POSITIVELY AWARE
THE HIV TREATMENT JOURNAL OF TEST POSITIVE AWARE NETWORK
JULY+AUGUST 2015

START NOW
STUDY CONFIRMS THAT EVERYONE WITH HIV SHOULD BE ON TREATMENT

HIV SUMMER READING LIST
COMPELLING IDEAS IN FIGHTING HIV

MY GENOTYPE, MY OPTIONS
CHOOSING THE BEST HCV TREATMENT

THE THIRD ANNUAL

HEPATITIS C DRUG GUIDE

POSITIVELY AWARE TEAMS UP WITH **PROJECT INFORM** FOR A GUIDE TO THE STANDARD OF CARE FOR HCV

RENÉ
LIVING WITH HIV, AND TACKLING HCV.

What is STRIBILD?

STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL of virus in their blood) and whose healthcare provider determines that they meet certain other requirements. STRIBILD combines 4 medicines into 1 pill to be taken once a day with food. STRIBILD is a complete single tablet regimen and should not be used with other HIV-1 medicines.

STRIBILD does not cure HIV-1 infection or AIDS. To control HIV-1 infection and decrease HIV-related illnesses you must keep taking STRIBILD. 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 STRIBILD?

STRIBILD can 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 (not normal) 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 (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include 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.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight (obese), or have been taking STRIBILD for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and stop taking STRIBILD, your hepatitis may suddenly get worse. Do not stop taking STRIBILD without first talking to your healthcare provider, as they will need to monitor your health. STRIBILD is not approved for the treatment of HBV.

Who should not take STRIBILD?

Do not take STRIBILD if you:

- **Take a medicine that contains:** alfuzosin, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, pimozide, sildenafil when used for lung problems (Revatio®), triazolam, oral midazolam, rifampin or the herbal supplement St. John's wort.
- **For a list of brand names for these medicines,** please see the Brief Summary on the following pages.
- **Take any other medicines to treat HIV-1 infection,** or the medicine adefovir (Hepsera®).

What are the other possible side effects of STRIBILD?

Serious side effects of STRIBILD may also include:

- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do regular blood and urine tests to check your kidneys before and during treatment with STRIBILD. If you develop kidney problems, your healthcare provider may tell you to stop taking STRIBILD.
- **Bone problems,** including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- **Changes in body fat** 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 STRIBILD.

The most common side effects of STRIBILD include nausea and diarrhea. 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 STRIBILD?

- **All your health problems.** Be sure to tell your healthcare provider if you have or had any kidney, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking STRIBILD without first talking with your healthcare provider.
- **If you take hormone-based birth control** (pills, patches, rings, shots, etc).
- **If you take antacids.** Take antacids at least 2 hours before or after you take STRIBILD.
- **If you are pregnant** or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in STRIBILD can pass into breast milk, and it is not known if this can harm the baby.

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 Brief Summary of full Prescribing Information with **important warnings** on the following pages.

*STRIBILD is a combination of the medicines TRUVADA (emtricitabine and tenofovir disoproxil fumarate), TYBOST (cobicistat), and VITEKTA (elvitegravir).

STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL of virus in their blood) and whose healthcare provider determines that they meet certain other requirements. STRIBILD does not cure HIV-1 or AIDS.

I started my personal revolution

Talk to your healthcare provider about HIV-1 treatment.

STRIBILD is a complete HIV-1 treatment in 1 pill, once a day that combines the medicines in TRUVADA + TYBOST + VITEKTA.*

Ask if it's right for you.

STRIBILD®

elvitegravir 150mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg tablets

www.STRIBILD.com

GILEAD

Patient Information

STRIBILD® (STRY-bild)
(elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is STRIBILD?

