached that stage will only have a generic (or common) name. In some cases, it might not even have a name, but rather a series of letters and numbers (for example, MK-5172). For those drugs which have been FDA-approved, the brand name will appear first, at the top of the page, followed by the common name(s); for all other drugs the common or generic name will appear first.

FDA status

WE WILL INDICATE if a drug is approved, and any drug that has been submitted for FDA approval will have an estimate of its approval date.

Drug class

THE "DIRECT ACTING ANTIVIRAL" or DAA era of HCV treatment has seen the development of several different classes as well. Currently, there are five classes of HCV drugs, and five multi-class fixed dose combinations (with Epclusa, the SOF/VEL combination, approved by the FDA in June of 2016):

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

Genotype

GENOTYPE (GT) REFERS to the strains or variations of HCV. Worldwide, there are probably 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 off-label.

Dosage

HCV DRUGS ARE TAKEN in a variety of ways, 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

STAY TUNED TO POSITIVELY AWARE (POSITIVELYAWARE.COM) AND PROJECT INFORM (PROJECTINFORM.ORG) FOR UPDATES AND NEWS ON HEPATITIS C MEDICATIONS, PREVENTION, AND TREATMENTS.

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 are very 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 35.

Potential side effects and adverse events

THIS SECTION OFFERS information about side effects and adverse events associated with the HCV drugs. It's not an exhaustive list, but rather a selection of the most commonly reported side effects. The information comes from the package insert and study data for the FDA-approved drugs, and clinical trial data for the ones that have yet to receive FDA approval. 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.

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, and clinical trial data for the ones that have yet to receive FDA approval.

More information

THIS SECTION CONTAINS information that does not fit in any of the above sections, but is still important for you to know.

What's new in 2016?

WE HAVE SEEN several changes since last year's publication of the HCV Drug Guide: Pegylated interferon has been removed from this year's guide. This injectable medication was the standard of care (in combination with ribavirin) for over a decade, but it was a medicine that was taken over a long period of time, with severe side effects and a low cure rate. Today's medications do not need to use interferon any longer, but it can be found on positivelyaware.com.

We saw the FDA approval of the drugs Technivie, Daklinza, and Zepatier, as well as updates to Sovaldi, Harvoni, and Viekira Pak.

Most recently, approved by the FDA on June 28, Epclusa marks an exciting development in the treatment of HCV: A medication that treats all genotypes taken once daily without ribavirin and potentially curing HCV in as little as 12 weeks with minimal side effects.

WHICH HCV TREATMENT IS RIGHT FOR ME?

A quick guide to hepatitis C treatment options in 2016

BY ANDREW REYNOLDS

FIVE YEARS AGO, the list of hepatitis C (HCV) treatment options would have been very short. We now have seven FDA approved direct acting antivirals (DAAs), as well as ribavirin, for treating all HCV genotypes. With so many options, there can be confusion over what treatment to take.

PHOTO: ISTOCKPHOTO

AASLD/IDSA HCV TREATMENT GUIDELINES

THERE ARE MANY treatment options for people with various 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 goes for patients and providers alike!

The American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of American (IDSA) have produced a guide to help medical providers with expert guidance on screening, managing, and treating HCV. This brief article is designed to provide you with a listing of these

recommendations for treating HCV in treatment-naïve patients with and without cirrhosis. All of these treatments are FDA approved, but they also include some "off-label" options (that is, not FDA approved for a particular use but shown to be effective for that condition or population) for people with HCV.

As you will see on the next page, treatments are now shorter and more effective now than ever before. 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 first-line (first-time treatment) recommendations 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 will 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.

What about HIV/HCV co-infection?

EVERYONE LIVING WITH HIV and most everyone living with HCV should be treated for those infections, according to U.S. guidelines for the two conditions. 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, the combination of Daklinza plus Sovaldi is an option.

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.

YOUR GENOTYPE, YOUR

I have genotype 1A,
have never been on treatment before, and do not have cirrhosis. What can I take?

- **Zepatier** for **12 weeks** (16 weeks if NS5A resistant)
- **Harvoni** for **12 weeks**
- **Viekira Pak + ribavirin** for **12 weeks**
- **Olysio + Sovaldi** for **12 weeks**
- **Daklinza + Sovaldi** for **12 weeks**
- **Epclusa** for **12 weeks**

I have genotype 1A
and have never been on treatment before, but I do have compensated cirrhosis. What can I take?

- **Zepatier** for **12 weeks** (16 weeks if NS5A resistant)
- **Harvoni** for **12 weeks**
- **Epclusa** for **12 weeks**

I have genotype 1 ("A" or "B"),
have decompensated cirrhosis, and can take ribavirin. What can I take?

- **Harvoni + ribavirin** for **12 weeks**
- **Daklinza + Sovaldi + ribavirin** for **12 weeks**
- **Epclusa + ribavirin** for **12 weeks**

I am genotype 2,
have never been on treatment, and do not have cirrhosis. What can I take?

- **Sovaldi + ribavirin** for **12 weeks**
- **Daklinza + Sovaldi** for **12 weeks**
- **Epclusa** for **12 weeks**

I have genotype 2
and decompensated cirrhosis. What can I take?

- **Daklinza + Sovaldi + ribavirin** for **12 weeks**
- **Epclusa + ribavirin** for **12 weeks**

I have genotype 1B,
have never been on treatment before, and do not have cirrhosis. What can I take?

- **Zepatier** for **12 weeks**
- **Harvoni** for **12 weeks**
- **Viekira Pak** for **12 weeks**
- **Olysio + Sovaldi** for **12 weeks**
- **Daklinza + Sovaldi** for **12 weeks**
- **Epclusa** for **12 weeks**

I have genotype 1B
and have never been on treatment before, but I do have compensated cirrhosis. What can I take?

- **Zepatier** for **12 weeks**
- **Harvoni** for **12 weeks**
- **Viekira Pak** for **12 weeks**
- **Epclusa** for **12 weeks**

I have genotype 1 ("A" or "B"),
and decompensated cirrhosis, but I cannot take ribavirin. What can I take?

- **Daklinza + Sovaldi** for **24 weeks**
- **Harvoni** for **24 weeks**
- **Epclusa + ribavirin** for **12 weeks**

I have genotype 2,
have never been on treatment, and have compensated cirrhosis. What can I take?

- **Daklinza + Sovaldi** for **16 to 24 weeks**
- **Sovaldi + ribavirin** for **16 to 24 weeks**
- **Epclusa** for **12 weeks**

TREATMENT

I have genotype 3, have never been on treatment, and do not have cirrhosis. What can I take?

Daklinza + Sovaldi for **12 weeks**
Epclusa for **12 weeks**

I have genotype 3 and decompensated cirrhosis. What can I take?

Daklinza + Sovaldi + ribavirin for **12 weeks**
Epclusa + ribavirin for **12 weeks**

I have genotype 4 and have never been on treatment before, but I do have compensated cirrhosis. What can I take?

Technivie + ribavirin for **12 weeks**
Zepatier for **12 weeks**
Harvoni for **12 weeks**
Epclusa for **12 weeks**

I have genotype 5, have never been on treatment, and I have compensated cirrhosis. What can I take?

Harvoni for **12 weeks**
Epclusa for **12 weeks**

I have genotype 5, have never been on treatment, and I don't have cirrhosis. What can I take?

Epclusa + ribavirin for **12 weeks**

I have genotype 6, have never been on treatment, and I have compensatd cirrhosis. What can I take?

Harvoni for **12 weeks**
Epclusa for **12 weeks**

I have genotype 3 and have never been on treatment, but I do have compensated cirrhosis. What can I take?

Daklinza + Sovaldi with or without ribavirin for **24 weeks**
Epclusa for **12 weeks**

I have genotype 4, have never been on treatment before, and have cirrhosis. What can I take?

Technivie + ribavirin for **12 weeks**
Zepatier for **12 weeks**
Harvoni for **12 weeks**
Epclusa for **12 weeks**

I have genotype 4, and I have decompensated cirrhosis. What can I take?

Harvoni + ribavirin for **12 weeks**
Epclusa + ribavirin for **12 weeks**
Daklinza + Sovaldi + ribavirin for **12 weeks**

I have genotype 5 and have decompensated compensated cirrhosis. What can I take?

Epclusa + ribavirin for **12 weeks**

I have genotype 6, have never been on treatment, and I don't have cirrhosis. What can I take?

Harvoni for **12 weeks**
Epclusa for **12 weeks**

I have genotype 6, have decompensated cirrhosis. What can I take?

Epclusa + ribavirin for **12 weeks**

What about treatment-experienced patients, that is, people who tried treatment before, but it didn't work?

THERE ARE MANY OPTIONS currently available for treatment-experienced patients (and several more currently in development), but it can be complicated to decide which one is right for you. Your provider will need to know your treatment history, possible HCV drug resistance, and your overall liver health before she/he can decide which regimen is right for you. The AASLD/IDSA HCV Guidance does have a long list of recommendations with each of these variables, but due to the complications and space constraints of this guide, they are not listed here. They can, however, be found in the online version of this article, at positivelyaware.com.