- **STRIBILD is a prescription medicine** used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also be used to replace current HIV-1 medicines for some adults 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 past HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **STRIBILD is a complete HIV-1 medicine** and should not be used with any other HIV-1 medicines.
- **STRIBILD does not cure HIV-1 or AIDS.** You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- **Ask your healthcare provider about how to prevent passing HIV-1 to others.** Do not share or reuse needles, injection equipment, or personal items that can have blood or body fluids on them. Do not have sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

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

STRIBILD can cause serious side effects, including:

1. **Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take STRIBILD or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**
   - feel very weak or tired
   - have unusual (not normal) muscle pain
   - have trouble breathing
   - have stomach pain with nausea or vomiting
   - feel cold, especially in your arms and legs
   - feel dizzy or lightheaded
   - have a fast or irregular heartbeat
2. **Severe liver problems.** Severe liver problems can happen in people who take STRIBILD. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following symptoms of liver problems:**
   - 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
   - stomach pain

   You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time.
3. **Worsening of Hepatitis B infection.** If you have hepatitis B virus (HBV) infection and take STRIBILD, your HBV may get worse (flare-up) if you stop taking STRIBILD. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
   - Do not run out of STRIBILD. Refill your prescription or talk to your healthcare provider before your STRIBILD is all gone
   - Do not stop taking STRIBILD without first talking to your healthcare provider
   - If you stop taking STRIBILD, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking STRIBILD

Who should not take STRIBILD?

Do not take STRIBILD if you also take a medicine that contains:

- adefovir (Hepsera®)
- alfuzosin hydrochloride (Uroxatral®)
- cisapride (Propulsid®, Propulsid Quicksolv®)
- ergot-containing medicines, including: dihydroergotamine mesylate (D.H.E. 45®, Migranal®), ergotamine tartrate (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), and methylergonovine maleate (Ergotrate®, Methergine®)
- lovastatin (Advicor®, Altoprev®, Mevacor®)
- midazolam, when taken by mouth
- pimozide (Orap®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- sildenafil (Revatio®), when used for treating lung problems
- simvastatin (Simcor®, Vytorin®, Zocor®)
- triazolam (Halcion®)
- the herb St. John's wort

Do not take STRIBILD if you also take any other HIV-1 medicines, including:

- Other medicines that contain elvitegravir, cobicistat, emtricitabine, or tenofovir (Atripla®, Complera®, Emtriva®, Truvada®, Tybost®, Viread®, Vitekta®)
- Other medicines that contain lamivudine or ritonavir (Combivir®, Epivir® or Epivir-HBV®, Epzicom®, Kaletra®, Norvir®, Triumeq®, Trizivir®)

STRIBILD is not for use in people who are less than 18 years old.

What are the possible side effects of STRIBILD?

STRIBILD may cause the following serious side effects:

- **See "What is the most important information I should know about STRIBILD?"**
- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking STRIBILD. Your healthcare provider may tell you to stop taking STRIBILD if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take STRIBILD. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat** can happen in people who take HIV-1 medicine. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system** (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of STRIBILD include:

- Nausea
- Diarrhea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

- These are not all the possible side effects of STRIBILD. For more information, ask your healthcare provider.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking STRIBILD?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, bone, or liver problems, including hepatitis B infection
- If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
  - There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take STRIBILD.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - Two of the medicines in STRIBILD can pass to your baby in your breast milk. It is not known if the other medicines in STRIBILD can pass into your breast milk.
  - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements:

- STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works.
- Be sure to tell your healthcare provider if you take any of the following medicines:
  - Hormone-based birth control (pills, patches, rings, shots, etc)
  - Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or after you take STRIBILD
  - Medicines to treat depression, organ transplant rejection, or high blood pressure
  - amiodarone (Cordarone®, Pacerone®)
  - atorvastatin (Lipitor®, Caduet®)
  - bepridil hydrochloride (Vascor®, Bepadin®)
  - bosentan (Tracleer®)
  - buspirone
  - carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
  - clarithromycin (Biaxin®, Prevpac®)
  - clonazepam (Klonopin®)
  - clorazepate (Gen-xene®, Tranxene®)
  - colchicine (Colcrys®)
  - medicines that contain dexamethasone
  - diazepam (Valium®)
  - digoxin (Lanoxin®)
  - disopyramide (Norpace®)
  - estazolam
  - ethosuximide (Zarontin®)
  - flecainide (Tambocor®)
  - flurazepam
  - fluticasone (Flovent®, Flonase®, Flovent Diskus®, Flovent HFA®, Veramyst®)
  - itraconazole (Sporanox®)
  - ketoconazole (Nizoral®)
  - lidocaine (Xylocaine®)
  - mexiletine
  - oxcarbazepine (Trileptal®)
  - perphenazine
  - phenobarbital (Luminal®)
  - phenytoin (Dilantin®, Phenytek®)
  - propafenone (Rythmol®)
  - quinidine (Neudexta®)
  - rifabutin (Mycobutin®)
  - rifapentine (Priftin®)
  - risperidone (Risperdal®, Risperdal Consta®)
  - salmeterol (Serevent®) or salmeterol when taken in combination with fluticasone (Advair Diskus®, Advair HFA®)
  - sildenafil (Viagra®), tadalafil (Cialis®) or vardenafil (Levitra®, Staxyn®), for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your healthcare provider or get medical help right away.
  - tadalafil (Adcirca®), for the treatment of pulmonary arterial hypertension
  - thioridazine
  - voriconazole (Vfend®)
  - warfarin (Coumadin®, Jantoven®)
  - zolpidem (Ambien®, Edlular®, Intermezzo®, Zolpimist®)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking STRIBILD without first talking with your healthcare provider.

Keep STRIBILD and all medicines out of reach of children.

This Brief Summary summarizes the most important information about STRIBILD. If you would like more information, talk with your healthcare provider. You can also ask your healthcare provider or pharmacist for information about STRIBILD that is written for health professionals, or call 1-800-445-3235 or go to www.STRIBILD.com.

Issued: December 2014

GILEAD

POSITIVELY AWARE

JOURNALISM. INTEGRITY. HOPE.

JEFF BERRY
EDITOR-IN-CHIEF
@PAeditor
"There's exciting news about HCV treatment that offers a cure. But it is too often priced out of the reach of many."

ENID VÁZQUEZ
ASSOCIATE EDITOR
@enidvazquezpa
"So great to work with Andrew Reynolds and Project Inform again—they're the best!"

RICK GUASCO
CREATIVE DIRECTOR
@rickguasco
"Out of the estimated four million in the U.S. who have hepatitis C, half of them don't even know they have it. When I contracted hep B in 1983, I didn't know either. So, you can bet I got tested for HCV."

JASON LANCASTER
PROOFREADER

CONTRIBUTING WRITERS
CARLOS A. PEREZ
JIM PICKETT
ANDREW REYNOLDS

PHOTOGRAPHERS
JOHN GRESS
CHRIS KNIGHT

ADVERTISING
LORRAINE HAYES
L.Hayes@tpan.com

DISTRIBUTION AND SUBSCRIPTION SERVICES
distribution@tpan.com

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

FRONT COVER BACKSTORY

PHOTO: JOHN GRESS

HIV-POSITIVE SINCE 2002, René, 52, photographed by John Gress for this issue's cover (and above), discovered five years ago that he'd also contracted the hepatitis C virus (HCV) through sexual contact.

"I'd been having flu-like symptoms—fever, cold sweats, and severe joint pain," René says.

His doctor determined that René had genotype 1 HCV, a form of hep C common in the U.S. The good news, however, was that there was no apparent cirrhosis or other liver damage.

Patients with HCV can go for as long as 20–30 years before showing signs of liver damage. With his liver in relatively good condition, and concerned about possible drug interactions with his medications for HIV and depression, René decided to hold off on pursuing HCV treatment.

Once he decided to treat his HCV co-infection, however, he ran into a roadblock. René is on disability, and Medicaid rejected his application to receive treatment. Although the new HCV drugs are a cure, their cost has prompted Medicaid to limit treatment only to the most seriously ill patients.

Still, René is determined to address his HCV infection, just as he has adhered to his HIV treatment.

"I am responsible for my own actions," René says. "I know that I've made some decisions that have had serious consequences, but I've also made the decision to take charge of my situation and do what I need to do to stay healthy."

—RICK GUASCO

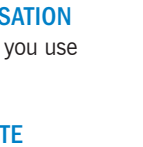
POSITIVELY AWARE

JULY+AUGUST 2015 VOLUME 27 NUMBER 4

DEPARTMENTS

FEATURES

ONLY ON POSITIVELYAWARE.COM



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

THE YELLOW PEOPLE: A PERFORMANCE GROUP PROMOTES THE 50TH INTERNATIONAL LIVER CONGRESS, ORGANIZED BY THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER (EASL), WHICH WAS HELD IN APRIL IN VIENNA, AUSTRIA.