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 to take.

Conclusions

THERE ARE MANY treatment choices available for people living with HCV. The charts are a snapshot of these 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.

HEPATITIS C MEDICATIONS
BY DRUG CLASS

CLASS	GENERIC/ COMMON NAME	BRAND NAME	FDA STATUS	GENOTYPE (FDA AND OFF-LABEL)	APPROVED FOR HIV/HCV CO-INFECTION?	MANUFACTURER	FIND IT ON PAGE
NS3/4A protease inhibitor	simeprevir, SMV	**Olysio**	APPROVED	1 4	YES	Janssen	34
NS3/4A protease inhibitor	paritaprevir	FOUND IN **Viekira Pak** AND **Technivie**	APPROVED	Viekira Pak: 1 Technivie: 4	YES	AbbVie	34, 35
NS3/4A protease inhibitor	grazoprevir	FOUND IN **Zepatier**	APPROVED	1 4	YES	Merck	32
Nucleotide NS5B polymerase inhibitor	sofosbuvir, SOF	**Sovaldi** ALSO FOUND IN **Epclusa** AND **Harvoni**	APPROVED	1 2 3 4	YES	Gilead Sciences	29, 30
NS5A inhibitor	ledipasvir, LDV	FOUND IN **Harvoni**	APPROVED	1 4 5 6	YES	Gilead Sciences	29
NS5A inhibitor	daclatasvir, DCV	**Daklinza**	APPROVED	3	YES	Bristol-Myers Squibb	33
NS5A inhibitor	ombitasvir	FOUND IN **Viekira Pak** AND **Technivie**	APPROVED	Viekira Pak: 1 Technivie: 4	YES	AbbVie	34, 35
NS5A inhibitor	elbasvir	FOUND IN **Zepatier**	APPROVED	1 4	YES	Merck	32
NS5A inhibitor	velpatasvir, VEL, (GS-5816)	FOUND IN **Epclusa**	APPROVED	1 2 3 4 5 6	NO	Gilead Sciences	31
Non-nucleoside NS5B polymerase inhibitor	dasabuvir	FOUND IN **Viekira Pak**	APPROVED	1	YES	AbbVie	34
Nucleoside analog	ribavirin, RBV	**Moderiba**	APPROVED	1 2 3 4 5 6	YES	AbbVie	37
Nucleoside analog	ribavirin, RBV	**Ribasphere**	APPROVED	1 2 3 4 5 6	YES	Kadmon	37

Harvoni

COMMON NAMES: ledipasvir/sofosbuvir, LDV/SOF

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

FDA STATUS
✔ APPROVED

GENOTYPE
1 4 5 6

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
A fixed-dose combination (FDC) 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 weeks of treatment is possible. See chart this page for duration indications.

MANUFACTURER
Gilead Sciences

AWP
$37,800 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
Harvoni is a very well tolerated medication with minimal side effects. The most commonly reported side effects are fatigue, headache, nausea, diarrhea, and insomnia. In all cases, the side effects were considered mild and discontinuing Harvoni because of them 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 while undergoing treatment. Harvoni 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. It is recommended that Harvoni should only be used during pregnancy if the potential benefit outweighs the potential risk.

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. Harvoni cannot be taken with the antiarrhytmic medication amiodarone. Several cases of serious symptomatic bradycardia (a potentially dangerous, very low heart rate) have occurred with this combination; see the Sovaldi page for more information. Harvoni should not be taken within four hours of antacids. H2 blockers (such as famotidine, brand name Pepcid, and ranitidine, brand name Zantac) can be taken at the same time as Harvoni or 12 hours apart at a dose not higher than a comparable dose of Pepcid 40 mg twice daily; Zantac 150 mg twice daily; Tagamet 800 mg twice daily. Proton pump inhibitors (PPIs) can be taken with Harvoni at the same time, on an empty stomach, at doses comparable to 20 mg or less of omeprazole (Prilosec) or Aciphex; Prevacid 30 mg daily; Protonix 40 mg daily. See more information below. Do not take with the HIV antiretrovirals Aptivus/Norvir (tipranavir/ritonavir), elvitegravir (found in Genvoya and Stribild), cobicistat (Tybost, found in Evotaz, Genvoya, Prezcobix, and Stribild), emtricitabine (Emtriva, found in Atripla, Descovy, Genvoya, Odefsey, Stribild, and Truvada), or tenofovir DF; tenofovir levels may be increased, and it has not been studied in terms of safety. Consider alternative HCV or HIV regimens to avoid these combinations, and monitor for tenofovir-related adverse events if taken together. Safe to take with other HIV antivirals with no clinically relevant changes or dose adjustments necessary; there are no interactions with methadone. The following cannot be taken with Harvoni: St. John's wort, rifampin, rifabutin, or rifapentine. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the therapeutic effectiveness of Harvoni.

MORE INFORMATION
Harvoni was an exciting development for treating HCV: One pill, once daily potentially curing HCV in as little as 12 or 24 weeks with minimal side effects was an astounding achievement. The FDA has updated who can be treated with this medication since its approval: Genotype 4, 5, and 6; HIV/HCV co-infected persons; treatment-experienced patients; those with decompensated cirrhosis; and post-transplant patients can all take Harvoni.

Harvoni treatment durations
FOR HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

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

Sovaldi

COMMON NAMES: sofosbuvir, SOF, SOV
DRUG CLASS: Nucleotide analog NS5B polymerase inhibitor

FDA STATUS
✔ APPROVED

GENOTYPE
1 2 3 4

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
Take one 400 mg tablet once daily with or without food; must be taken in combination with either ribavirin or pegylated interferon and ribavirin (see this page for more 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.

MANUFACTURER
Gilead Sciences

AWP
$33,600 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

When Sovaldi is taken with pegylated interferon and ribavirin (not recommended for use any longer, except for people with GT3 and cirrhosis) 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. When Sovaldi is used with ribavirin, women of childbearing age and their male partners must use two forms of birth control. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Sovaldi may interact with other drugs: 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, before starting this regimen, and inform them of any changes as they happen.

After FDA approval, several cases of symptomatic bradycardia, and cases of fatal heart attacks and cases requiring a pacemaker, have been associated with the use of sofosbuvir with amiodarone. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness and excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these occur. The mechanism for this is unclear, but no sofosbuvir-based HCV regimens are to be used with amiodarone. Sovaldi is safe to take with HIV antivirals except Aptivus/Norvir (tipranavir/ritonavir), with no clinically relevant changes or dose adjustments necessary. Sovaldi has no interactions with methadone. The following cannot be taken with Sovaldi: 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 has a lot of "firsts": first drug of its class; first drug to receive FDA approval for use without interferon, and first DAA to receive FDA approval for use in HIV/HCV co-infected patients. Sovaldi with ribavirin remains the recommended regimen for GT 2, and is still an option for GT 3. Sovaldi has been shown to be effective in both fixed-dose combinations and taken separately with other HCV DAAs: Harvoni is a fixed-dose combination of Sovaldi and ledipasvir for the treatment of genotype 1, 4, 5, and 6 (see drug page for more information on this combination). The combination of Sovaldi and Olysio with or without ribavirin received FDA approval in late 2014, and remains an option for the treatment of GT 1. The approval of the BMS drug Daklinza (see page 33), a drug that has also been shown to be highly effective when used with Sovaldi, has created new treatment opportunities, particularly for people with the harder-to-treat genotype 3, and has shown excellent results in people with HIV/HCV co-infection. And finally, Sovaldi is part of the newest FDC from Gilead, Epclusa (sofosbuvir/velpatasvir), for the treatment of all HCV genotypes.

Sovaldi approved treatment durations

HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

GENOTYPE	PATIENT POPULATION / TREATMENT LENGTH
1 4	**Sovaldi + pegylated interferon + ribavirin:** 12 weeks
2	**Sovaldi + ribavirin:** 12 weeks
3	**Sovaldi + ribavirin:** 24 weeks

Epclusa

COMMON NAMES: sofosbuvir/velpatasvir, SOF/VEL

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

FDA STATUS
✔ APPROVED

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
NOT FDA APPROVED FOR CO-INFECTION, but off-label use is possible.

DOSAGE
One fixed-dose combination of sofosbuvir 400 mg/velpatasvir 100 mg tablet once daily, with or without food.

MANUFACTURER
Gilead Sciences

AWP
$29,904 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Sde effect data come from conference presentations and articles from peer-reviewed journals. A complete listing of side effects are included in the package insert. Epclusa is a very well tolerated medication with minimal side effects. In the ASTRAL-1 clinical trials the most commonly reported side effects are headache, fatigue, nasopharyngitis (cold-like symptoms), nausea, insomnia, and diarrhea. Less commonly reported side effects include asthenia (weakness), arthralgia (joint pain), cough, back pain, and myalgia (muscle pain). In all cases, the side effects were considered mild, with only 1 out of 624 participants dropping out of the ASTRAL-1 study (see results below). A separate review from earlier this year found that age, level of cirrhosis, or the presence of mild kidney disease did not influence the side effect experience. 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.

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 is safe and well tolerated in combination with the HIV medications Genvoya, Stribild, Reyataz + Truvada, Prezista + Norvir + Truvada, and Kaletra + Truvada. Epclusa should not be taken with efavirenz (Sustiva, found in Atripla). Epclusa is safe to take with oral contraceptives and immunosuppressants, and it appears to be safe to take with most statins. We don't have data yet on any interactions with methadone, buprenorphine, or naloxone, but it is likely to be safe.

Finally, as this is a sofosbuvir-containing regimen, this medication should not be combined with amiodarone, as it has led to several cases of symptomatic bradycardia (very low heart rate), and cases of fatal heart attacks and cases requiring a pacemaker (see Sovaldi page). Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, and excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these occur.

MORE INFORMATION

This new combination, which received FDA approval on June 28, 2016, marks an exciting development for treating HCV: A pan-genotypic medication that is taken once daily without ribavirin and potentially curing HCV in as little 12 weeks with minimal side effects. It was approved in Europe in June, also under the brand name Epclusa. The ASTRAL-1 study, which looked at 624 people with GT 1, 2, 4, 5, and 6 (including people with cirrhosis and those who were treatment-experienced) saw an overall sustained virologic response (SVR, or cure) rate at week 12 of 99% (618 of 624 were cured). This combination also looks to be an effective and highly tolerable treatment option for people with GT3, with an SVR as high as 98% for treatment-naïve patients without cirrhosis. The presence of cirrhosis looks to lower the SVR12 rates a bit in GT3 (93%), but it 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 SOF/VEL alone, but it increased to 94% when ribavirin was added. 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.

Gilead is also embarking on combining Epclusa with another one of their direct acting antivirals (DAAs) in development, GS-9857, showing some very promising, if small in number, results for treatment-experienced patients, as well as in shorter—6 or 8 week—treatment durations. Watch for more news on this combination in the coming year.

Epclusa treatment durations

FOR HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

Patients without cirrhosis: Epclusa for 12 weeks

Patients with compensated cirrhosis: Epclusa for 12 weeks

Patients with decompensated cirrhosis: Epclusa + ribavirin for 12 weeks

Zepatier

COMMON NAMES: grazoprevir/elbasvir, or GZR/EBR
DRUG CLASS: grazoprevir: NS3/4A protease inhibitor; elbasvir: NS5A inhibitor

FDA STATUS
✔ APPROVED

GENOTYPE
1 4

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
A fixed dose combination (FDC) 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. See treatment chart below for dosing recommendations.

MANUFACTURER
Merck

AWP
$21,840 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
Zepatier is very well tolerated. The most commonly reported side effects are fatigue and headache, 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, 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.

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, before starting this regimen, and inform them of any changes as they happen.

Do not take with Prezista or Reyataz when boosted by Norvir or cobicistat (which includes Prezcobix and Evotaz), efavirenz (Sustiva, found in Atripla), or Kaletra. No dose adjustments needed when taken with Isentress/Norvir/Truvada. Do not take with the antibiotic nafcillin, the antifungal ketoconazole, or the pulmonary artery hypertension medication bosentan. Zepatier will increase the concentrations of several statins, including atorvastatin, rosuvastatin, fluvastatin, lovastatin, and simvastatin; dosages of these medications should be adjusted. Consult with your medical provider about this interaction. No dose adjustments needed when taken with buprenorphine, methadone, or naloxone. Zepatier is safe to use with oral contraceptives.

MORE INFORMATION
Although Merck was one of the first companies to get into the HCV DAA treatment field with Victrelis (no longer produced), they were relatively late to the interferon-free DAA market with Zepatier gaining approval in January 2016. Now that they are here, they've been quite impactful: Zepatier came in at a relatively low price, increasing the hope among patients and advocates that it will improve access and force the other companies to possibly lower their prices. Merck has also offered aggressive discounts to the VA. This combination of lower price and high cure rates should make it an attractive option for payers and patients alike. 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 a sustained virologic response, or SVR (cure), at week 12. Finally, if you are HCV genotype 1a, it's important for you to get a drug resistance test before starting Zepatier: If you have drug resistance, you'll need to add ribavirin and take this combination for 16 weeks total. While this may feel disappointing, the good news is this regimen did achieve a 100% SVR12 rate in clinical trials.

Zepatier treatment durations
FOR HCV MONO-INFECTION, HIV/HCV CO-INFECTION, AND HCV-INFECTION WITH RENAL (KIDNEY) DISEASE

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

Daklinza

COMMON NAMES: daclatasvir, DCV
DRUG CLASS: NS5A replication complex inhibitor

FDA STATUS
✔ APPROVED

GENOTYPE
1 3

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
Take one 60 mg tablet once daily with or without food; 30 mg tablets are also available. Check package insert for complete dosing details. Treatment duration is 12 weeks. Must be taken in combination with Sovaldi (sofosbuvir); ribavirin may be included for some genotypes, treatment-experienced patients, or for those with cirrhosis. See treatment chart.

MANUFACTURER
Bristol-Myers Squibb

AWP
$25,200 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
Side effect data reported here come from the package insert, clinical trials, and from post-marketing experience. When used in combination with sofosbuvir, commonly reported side effects are headache, nausea, and fatigue; less commonly reported side effects include loss of appetite, insomnia, dizziness, cough and nasal congestion, arthralgia (joint pain), myalgia (muscle pain), pruritis (itching), dry skin, alopecia (hair loss), rash, depression, and anxiety. Not all people experience all side effects, and most are considered mild to moderate: No one discontinued therapy because of them. If used with ribavirin, women of childbearing age and their male partners must use two forms of birth control; see ribavirin page. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS
Be sure to tell your medical provider or pharmacist about all medications, supplements, and herbs you take, whether prescribed, over-the-counter, or illicit, before starting this regimen, and inform them of any changes as they happen. Do not take with the anti-seizure medications phenytoin, carbamazepine, oxcarbazepine, or phenobarbital; anti-tuberculosis medications rifampicin, rifabutin, or rifapentine; the steroid dexamethasone; or St. John's wort. All of these medications weaken Daklinza's effectiveness and the treatment will not work. Dose adjustments of Daklinza will be required when used with the HIV medications Reyataz/Norvir, Intelence, efavirenz (Sustiva, found in Atripla), or cobicistat (Tybost)-containing regimens (Evotaz, Genvoya, and Stribild), but no adjustment is needed if the cobicistat is taken along with darunavir (Prezcobix or Prezista/Tybost). Daklinza can also be safely taken with Kaletra, rilpivirine (found in Complera and Odefsey), dolutegravir (Tivicay, found in Triumeq), Isentress, and tenofovir DF (Viread, found in Truvada). Safe to take with immunosuppressants cyclosporine, tacrolimus, sirolimus, and mycophenolate mofetil. Daklinza may increase the concentrations of statins, including atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin, and simvatatin. You can still take them together, but monitor for increased symptoms and side effects related to the statins (muscle aches, memory loss, and confusion) and monitor for liver toxicities. No interactions with methadone, but it may increase concentrations of buprenorphine and naloxone. It is still safe to take, but monitor for buprenorphine-associated symptoms. If taken with Sovaldi, see amiodarone warning on that drug page.

MORE INFORMATION
Daklinza was approved on February 5, 2016 in the United States. When combined with Sovaldi, it's an excellent option for patients with genotype 3 without cirrhosis, and is very effective in HIV/HCV co-infected persons. It's worth noting that in Europe, it was also approved for use in people with HCV GT 4, but not in the United States. There has also been research to show that Daklinza is effective against GT 2, and it may be an option for "off-label" use (that is, not FDA approved, but has enough evidence to support its effectiveness). In fact the AASLD/IDSA guidelines do list Daklinza as a potential option for treating GT 2. Talk with your medical provider about which treatment is right for your genotype, and check to see if your insurance will cover off-label treatments. This regimen looks to be especially promising for HIV/HCV co-infected persons, as the drug interactions are minimal and the need to change HIV medications to accommodate it is less likely to be needed.

Daklinza treatment durations

FOR HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

The information below comes from the package insert. The AASLD/IDSA HCV Guidance recommends considering 24 weeks of treatment with the regimens below for patients with cirrhosis. Talk with your medical provider about with length is best for you.

PATIENT POPULATION	GENOTYPE 1 REGIMEN AND DURATION	GENOTYPE 3 REGIMEN AND DURATION
No cirrhosis	Daklinza + Sovaldi for 12 weeks	Daklinza + Sovaldi for 12 weeks
Compensated cirrhosis (Child-Pugh A)	Daklinza + Sovaldi for 12 weeks	Daklinza + Sovaldi + ribavirin for 12 weeks
Decompensated cirrhosis (Child-Pugh B or C)	Daklinza + Sovaldi + ribavirin for 12 weeks	Daklinza + Sovaldi + ribavirin for 12 weeks
Post-transplant	Daklinza + Sovaldi + ribavirin for 12 weeks	Daklinza + Sovaldi + ribavirin for 12 weeks

Viekira Pak

COMMON NAMES: ombitasvir/paritaprevir/ritonavir and dasabuvir, or OMB/PTV-r + DAS

DRUG CLASS: ombitasvir: NS5A inhibitor; paritaprevir: NS3/4A protease inhibitor, boosted with ritonavir; dasabuvir: Non-nucleoside NS5B polymerase inhibitor

FDA STATUS
✔ APPROVED

GENOTYPE
1

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
Take two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily, ideally in the morning and one dasabuvir 250 mg tablet twice daily (morning and evening) with food. Daily dosing comes co-packaged to facilitate proper adherence. If ribavirin is prescribed, take a weight-based dose, two times daily with food. Take your missed dose as soon as possible, unless it's too close to your next dose. Never double your dose.