THE THIRD ANNUAL HEPATITIS C DRUG GUIDE

YELLOW PEOPLE: ©EASL

LET'S CONNECT

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.

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

EMAIL: inbox@tpan.com.

TWEET: @PosAware

READERS POLL

IN THE MAY+JUNE ISSUE WE ASKED

How often do you use condoms?

MY PARTNER AND I are monogamous and HIV-positive, both virally suppressed, so we choose not to use condoms.

SOME OF THE TIME. It's too easy to lose yourself in the moment.

NEVER. I have an undetectable viral load and 575 T-cells, and go for a check-up every six months.

MOST OF THE TIME. Straight woman here. I've had sex with several men over the years, including with ones I had only known for a few hours. I always used condoms. I have had HPV several times, but that's been it as far as STIs. Also, I got married in my 40s and had two kids (no medical help necessary in getting pregnant). Condoms worked for me as birth control as well!

AS AN HIV-POSITIVE MALE in a serodiscordant relationship, not using a condom is not an option!

NEVER. Why?

NEVER. I have an undetectable viral load and am in a stable magnetic relationship.

RARELY. Just into jacking off the other guy and oral.

MOST OF THE TIME. My primary partner and I are non-monogamous. We don't always use condoms with each other, but we always use condoms with other people.

RARELY. Most gay men have stopped using condoms after 30 years. We need to accept that reality. TASP and PrEP work, so we should be using them, rather than making people feel guilty. Sex should be fun, and people living with HIV deserve to have fun sex like everybody else.

NEVER. I'm not arguing that it's a good decision, but being on PrEP helps.

RARELY. I prefer not to, but I let my partner make the decision based on his comfort level. I'm on PrEP.

RARELY. I only use them if the other guy puts one on him or me.

NEVER. I'm on birth control with a mutually monogamous partner. But condom use would increase to all of the time if any of that were to change.

RARELY. I serosort with other undetectable poz men.

NEVER. They don't feel good. It's not really sex; it's simulated sex. I'd rather masturbate than use them.

SOME OF THE TIME. I'm on PrEP, and depending on the partner, after careful discussion, I sometimes choose not to use one.

RARELY. I'm HIV-positive and serosort with other HIV-positives who are healthy and undetectable.

RARELY. Poz and undetectable, so I let my negative partners determine whether they want me to use condoms or not. I actively encourage HIV-negative potential partners to be on PrEP.

RARELY. As a straight guy who is a non-drug user and positive, I know it is less risky. I hope we all can someday live without this human disease.

FOR INTERCOURSE, always. Had a few occasions of [condomless] oral, but I usually insist a girl uses a hat, even though they say it's not necessary just for this. A straight guy and recovering addict from heroin, coke, and alcohol, clean since 8/6/96! HIV-positive since '94 and as the Simple Minds song says, alive and kicking!

THIS ISSUE'S QUESTION

Are you more concerned about your T-cells or your viral load?

VOTE AT POSITIVELYAWARE.COM.

EDITOR'S NOTE JEFF BERRY

A CURE DELAYED

WELCOME TO the 3rd Annual POSITIVELY AWARE HCV Drug Guide. A big thanks and huge shout out to Andrew Reynolds of Project Inform, for his superhuman efforts in writing and putting together this guide for the second year in a row.

As treatment continues to evolve and improve for people with HCV infection, as well as those co-infected with HIV, we have the ability to eradicate a disease which today affects between 3 and 5 million people in the U.S. alone. SVR (cure) rates are now at 95–100% for all-oral regimens that last as few as eight, 12, or 24 weeks, with little to no side effects. It's exciting to hear the news of friends, family members, and co-workers who, one by one, are being cured of HCV.

Sadly, these live-saving and life-changing medications continue to be out of reach for most.

In "The Value of an HCV Cure," Andrew Reynolds talks about the personal, public health, and societal benefits of a cure, and makes a strong argument that a cure should be made available to everyone living with HCV. Unfortunately, availability doesn't always ensure access.

"There's a difference between prescribing (hepatitis C) drugs and actually being able to get these drugs for our patients," said Dr. Andrew Aronsohn, a liver specialist at the University of Chicago Medical Center, in a story for the *Chicago Tribune* dated November 16, 2014. "It's becoming a very complicated issue."

Federal law requires that Medicaid must make drugs from certain pharmaceutical companies available, but that access can come with strings attached. According to the *Tribune* article, with higher costs facing an already cash-strapped state, and states being allowed to restrict who gets access, Illinois Medicaid will only pay for treatment for the sickest patients. Other criteria such as no history of alcohol or drug abuse in the last 12 months, or requiring patients to come in for medication refills every two weeks, place additional roadblocks that are unnecessary, and, frankly, bordering on unethical. In Illinois, "a 'once in a lifetime' provision in the criteria means that if treatment fails, the program will not pay for the patient to try again."

In my own experience, I have several friends who have recently been cured of HCV, and another, Doug, who just started treatment. Doug is one of the lucky ones because he's on Medicare, but even that comes with a monthly $1,500 co-pay for just his HCV treatment. He opted to add ribavirin (and its side effects) to his regimen, which cuts the duration of his treatment down from 24 to 12 weeks, thereby avoiding three additional months of co-pays. But at a cost.

René, who's featured on our cover, is not as lucky (see page 4). Medicaid has denied his application to receive HCV therapy four times. But he will continue to persevere, and hopefully one day get access to a cure which remains elusive for so many.

Some have chosen not to wait, and are taking matters into their own hands by engaging in medical tourism. Medical tourism is an industry popping up for people who choose to travel to another country to obtain access to less expensive medications and treatments that are cost-prohibitive, or unavailable, in their own country. Of course medical tourism comes with certain obvious risks, including counterfeit medications. But there are reports of people who are successful, as in one man who traveled from Australia to India to get his entire course of treatment for HCV using generic drugs, for only $1,000.

Others, like Vermont Sen. Bernie Sanders, are asking the government to intercede. In May Sanders asked the Department of Veterans Affairs "to invoke emergency powers to make expensive hepatitis C drugs available at affordable prices to treat tens of thousands of veterans now being denied the most effective care."

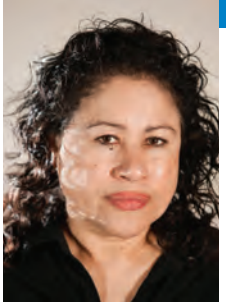
So while there continue to be barriers to access and treatment, the future is looking brighter for people living with HCV, as newer and easier-to-take medications become available. A cure is now attainable, and advocates and policy makers will continue to fight to ensure access for everyone, until one day this disease is finally eradicated, once and for all. Let's hope when a cure for HIV is available, it's not priced out of our reach as well.

Take care of yourself and each other.

It's exciting to hear the news of friends, family members, and co-workers who, one by one, are being cured of HCV. Sadly, these live-saving and life-changing medications continue to be out of reach for most.

FOLLOW JEFF @PAEDITOR

PHOTO: CHRIS KNIGHT



Briefly

BY **ENID VÁZQUEZ**

MORE THAN 2,500 CYCLISTS AND 700 VOLUNTEER "ROADIES" participated in AIDS/LifeCycle, a 545-mile journey from San Francisco to Los Angeles during the first week of June to raise awareness about HIV/AIDS, raising more than $16.3 million for the San Francisco AIDS Foundation and the HIV/AIDS-related services of the Los Angeles LGBT Center. On June 5, 2015, the sixth day of AIDS/LifeCycle, participants gathered at San Buenaventura State Beach for a candlelight vigil to remember those lost in the fight against HIV/AIDS.

MORE STI PREP POTENTIAL

A small pilot study in HIV-positive gay men showed promise in preventing STIs with a daily pill. A daily dose of the antibiotic doxycycline may help positive people avoid infections of gonorrhea, syphilis, and chlamydia. Results were published in the February issue of the journal *Sexually Transmitted Diseases*. Read a report on the study from the San Francisco AIDS Foundation at bit.ly/1Hgpz50.

SIMPLIFYING THERAPY

In May, ViiV Healthcare announced the start of its Phase 3 study looking at switching people from a triple-drug regimen to the two-drug regimen of Tivicay (dolutegravir) and Edurant (rilpivirine). Last year, ViiV entered into an agreement with Janssen Pharmaceuticals to co-formulate its Tivicay with Janssen's Edurant. Read the press release about the Phase 3 SWORD-1 and SWORD-2 research at bit.ly/1EZW4QG.