MANUFACTURER
AbbVie

AWP
$33,321 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
The most commonly experienced were headaches, fatigue, nausea, pruritus (itching), skin reactions, insomnia, and asthenia (loss of strength); all side effects were considered mild and less than 1% of participants in the clinical trials discontinued Viekira Pak because of them. Monitor for elevated ALTs (a measure of liver function), particularly in the first 4 weeks of treatment. This was a rare issue in clinical trials, but did occur more frequently in women who were using ethinyl estradiol-containing contraceptives and other estrogens. Women using estrogens while on Viekira Pak should monitor hepatic labs during treatment as needed, and consult with their medical provider should they experience fatigue, weakness, lack of appetite, nausea, vomiting, jaundice, or discolored feces. When taken with ribavirin, there is an increased risk of fatigue, nausea, headaches, and pruritus. For more information on the side effects of ribavirin, refer to its drug page on page 37. When this regimen is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

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, before starting this regimen, and inform them of any changes as they happen. Viekira Pak interacts with many drugs; for a complete listing, refer to the package insert. Do not take with St. John's wort. Do not take with the HIV medications efavirenz (found in Atripla and Sustiva), Kaletra, Norvir- or cobicistat-boosted Prezista (including Prezcobix), or rilpirivine (found in Complera and Odefsey). Reyataz is the only HIV protease inhibitor that can be taken with Viekira Pak, but do not take it with cobicistat (Tybost or Evotaz) or ritonavir (Norvir). Take Reyataz in the morning with the OMB/PTV-R tablets, since they already have the ritonavir booster in them. Do not take with anticonvulsants carbamazepine, phenytoin, or phenobarbital. Do not take with rifampin. Do not take with PDE5 inhibitors Viagra, Cialis or Levitra. Do not take with the sedatives triazolam or midazolam. Do not take with lovastatin. Women taking ethinyl estradiol-containing medications should monitor for ALT elevations (see above). Methadone, buprenorphine, and naloxone are safe to take with Viekira Pak, but monitor for sedation and cognitive effects.

MORE INFORMATION
Viekira Pak offers people another interferon-free regimen, and in the case of people with genotype 1b and no cirrhosis, a ribavirin-free one, too. It is a twice-a-day medication regimen, making it a less ideal choice for those with adherence issues or who can't take ribavirin. AbbVie came onto the HCV treatment scene and struck deals with some pharmacy benefits managers to offer the regimen at a lower cost than their competitors and with no treatment restrictions. It was a move that highlighted the importance of competition in the HCV treatment marketplace to improve access to HCV cures for people who would otherwise be denied. Viekira Pak is able to be used in patients who are treatment-naïve and -experienced, HIV/HCV co-infected, have renal (kidney) disease, and in liver transplant recipients with normal functioning and mild fibrosis (F2 or less), with ribavirin for 24 weeks. It is not recommended for people with decompensated cirrhosis, as some people with this advanced state of liver disease who were incorrectly prescribed Viekira Pak suffered serious consequences. People with moderate to severe cirrhosis—Child-Pugh B and C—should not take Viekira Pak.

Viekira Pak treatment durations
FOR HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

GENOTYPE	PATIENT POPULATION / TREATMENT LENGTH
1A	**No cirrhosis:** Viekira Pak + ribavirin for 12 weeks.
	With compensated cirrhosis: Viekira Pak + ribavirin for 24 weeks.
1B	**No cirrhosis:** Viekira Pak for 12 weeks.
	With compensated cirrhosis: Viekira Pak for 12 weeks.

Technivie

COMMON NAMES: ombitasvir/paritaprevir/ritonavir, or OMB/PTV-r
DRUG CLASS: ombitasvir: NS5A inhibitor; paritaprevir: NS3/4A protease inhibitor, boosted with ritonavir

FDA STATUS
✔ APPROVED

GENOTYPE
4

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

DOSAGE
Take two fixed dose combination (FDC) ombitasvir 12.5 mg/ paritaprevir 75 mg/ ritonavir 50 mg tablets once daily with food. Daily dosing comes co-packaged to facilitate proper adherence. Must be taken with ribavirin, at a weight-based dose, two times daily with food. Take your missed dose as soon as possible, unless it's too close to your next dose. Never double your dose.

MANUFACTURER
AbbVie

AWP
$30,661 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
The most commonly experienced were headaches, fatigue, nausea, pruritus (itching), skin reactions, insomnia, and asthenia (loss of strength); all side effects were considered mild and none of the participants in the clinical trials discontinued Technivie because of them. Monitor for elevated ALTs, a measure of liver function, particularly in the first 4 weeks of treatment. This was a rare issue in clinical trials, but did occur more frequently in women who were using ethinyl estradiol-containing contraceptives and other estrogens. Women using estrogens while on Technivie should monitor hepatic labs during treatment as needed, and consult with their medical provider should they experience fatigue, weakness, lack of appetite, nausea, vomiting, jaundice, or discolored feces. As Technivie is taken with ribavirin, there is an increased risk of fatigue, nausea, headaches, and pruritus. For more information on the side effects of ribavirin, refer to its drug page on page 37. 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. Changes in hematological (blood) values were also seen in the clinical trials, and routine blood testing to look for anemia, neutropenia, and other blood conditions are recommended.

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, before starting this regimen, and inform them of any changes as they happen. Technivie interacts with many drugs; for a complete listing, refer to the package insert. Do not take with St. John's wort. Do not take with the HIV medications efavirenz (found in Sustiva and Atripla), Norvir-boosted Prezista, Kaletra, or rilpirivine (found in Complera and Odefsey). Norvir-boosted Reyataz must be taken in the morning. Do not take with anticonvulsants carbamazepine, phenytoin, or phenobarbital. Do not take with rifampin. Do not take with PDE5 inhibitors Viagra, Cialis, or Levitra. Do not take with lovastatin or simvastatin. Women taking ethinyl estradiol-containing medications should monitor for ALT elevations (see above). Do not take with the benzodiazepines sedatives triazolam or midazolam as Technivie can increase their concentrations and lead to possible overdose and death. Methadone, buprenorphine, and naloxone are safe to take with Technivie, but monitor for sedation and cognitive effects.

MORE INFORMATION
Technivie was approved in July 2015, as a new option for people with HCV genotype 4. It contains the same medications found in Viekira Pak, minus the dasabuvir. It is a once-a-day medication, but it still needs ribavirin that needs to be taken twice a day, making it a less ideal choice for those with adherence issues or who can't take ribavirin. Technivie is able to be used in patients who are treatment-naïve and -experienced, HIV/HCV co-infected, have renal (kidney) disease, or are post-transplant, but is not recommended for people post-liver transplant or with decompensated cirrhosis. People with moderate to severe cirrhosis—Child-Pugh B and C—should not take Technivie.

Technivie treatment durations
FOR HCV MONO-INFECTION, HIV/HCV CO-INFECTION, AND HCV-INFECTION WITH RENAL (KIDNEY) DISEASE

GENOTYPE	PATIENT POPULATION / TREATMENT LENGTH
4	**No cirrhosis:** Technivie + ribavirin for 12 weeks
	With compensated cirrhosis: Technivie + ribavirin for 12 weeks

Olysio

COMMON NAMES: simeprevir, SMV
DRUG CLASS: NS3/4A protease inhibitor

FDA STATUS
✔ APPROVED

GENOTYPE
1

HIV/HCV CO-INFECTION
Olysio + Sovaldi is **FDA APPROVED FOR USE IN HIV/HCV CO-INFECTION.**

DOSAGE
Take one 150 mg capsule once daily with food; must be taken in combination with Sovaldi, with or without ribavirin. It may be taken with pegylated interferon/ribavirin, but this is highly unlikely to be prescribed due to toxicity as well as the availability of Sovaldi. Do not crush or dissolve the capsule. Olysio 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 and durations.