REPRIEVE STUDIES HIV CARDIOVASCULAR CARE

The National Institutes of Health (NIH) has launched the largest study ever looking at whether the use of statin drugs can reduce the risk for heart attacks, strokes, and other major cardiovascular events in people with HIV. Statins, which lower cholesterol levels, include medications such as Crestor (rosuvastatin), Lipitor (atorvastatin), and Pravachol (pravastatin). For more information on REPRIEVE (Randomized Trial to Prevent Vascular Events in HIV), including a list of study sites around the country, go to niaid.nih.gov/about/organization/daids/research/Pages/reprieveTrial.aspx.

NEW HIV CURE PARTNERSHIP

In May, the University of North Carolina (UNC) announced that it had teamed up with pharmaceutical giant GlaxoSmithKline (GSK) to form the HIV Cure Center and a company, Qura Therapeutics, to handle the business end of the endeavor. "This first of its kind, joint-ownership model is a novel approach toward finding a cure, and we hope it serves as an invitation to the world's best researchers and scientists," UNC Chancellor Carol Folt said in a press release. "Today, Carolina's best are taking another major step in the global fight against HIV/AIDS." Read the release at prn.to/1AnHBSZ.

SETTLEMENT IN MEDICAL DISCRIMINATION CASE

In April, the AIDS Law Project of Pennsylvania reached a settlement with a health care practice, including financial compensation, for an HIV-positive patient. The man said that he, his wife, and their child were denied medical care after he was accused of leaving blood in a bathroom. See TheBody.com for more information, at bit.ly/1AnQxI2.

NEW HEP B GUIDELINES

The HIV OI (opportunistic infections) guidelines were updated in April to provide new information on hepatitis B. There is new information on immunization regimens, techniques to evaluate the stage of liver fibrosis, and recommendations for the length of hep B treatment following the start of HIV therapy. See the hep B section at 1.usa.gov/1B02SNE.

EMPLOYMENT SESSION

The National Working Positive Coalition has once again organized a free, full-day pre-conference Institute on HIV and Employment for the U.S. Conference on AIDS, to be held in Washington, D.C. September 10–13. "Join us to discuss strategies to improve HIV health and prevention outcomes focused on improving access to employment opportunities and effective employment services for people living with or at higher risk for HIV," the coalition stated in a press release. The Institute will take place Wednesday, September 9 in the Equality Forum of the Human Rights Campaign, 1640 Rhode Island Ave., NW. For more information, contact markmisrok@gmail.com. See "Yes, There is a Job for You," featuring an interview with Misrok, at hivplusmag.com/features/2015/04/14/yes-there-job-you.

VÁZQUEZ: CHRIS KNIGHT | CANDLELIGHT VIGIL: GEORG LESTER

TRAUMA-INFORMED CARE

The Positive Women's Network-USA (PWN-USA) has collaborated on a trauma-informed model of health care. According to a press release from the organization, "Advocates believe that failure to heal from the effects of current and past trauma explains the crater in the HIV care continuum for women: Only 70% of women with HIV link to care, and fewer than half remain connected to care." Naina Khanna, the organization's executive director, co-wrote the paper presenting the model with Edward L. Machtinger, MD, director of the Women's HIV Program at UCSF. It was published May 6 in the journal *Women's Health Issues*. Read it at whijournal.com/article/S1049-3867(15)00033-X/fulltext. See page 18.

JACK MACKENROTH NAMED TO GLOBAL FORUM COMM POST

In May, the Global Forum on MSM & HIV (MSMGF) appointed HIV activist Jack Mackenroth as its new Senior Communications Officer. Jack will be responsible for implementing the MSMGF's communications strategy and for ensuring the agency's brand recognition. The agency's commitment to global information exchange and knowledge translation helps to ensure that advocates and community members working for the health and human rights of men who have sex with men are well supported to continue their respective work. Go to msmgf.org.

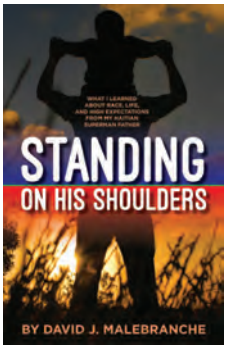
A DAY WITH HIV EXHIBIT IN INDIANA

In May, pictures from A Day with HIV, the anti-stigma campaign of POSITIVELY AWARE, traveled to Austin, Indiana, the site of a recent HIV outbreak. The exhibit was there thanks to PA's partnership with the CDC's *Let's Stop HIV Together* campaign. "This is amazing, that A Day with HIV was part of an event that seeks to inform others and to break the cycle of stigma and shame surrounding HIV and AIDS in the Austin community," said POSITIVELY AWARE editor Jeff Berry.

The photo display accompanied Jeanne White-Ginder as she presented "The Legacy of Ryan White" at Austin High School. In 1984 at the age of 13, her son Ryan was one of the first children with hemophilia in the country diagnosed with AIDS, and the entire family was stigmatized and discriminated against as a result. Ryan White died five years later. The Ryan White CARE Act, named after the young advocate, has benefitted hundreds of thousands of people living with HIV to this day. Indiana's outbreak resulted from political opposition to syringe exchange.

REMEMBERING OUR FATHERS

In a newly-released memoir, *Standing on His Shoulders*, HIV physician and researcher David Malebranche celebrates the lessons he learned from his father, a Haitian physician who immigrated to the United States in the 1960s. Malebranche provides a counter narrative to the current focus on absentee fathers in Black communities across the country, chronicling the ways his relationship with his father morphed, evolved, and ultimately grew stronger throughout his life. Order the book now on standingonhisshoulders.com and Amazon.com.



HIV COLUMN LAUNCHED

The international news wire service Q Syndicate has launched a new column, "Positive Thoughts," through a partnership with four of the leading HIV information providers in the country. The editors of *Plus*, POSITIVELY AWARE, *POZ*, and TheBody.com will contribute to a monthly column on an alternating cycle. Go to qsyndicate.com.

HIV AND ARTERIES

In May, study results published online by *Clinical Infectious Diseases* reported that HIV is associated with increased risk of hardening of the arteries, but not with carotid artery thickness. Good news: people with more than 500 T-cells didn't have increased risk compared to HIV-negative counterparts. Read a story about the study from London's AIDSMap at aidsmap.com/HIV-infection-and-low-CD4-count-associated-with-hardening-of-arteries/page/2964936.

TRANSGENDER HEALTH CARE

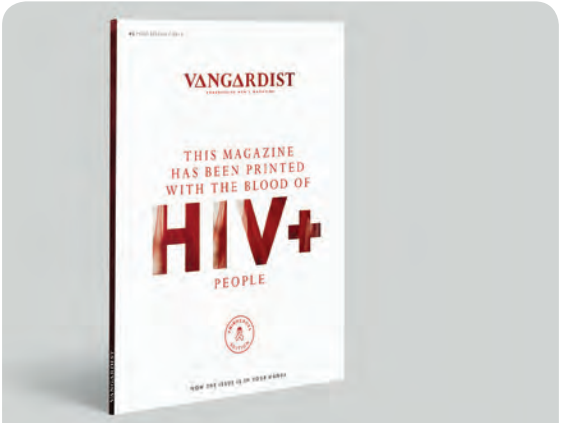
According to preliminary results from a study, some transgender individuals may forgo health care due to stigma. "There is evidence that health care providers do tend to be judgmental, and it's unwelcoming," said Adrian Juarez, PhD, a public health nurse and assistant professor of nursing at the University of Buffalo School of Nursing. The study included Latino transgender people in El Paso, Texas. Read the university's story about Juarez's work at buffalo.edu/news/releases/2015/04/062.html.

HIV RESEARCH SITE OPENS AT LGBT CENTER

In May, Northwestern University opened an HIV research center at Chicago's Center on Halsted as part of a five-year grant from the NIH. The study will examine factors affecting HIV risk and prevention, and will include the faster tests available for HIV, and also test for other STIs.

A DRUG FOR NECK FAT

The FDA in May approved an injectable drug to reduce fat under the chin. Many people living with HIV continue to have excess fat in their necks from early HIV therapy, and Dr. Paul Sax discusses the new drug, Kybella (deoxycholic acid), in his blog, HIV and ID Observations. Go to bit.ly/1LcLlXR.