MANUFACTURER
Janssen Therapeutics

AWP
$26,544 for 4 weeks

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
Olysio is associated with a rash and photosensitivity. The rash was generally mild, with very few people experiencing a severe rash. The photosensitivity is considered mild to moderate, and anyone taking Olysio should wear sunscreen and take other protective measures. There have been reports of liver decompensation and liver failure in patients with advanced liver disease: monitor liver chemistry tests before and during treatment with Olysio. Other side effects include pruritus (itching), nausea, myalgia (muscle pain), and shortness of breath. If Olysio is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS
Talk to your medical provider or pharmacist about any and all medications you are taking whether they're prescribed, over-the-counter, or illicit. Olysio interacts with many other medications, and this is not a complete list. For a more detailed review of drug interactions, see the package insert. Risk of serious symptomatic bradycardia when co-administered with Sovaldi (sofosbuvir) and amiodarone—see Sovaldi drug page for more details; Olysio + Sovaldi should not be taken with amiodarone. Olysio should not be taken with any HIV protease inhibitors (PIs); the non-nucleoside reverse transcriptase inhibitors (NNRTIs) Sustiva (efavirenz, also in Atripla), Viramune (nevirapine), or Intelence (etravarine); or with cobicistat. Olysio can be taken with rilpivirine (Edurant, found in Complera and Odefsey), Isentress (raltegravir), Tivicay (dolutegravir, found in Triumeq), and the nucleoside reverse transcriptase inhibitors including Truvada, Descovy, Ziagen (abacavir), Emtriva (emtricitabine), Epivir (lamivudine), Epzicom, and Viread (tenofovir DF). Olysio boosts the levels of PDE5 inhibitors drugs Viagra, Cialis, and Levitra. Start with the lowest dose possible and increase as needed. Do not use with the herbs milk thistle (silymarin) or St. John's wort. Anticonvulsants such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine should not be used as they reduce the concentrations of Olysio, thus reducing its effectiveness. Rifampin, rifabutin, and rifapentine should not be taken. Antibiotics erythromycin, clarithromycin, and telithromycin increase levels of Olysio so they should be avoided, as should the antifungals fluconazole, voriconazole, itraconazole, ketoconazole, and posaconazole. Antiarrhythmics such as Tambocor and Cordarone should not be taken; no interactions with methadone and buprenorphine.

MORE INFORMATION
Although it is approved for the treatment of GT 1 or 4 with the combination of Olysio + pegylated interferon + ribavirin, this regimen is not recommended for use: The SVR (or cure) rates don't stand up to the interferon-free regimens, to say nothing of the severity of side effects and length of treatment. There is an option for an interferon-free version: The combination of Olysio plus Sovaldi with or without ribavirin. This combination is still listed as a recommended regimen for use in people with GT1 based on the results of the COSMOS study, which saw high SVR rates and minimal side effects for both treatment-naïve and prior non-responders.

Olysio with sofosbuvir treatment durations
FOR HCV MONO-INFECTION AND HIV/HCV CO-INFECTION

Treatment-naïve without cirrhosis: Olysio + Sovaldi for 12 weeks

Treatment-experienced without cirrhosis: Olysio + Sovaldi for 12 weeks

Treatment-naïve with cirrhosis: Olysio + Sovaldi for 24 weeks

Treatment-experienced with cirrhosis: Olysio + Sovaldi for 24 weeks

Moderiba; Ribasphere

COMMON NAMES: ribavirin, RBV
DRUG CLASS: Nucleoside analog

FDA STATUS
✔ APPROVED

GENOTYPE
1 2 3 4 5 6

HIV/HCV CO-INFECTION
✔ APPROVED for use in HIV/HCV co-infection.

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 your dose.

MANUFACTURER
Moderiba: AbbVie
Ribasphere: Kadmon

AWP
Moderiba 200 mg
168ct: $474.00
Moderiba 1,000 mg/day
56ct: $1,153.37
Moderiba 1,200 mg/day
56ct: $1,384.00

Ribasphere 200 mg
168ct: $474.00
Ribasphere 600 mg
56ct: $2,698.85

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 (pruritis), 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.

POTENTIAL DRUG INTERACTIONS
Ribavirin cannot be used with the rarely used HIV medicine 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 will continue to play an important role in the future. We are fully in the interferon-free era, and while there are some scenarios where ribavirin is not needed for the treatment of genotype 1, it's still a component of treatment for all HCV genotypes. That said, we are entering the ribavirin-free era with the introduction of Epclusa, as this regimen will treat all HCV genotypes on its own.

The side effects can be difficult, even without interferon. 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. Some people who are taking ribavirin experience what is popularly called "riba-rage", that is they get easily irritated and get angry easier. It's 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. For these reasons, and more, patients, advocates, and medical providers are excited for ribavirin-free treatments in the immediate future.

Important labs for monitoring your hematological levels

Ribavirin (and some other HCV medications), can affect your body's production of red blood cells, white blood cells, and platelets. Follow your medical provider's directions for regular screening to check for these conditions. Be sure to keep copies of your lab results and track them over time. Note: Whenever a lab test is out of range, there is usually an indication (such as a star or other way to highlight it).

CONDITION	LAB TEST	NORMAL RANGE	SYMPTOMS
Anemia	**Hemoglobin**	MALE: 13.5–17.5 FEMALE: 12.0–16.0	Fatigue, shortness of breath, chills, rapid heart rate, depression
	Hematocrit	MALE: 42–54 FEMALE: 37–47	
Neutropenia	**Neutrophils**	45–75% of white blood cells	None
Leukopenia	**Leukocytes**	4.5–11.0 (x 103/mm^3)	Usually none, but regular or unusual infections may indicate this condition
Thrombocytopenia	**Platelets**	150–399 (x 103/mm^3)	Easy or excessive bleeding, spontaneous nosebleeds or bleeding gums, unusually heavy menstrual flows, and/or blood in urine or stools

AFTER THE CURE: POST-TREATMENT CARE

A hepatitis C cure, also called a sustained virologic response (SVR), almost always results in improved liver health.

A concern that many people have after they've been cured is whether or not the virus is truly gone. Less than 1% of people cured of HCV experience a return of the virus, so an SVR is a true cure. You will still have HCV antibodies, for which you will always test positive, but that does not mean you are still infected, because there is no virus to potentially damage your liver. People also often wonder about the risk of infecting others: With no virus, there's nothing to transmit. Antibodies are not infectious.

Following your cure, the AASLD/IDSA HCV Guidelines recommend the following:

- If you've been cured with little to no fibrosis (F0-F2), you should receive the same standard of care as if you never had HCV.
- Although HCV recurrence following cure is exceedingly rare, reinfection of HCV can happen. If you don't have ongoing risk for HCV (for example, injection drug use), you don't need to screen for HCV routinely. If you do still have risk, a known exposure to HCV, or an unexpected rise in your liver enzyme tests, you should screen for HCV using a quantitative HCV RNA test (viral load) rather than an HCV antibody test to detect reinfection.
- If you've been cured after developing more advanced liver disease (F3 or F4), you should be screened for hepatocellular carcinoma (HCC or liver cancer) with twice-yearly ultrasounds (every 6 months).
- If you've been cured after developing cirrhosis, you should get an endoscopy to check for varices (enlarged veins in the torso, which can burst). If varices are found, they will be treated appropriately and you will not likely get them again (it's rare for them to return after getting cured).

OTHER IMPORTANT CONSIDERATIONS

ALCOHOL USE: Without the virus, it's common to wonder if it's safe to drink alcohol again. We know that alcohol, even drinking just 1–2 glasses per day, accelerates HCV disease and increases risks of cirrhosis and other liver complications. But what about after someone has been cured? We don't know; there has not been any research to help us make an informed recommendation on this subject. If you have cirrhosis, you cannot drink alcohol safely. If you have more moderate levels of fibrosis you should speak with your medical provider as she/he knows your liver health and other potential complications that may help you determine if you can or cannot drink alcohol.

HCV REINFECTION: Once cured, you'll have HCV antibodies but they don't necessarily offer protection from reinfection. If you use drugs, don't share injecting equipment (syringes, cookers, cotton filters, water, etc.), straws for snorting, or pipes from smoking. If you're HIV-positive, be mindful of sexual transmission of HCV, and use condoms and other practices to minimize risk of blood exposure during sex. Screen for HCV at least once a year, but you might want to do it more frequently to catch HCV reinfection as quickly as possible.

CIRRHOSIS AND FIBROSIS: These two conditions may reverse after a cure. Yes, your liver may return to normal.

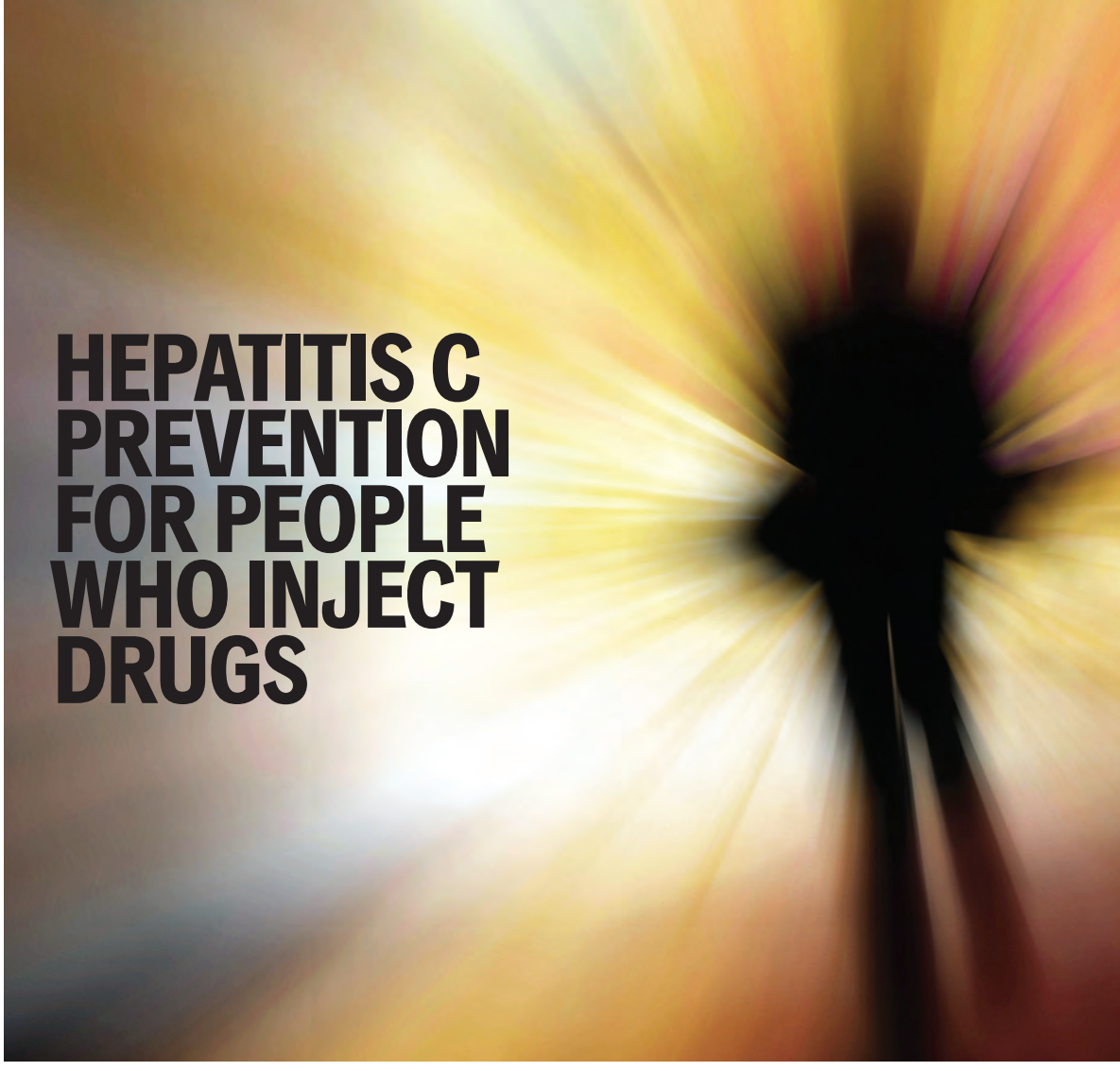
Talk with your medical provider about any other lab tests or follow-up that she/he recommends for your specific health needs.

If you have any other questions, call HELP-4-HEP at (877) HELP-4-HEP, (877) 435-7443, to speak with a trained HCV counselor/health educator.

Tips for healthy living with cirrhosis

With these and any other tips, talk with your medical provider about the best things you can do to live as healthy as you can with cirrhosis.

- Keep all medical appointments with your provider.
- Take all medications as prescribed.
- Don't take any medications—prescription or over-the-counter—without consulting your medical provider.
- Get vaccinated against pneumonia and your annual flu shot, as people with cirrhosis are vulnerable to infections.
- Maintain healthy bowel movements as constipation can lead to more toxins in the body. You may need to take medications to help with this.
- Do not take Tylenol as that can be damaging to an already damaged liver. Check the labels of medications as acetaminophen, the active ingredient in Tylenol, can be found in many over-the-counter and prescribed medications.
- Eat a well-balanced diet that's low in fat and has a proper amount of protein. Too much animal protein can lead to encephalopathy (mental confusion). A vegetarian diet may be a better option.
- Cut down on, if not eliminate, salt (sodium). Salt can lead to water retention, mess with your blood pressure, and increase the risk of developing ascites.
- Drink coffee. Coffee appears to have many health benefits, including slowing cirrhosis and reducing risk of developing liver cancer.



HEPATITIS C PREVENTION FOR PEOPLE WHO INJECT DRUGS

USING NEW INSIGHTS AND BEST PRACTICES TO PREVENT INFECTION

BY ANDREW REYNOLDS

With over 30,000 infections reported in 2014—at least 70% of which occurred among people who inject drugs (PWID)—and all the challenges that can come with HCV prevention, it can sometimes feel like infection is inevitable in people who inject drugs, but it doesn't have to be.

Hepatitis C virus is mainly transmitted from blood to blood contact when someone shares a syringe or other injecting equipment with someone infected with the virus. The gold standard of HCV prevention is using a new syringe and unused injection equipment each and every time you inject, and you never have to share anything. This is easier said than done: Sometimes you have no other option but to re-use a syringe. When faced with this situation, there are things you can do to help prevent infection.

The strategies given here also serve to prevent HIV. We are fortunate that there are some very thoughtful researchers who have looked are various ways to prevent HCV infection. Their work helps people make informed decisions over how to best minimize their risk for infection. The information in this article draws on this work, focusing on ways in which HCV can be transmitted through the sharing of injecting equipment, ways to kill HCV, and some practices that people who have been injecting drugs for a long time yet never got HCV do to stay negative. This is not an exhaustive review of safer injecting practices, for that we have a list of resources at the end of this article to help you learn more on the subject.

A word on preventing hepatitis C infection: There's a lot to think about in this article, and it can look so overwhelming as to feel like it's almost impossible to do all the things listed below. The principles of harm reduction will guide our work here--you do what you can, with no judgment around what you can't.

PHOTO: ©HEIKO KÜVERLING/ISTOCKPHOTO

ILLUSTRATIONS: ISTOCKPHOTO

SAFER INJECTING: MORE THAN JUST THE SYRINGE

THE PRIMARY WAY in which HCV infection occurs is through the sharing of syringes: That's where the most blood is (especially in high dead-space syringes) and that is the most direct way for HCV to get into a person. That said, the sharing of other injecting equipment—cookers, cotton, water—can lead to HCV infection, too.

Hepatitis C can live for a while on surfaces and in injecting equipment ("works" like cookers, cotton, and water).

Syringes: The type of syringe matters. All syringes have a thing called "dead space," that is a small amount of space where fluid—in this case blood—remains even when the plunger if fully depressed. The dead space is also called a "void." You may be using low dead space (or low void) or high dead space (or high void) syringes when you inject. Ask your local syringe access program or pharmacy where you get syringes for specifics about the syringe you are getting, but in general, syringes with a fixed needle are low dead-space (low-void) and ones with a detachable needle are high dead-space (high-void). Low dead-space ones are easier to clean if you have to re-use them. If you're not sure what type of syringe you have, bleach works really well on either type. For other disinfectants, check out the instructions below for the number of times you need to use them and rinse and repeat to kill hep C.

Surfaces: The research on surfaces is on things like tables or counters. Wiping them down with a bleach or other cleaners will kill hep C. They haven't really studied how well you can disinfect a cooker, but cleaning it with bleach should be good enough to do the trick if you have to re-use one.

Water: If you get HCV-infected blood in water, it can contaminate the container it's in. The type of container matters: Plastic and aluminum can hold HCV-infected blood in its pores even if you dump out the water. If you place clean water back in that plastic or aluminum container, that water will get contaminated with hep C. Recycle the plastic or can and get a new one. Glass won't do this: If blood gets in the water of a glass container, dump the water, clean the glass with bleach and rinse it out well with soap and water and you'll be able to put in fresh water for use in drug prep.

Cotton: There's no way to disinfect cotton if it gets HCV-infected blood in it.

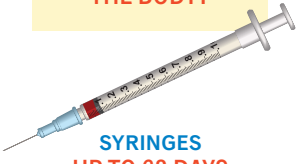
WHAT KILLS HEPATITIS C: BLEACH, RUBBING ALCOHOL, DISH SOAP, AND MORE

IF HCV IS such a tough virus, is there anything that can kill it and reduce the chances for transmission? Researchers from Yale have looked at various disinfectants to see what works and what doesn't work. Bleach kills HCV nearly all the time, and there are other cleaners or disinfectants you can use, too, that also work against the virus.

Bleach: Bleach has been shown to kill HCV in more than 99% of contaminated syringes. There are many variables, though: How fresh is your bleach? How much blood is in the syringe? Research has shown that when you draw up the bleach and immediately rinse it out, you'll disinfect the syringe. If you see blood in the syringe, rinse it once with cold water to dilute the blood. After you've rinsed out the bleach, rinse the syringe thoroughly with cold water.

Over time, bleach can damage the syringe and needle, so ideally you don't have to use the same needle and bleach it over and over: After 20 rinses with bleach, there is a lot of damage to the syringe. Besides, the more you have to use a syringe, the duller the needle point becomes and the greater the risk for abscesses and damaged veins. Get a new, unused

HOW LONG DOES HCV LIVE OUTSIDE THE BODY?



SYRINGES
UP TO 63 DAYS

SURFACES
UP TO 42 DAYS

WATER
UP TO 21 DAYS

COTTON FILTERS
24 HOURS,
OR 48 HOURS
IF WRAPPED IN FOIL

METHODS OF KILLING HCV

MOST EFFECTIVE:

BLEACH
1 RINSE
CAN KILL HCV

EFFECTIVE:

DAWN ULTRA
(diluted with water)
2 RINSES
CAN KILL HCV

RUBBING ALCOHOL
(diluted with water)
3 RINSES
CAN KILL HCV

LYSOL
3 RINSES
CAN KILL HCV

HYDROGEN PEROXIDE
3 RINSES
CAN KILL HCV

NOTE:
WATER, BEER, OR WINE
WILL NOT KILL HCV

SOURCE: BINKA M, PAINTSIL E, PATEL A, LINDENBACH BO, HEIMER R. DISINFECTION OF SYRINGES CONTAMINATED WITH HEPATITIS C VIRUS BY RINSING WITH HOUSEHOLD PRODUCTS. *OPEN FORUM INFECTIOUS DISEASES*. 2015; 2(1) :ofv017. doi :10.1093/ofid/ofv017. ACCESSED MAY 20, 2016.

syringe as quickly as possible: Ideally, you just use one syringe (and other equipment) for each injection.

Alcohol, hydrogen peroxide, and kitchen sink detergent (for example, Dawn Ultra) can kill HCV also, and are less damaging to the syringe. But they are all less effective than bleach, and require multiple rinses. They are good alternatives when an unused syringe or bleach are not available.

Alcohol and hydrogen peroxide: Rubbing alcohol (check the label for 70% isopropanol), hydrogen peroxide, and Lysol can kill HCV. Draw up alcohol, rinse, and repeat twice more for a total of three rinses. You can do the same with hydrogen peroxide and Lysol. The length of time doesn't seem to matter: You just have to do the draw-up, rinse, and repeat pattern three times.

NOTE: Neither beer (5% alcohol) nor fortified wine (20% alcohol) is strong enough to kill HCV.

Kitchen sink detergents (Dawn Ultra): Recent research has shown that common cleaning supplies, such as Dawn Ultra, can kill HCV. Put the liquid soap into some water to dilute it and make it easier to draw into the syringe. Rinse and repeat at least one more time. The length of time doesn't seem to matter: You just need to draw-up, rinse, and repeat the pattern three times.

Industrial-grade disinfectants should not be used. These include Barbicide (that blue stuff they use in barbershops and nail salons) as well as Cavicide and Clorox Quartanary Cleaner (both used in medical settings) that can be used on surfaces and for cleaning up blood spills, but should not be used in injecting or other drug-using equipment.

Wiping down surfaces where drug preparation and blood occur with bleach is also a good thing to do to avoid blood contact from surfaces.

BEST PRACTICES FOR STAYING HCV-NEGATIVE: LESSONS ON STAYING SAFE

ALTHOUGH IT CAN FEEL like injecting drugs and HCV go hand-in-hand, it can be prevented, and there are people who have been injecting for years and years but who have never been infected with HCV. In addition to bleach and other disinfectants, there are a number of practices that people use to help minimize their risk of HCV.

If you're ready to stop injecting drugs, that's the most direct way to keep hepatitis C infection from happening. This is not always easy: Sometimes it can be hard to get into a treatment program, there may not be one that is a good fit for you, or you may not be ready to stop right now.

If you can't stop, and you want or need to keep injecting drugs, there are things you can do to prevent infection (these can also be used to prevent reinfection). There are several practices for preventing hep C that longtime injectors who have never been infected have used. Again, refer back to a principle of harm reduction, which says that drug users themselves are the experts and "the primary agents of reducing the harms of their drug use and seeks to empower users to share information and support each other in strategies which meet their actual conditions of use." It is with this in mind that the "Staying Safe Project" sought to learn directly from people who inject drugs (PWID) on how people can potentially stay HCV negative while injecting drugs. The study was international in its scope, but the tips below come from an article published from the London study.

The following list describes a selection of strategies and practices that people who have stayed HCV negative use. You may be able to do some of these things, while others may be difficult. Do what you can and don't beat yourself up over the things you find challenging:

Set-up your own personal rules about not sharing injecting equipment and disposing of syringes:

If possible, don't share anything: syringes, cookers, water, cotton filters, and tourniquets for both drug preparation and injection. If you need to re-use a syringe, clean it out with bleach or other disinfectants (see above), and do the same with cookers. Cotton filters and water can't be disinfected if HCV blood gets in them. You'll need to discard them and get unused cotton filters and fresh water.

When done with syringes and works, dispose of them in a sharps container (those red containers people put syringes in) and/or take them to your local syringe access site to dispose of them.

Take charge of your drug preparation and injection:

Try to take time to slowly and carefully prepare for your injection. Wash your hands with soap and water before you begin. Wipe down the surface where your drug preparation is going to happen with bleach or other cleaners. If you don't have anything, lay down some newspaper or napkins to prepare on.

Prepare your own drug mix. If you're injecting with others, volunteer to do the prep and split it with them in a way that does not lead to blood getting into the process. For example, split the drug up before preparing it all so each person has their own. You can also use an unused syringe to draw up the prepared drug and use it to put into each person's syringe ("backloading" or "frontloading"; check out the Harm Reduction Coalition's "Getting Off Right" booklet for more safe injecting info).

Separate and/or mark your drug injecting equipment:

Mark your syringes and injecting equipment to avoid mixing your stuff with that belonging to others. You can use a permanent marker or scratch off a number on the barrel of a syringe and so on. Store your injecting equipment in a kit that is clearly yours.

If possible, keep an extra stash or two of unused syringes and injecting equipment. You can keep one for yourself, and have one for someone else who might need something.

Prepare and plan ahead:

If you inject heroin, the need to avoid withdrawal symptoms and getting dope-sick can lead a person to take more injecting risks than they usually would. Snorting or smoking a little before injecting could take the edge off while you prepare your injection (remain mindful of the risk of drug overdose: inject less if you took a little before). Stockpiling a little methadone or buprenorphine to take when you need it can help during these times, too.

Take a break from injecting for a while:

If you can sniff or smoke your drug, try that for a while. This can give your veins a break and make injecting later a little easier. If there's no unused syringes or injecting equipment, try sniffing or smoking the drug to avoid sharing works.

If you smoke, try not to share pipes, especially if you have cracked lips or sores in your mouth: Blood from a pipe is a less efficient way of HCV transmission, but it can happen. The same is true with sniffing: sharing straws can lead to blood-to-blood contact in the nose. Again, it's less efficient than injecting, but definitely possible. Grab a few extra straws from a coffee shop so you have some on hand when needed (see the box for more harm reduction tips to reduce risk).

Preventing hepatitis C is not easy, but there are things you can do to help minimize your risk. In addition to the strategies listed here, you can find more information in the resources listed below. Regardless of what you do, try to integrate HCV testing into your care, and test routinely, at least once a year, but you can do it more frequently too, if you like.

SOURCE: McGOWAN C; HARRIS M, RHODES T (2013) HEPATITIS C AVOIDANCE IN INJECTION DRUG USERS: A TYPOLOGY OF POSSIBLE PROTECTIVE PRACTICES. PLoS ONE 8(10): e77038. DOI:10.1371/journal.pone.0077038. ACCESSED MAY 15, 2016.

FOR MORE INFORMATION and one-on-one support around hepatitis C harm reduction and prevention, you can call the HELP-4-HEP line at (877) HELP-4-HEP, (877) 435-7443.

NON-INJECTION DRUG USE AND HCV

SHARING STRAWS while snorting drugs, or pipes while smoking them, can transmit HCV. The risk is less than it is from sharing injection equipment, but rates of HCV among this group is high enough that it's worth testing for it at least once a year. The risk of transmission of HCV from sharing straws or pipes is less than we find in injection drug use, but it's worth thinking about ways to reduce your risk further through harm reduction. The following tips for safer snorting and safer smoking can help reduce the risk for HCV infection:

SAFER SNORTING

- Blood on the tip of a straw can transmit HCV.
- Carry a few extra straws (grab some from a coffee shop, fast food restaurant, etc.) so you don't run out and have some to give to friends.
- If snorting with others, watch where the drug is sitting and keep blood off the surface of the mirror, table, etc. You and your friends should avoid putting your straws on the snorting surface to keep blood off of it.
- If there's only one straw, see if there's something else to use (keys, small spoon, etc.).
- Check out the section "What kills HCV" for tips on how to clean a straw as the next best thing to using a brand new one.

SAFER SMOKING

- Blood from bleeding gums or lips on the stems of crack or crystal meth pipes can transmit HCV.
- Changing stem covers (such as rubber spark plug covers) between partners can prevent blood-to-blood contact.
- If only one pipe is available, see if you can find something else to use as a pipe (e.g., an aluminum can).
- Let the pipe cool before using it again to avoid burns to the lips.
- Check out the "What kills HCV" section for tips on how to clean a used pipe as the next best thing to using a brand new pipe or personal stem cover.

RESOURCES

The Harm Reduction Coalition
harmreduction.org
An advocacy and education organization which, among other things, has an excellent safer injecting booklet called "Getting Off Right" which can be found at harmreduction.org/wp-content/uploads/2011/12/getting-off-right.pdf.

The Chicago Recovery Alliance
anypositivechange.org
An action organization, comprised with a racially and ethnically diverse group of people living with HIV, HCV, and substance use who work to improve the health of people impacted by drug-related harm. They have an excellent safer injection guide, "Better Vein Care/Safer Injection Guide," along with educational videos, found at anypositivechange.org/bvcsiALL.pdf.

Overdose Prevention Alliance
overdoseprevention alliance.org
The Overdose Prevention Alliance (OPA) is a place for information and debate on drug overdose worldwide, with the overarching goal of educating people and stopping overdose deaths. The site has an "Overdose Prevention Program Locator" where you can enter your ZIP code and find the program closest to you. Go to overdoseprevention alliance.org/p/od-prevention-program-locator.html.

REFERENCES AT positivelyaware.com.

HEPATITIS C CO-PAY AND PATIENT ASSISTANCE PROGRAMS

TREATMENT FOR HCV CAN BE EXPENSIVE, but the good news is that help is out there. Many of the pharmaceutical companies have a patient assistance program (PAP) to help uninsured and underinsured people 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.

DRUG NAME	MANUFACTURER	PHONE NUMBER	WEBSITE
Daklinza	Bristol-Myers Squibb	(844) 44-CONNECT (844) 442-6663	daklinza.bmscustomerconnect.com/patient-support
Epclusa	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284	mysupportpath.com
Harvoni	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284	mysupportpath.com
Moderiba	AbbVie	(844) MODERIBA (844) 663-3742	moderiba.com/patient-support/financial
Olysio	Janssen Therapeutics	(855) 5-OLYSIO 855) 565-9746	olysio.com/support
Ribasphere	Kadmon	(888) 668-3393	ribapak.com/hcp/resources.html
Sovaldi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284	mysupportpath.com
Technivie	AbbVie	(844)-2PROCEED (844) 277-6233	viekira.com/proceed-support
Viekira Pak	AbbVie	(844)-2PROCEED (844) 277-6233	viekira.com/proceed-support
Zepatier	Merck	(866) 251-6013	merckhelps.com/ZEPATIER

ADDITIONAL FINANCIAL ASSISTANCE AND ACCESS ADVOCACY PROGRAMS

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
1-800-532-5274
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.

PHOTO: ISTOCKPHOTO

ACCESSING HEPATITIS C MEDICATIONS

Tips for overcoming insurance denials

You would think that accessing hepatitis C treatment would be as simple as the following scenario:

PATIENT: Hey doc, I want to take hepatitis C medications and be cured of the virus once and for all.
PROVIDER: I want you to be cured, too. Here's your prescription.
PHARMACIST: Here's your bottle of pills. Let me know if you have any questions and good luck!

Unfortunately, it is not that easy, and there are often multiple steps you, your medical provider, and even your pharmacist might have to go through in order to get your hepatitis C treatment. Just about every insurance plan has restrictions and it can be hard to figure out what they are. Sometimes these restrictions are clearly listed, but other times you won't know until you try to get the treatment and you get denied. This is a frustrating situation for patients, providers, and advocates alike; hepatitis C is a progressive disease that causes much suffering, and all of this suffering is avoidable with a cure. Everyone with hepatitis C deserves a cure, but barriers can make it challenging.

Restrictions are lifting slowly. Pharmaceutical and insurance companies are striking deals for discounts on medications in return for better access. Patients, advocates, and medical providers are working every day to improve access to hepatitis C medications. In the meantime, there are things you can do to improve your chances for getting your treatment approved. There's no one-size-fits-all solution for everyone, and this list is not exhaustive, but the following tips may provide some help for you in accessing HCV medications:

Try again.

IF YOU ARE DENIED treatment, don't give up. Talk with your medical provider about appealing the denial and try again with updates about your medical condition. It's also worth trying again as insurance plans might change their rules and lift restrictions.

Get a specialist.

EVEN IF YOUR PRIMARY CARE provider is able to manage your care and treatments, some insurance plans will only accept a prescription from a specialist, such as a hepatologist or gastroenterologist. If you don't have a specialist, talk with your medical provider about getting referred to one and having her/him write your prescription and oversee your care.

Check to see if a different drug is covered.

SOME INSURANCE PLANS strike deals with pharmaceutical companies and are able to purchase HCV medications at a discount. These drugs become preferred and may be more likely to get approved. Check to see if the medication your medical provider prescribed for you is preferred by your insurance.

Check with the pharmaceutical company's patient assistance program (PAP).

EVERY PHARMACEUTICAL COMPANY that produces hepatitis C medications has patient assistance programs and co-pay assistance programs. Many have restrictions for insured or underinsured people, but some do not. Even in those that do have restrictions, they have staff who may be able to help you navigate the system.

Refer back to the AASLD/IDSA HCV Treatment Guidance.

AS YOU AND YOUR PROVIDER APPEAL a denial, cite and quote the AASLD/IDSA HCV Treatment Guidance recommendations found at hcvguidelines.org. These recommendations call for all people with hepatitis C to be treated regardless of disease stage or substance use history. Citing these expert recommendations can help support your argument for your right to treatment.

Track and talk about your symptoms at every provider visit.

IF YOU AND YOUR PROVIDER CAN DEMONSTRATE how HCV impacts your quality of life, your insurance company may approve you. HCV can cause any number of symptoms—some objective, and others, like fatigue or chronic pain, are more subjective. Keep a health journal and track your symptoms and their impact on your quality of life. Talk to your provider about them at every visit and make them a part of your medical record to reference in your appeal.

Explore clinical trials as an option.

CLINICAL TRIALS CAN BE an option for treatment. There are many next-generation HCV treatment options in the pipeline from a number of companies. Clinical trials have the benefit of covering the treatment, as well as the labs and requisite provider visits. Some even pay you for your time and effort. Go to clinicaltrials.gov.

Talk to other HCV patients who've gone through this and received treatment.

GO TO SUPPORT GROUPS, check out patient listservs, join a social media group (Facebook, Reddit, etc.) and ask people what they did to get treatment. Some of the things may not be applicable to you, but you never know; one person's strategy may be a good fit for you. And even if not, you'll get support and empathy from people to help you get through this stressful time.

Finally: Don't give up. Even if it looks bleak and there is no way you will get treatment—and it may very well be bleak—don't stop trying, and lean on your support network to help out. There are people working every day to lift restrictions and improve access to hepatitis C care. Call HELP-4-HEP at (877) 435-7443 to talk about your options and get support while waiting for the cure that you deserve.

PHOTO: ISTOCKPHOTO/ANDREAS HOYER

RESOURCES, SERVICES, AND INFORMATION

HELP-4-HEP
help4hep.org
877-435-7443 (toll-free)
National hepatitis C support line staffed by trained peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9am–7pm ET.

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

Hep C Alliance
hepcalliance.org
Based in Missouri, Hep C Alliance offers an array of HCV services locally, but also works with Quest Diagnostics to offer low-cost HCV diagnostics tests.

The Hepatitis C Mentor and Support Group, Inc.
hepatitiscmsg.org
Based in New York City, HCMSG is an excellent resource for HCV support groups throughout New York, and has links to many other resources for people living with HCV.

Hepatitis Education Project
hepeducation.org
Based in Seattle, HEP provides an array of service for people in the Seattle area, but also has a host of information and resources for all people living with HCV.

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

Hep
hepmag.com
An online and hard copy magazine that provides a wealth of news, health education, and personal stories related to hepatitis C (and hepatitis B). Lucinda Porter's blog posts are a must-read!

Liver Health Connection
liverhealthconnection.org
An 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. They produce fact sheets, policy papers, and annual Pipeline Report, available in Spanish and English. HCV drug factsheets were recently updated.

Test Positive Aware Network
tpan.com
Offers an array of services for people in the Chicago area, including HIV and HCV testing. Publishes the national bi-monthly magazine POSITIVELY AWARE as well as annual HIV and HCV drug guides at positivelyaware.com.

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

HIVandHepatitis.com
hivandhepatitis.com
Presents high quality and accurate news coverage on the prevention and treatment of HIV, HCV, and HIV/HCV co-infection.

HepatitisC.net
hepatitisc.net
A website that offers education, tools, and resources to help you manage your disease. Articles are written by people living with HCV (including some who have been cured), patient advocates, and medical providers. They also produce a weekly newsletter.

ProPatient
propatient.com
An innovative patient educational website covering a wide array of medical conditions, including hepatitis C. The website has an interactive video platform to provide up-to-date hepatitis C education.

Connecting with you and your hepatitis C patients **so they can finally connect to a cure**

At Walgreens Specialty Pharmacy, we work side by side with you to help improve your patients' lives. **Our passion is personal.**

To learn more, contact your local Walgreens Specialty Pharmacy representative or email us at **hepatitis@walgreens.com.**

Walgreens Specialty Pharmacy