MAGAZINE PRINTED WITH POSITIVE BLOOD

The Vienna-based magazine *Vangardist* printed its May issue with blood from three HIV-positive individuals mixed with ink. Editors of the men's magazine of cutting-edge style and technology told the press they wanted to raise awareness of the continuing epidemic and help erase stigma. The issue included coverage on HIV heroes. Go to vangardist.com.

PrEP TIMING

New research shows that taking Truvada for HIV prevention should start a week before a potential exposure and continue for four weeks after sex. "An intensive pharmacokinetic study of [Truvada] for [PrEP] showed that blood and rectal drug levels corresponding to high PrEP activity for men who have sex with men (MSM) are reached after about 1 week of daily dosing and appear to remain adequate for several days after the last pill, according to a report in the March 1 edition of *Clinical Infectious Diseases*," reported Liz Highleyman for HIVandHepatitis.com. Read her story at hivandhepatitis.com/hiv-prevention/hiv-prep/5169-study-suggests-truvada-prep-should-start-1-week-before-and-continue-4-weeks-after-sex.

CUT HERE

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.

❑ SIGN ME UP FOR PA UPDATE
POSITIVELY AWARE's free email news digest:

_____
EMAIL ADDRESS

❑ 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:

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.

MAY+JUNE 2015
_____ COPIES

MARCH+APRIL 2015
_____ COPIES

JAN+FEB 2015
_____ COPIES

NOV+DEC 2014
_____ COPIES

SEP+OCT 2014
_____ COPIES

JULY+AUGUST 2014
_____ COPIES

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 ST., SUITE 300
CHICAGO, IL 60640-3016

START NOW

A NEW STUDY CONFIRMS THAT EVERYONE WHO IS HIV-POSITIVE SHOULD BE ON TREATMENT

BY **JOEL GALLANT, MD, MPH**

THE START (Strategic Timing of AntiRetroviral Treatment) trial enrolled 4,685 HIV-positive adults beginning in 2009 and randomized them to start ART immediately, with a CD4 count above 500 cells/mm^3, or to wait until it had dropped below 350. An independent data and safety monitoring board (DSMB) reviewed the interim results and recommended that the results be released early because the data overwhelmingly support early ART. Participants in the early ART arm had a 53 percent lower risk of an AIDS-related illness, serious non-AIDS illness, or death compared to those who deferred ART.

START was a controversial study—not because the question wasn't important or because the study was poorly designed. Instead, many experts, especially in the U.S., felt that observational studies like NA-ACCORD, data supporting the prevention benefits of ART, and the reduction in inflammation and immune activation associated with ART already provided sufficient justification for starting treatment regardless of CD4 count. They argued that by the time the expensive START study was completed, guidelines and practice would have evolved, and universal treatment would have already become the standard of care. They raised the possibility that START would be inconclusive, since in people with high CD4 counts and low risk for opportunistic infections, the potential long-term benefits of early therapy couldn't be assessed within the time frame of the study. I was one of those skeptics, arguing that while in a world of unlimited resources it would be nice to have such a trial, there were better ways to spend our limited research dollars.

Both the DHHS and the IAS-USA guidelines panels agreed, recommending ART for all. Those recommendations were equally controversial, since they were not based on data from randomized, controlled clinical trials and were made while START was still enrolling. The criticisms on both sides of the Atlantic were loud and sometimes ugly, but with time the controversy in the U.S. subsided. Clinicians and their patients came to accept the idea that HIV infection should be treated after diagnosis. For the last few years it has been rare to hear a "When to Start" lecture at any HIV update conference since the question was felt to have been answered.

Now along come the early results of the START trial, which confirm current U.S. practice and treatment guidelines. Surprise: Treating a chronic, progressive disease that causes immunosuppression and inflammation with safe and effective drugs is good for you! Cynicism aside, these *are* important results, even if they come too late to affect guidelines and practice in the U.S. Few expected such a dramatic result, dramatic enough to cause the study to be stopped early. Besides providing a surprisingly definitive result and vindicating U.S. guidelines panels, these data will have tremendous importance globally, where most countries have not jumped on the American universal therapy bandwagon.

There will undoubtedly be a steady stream of additional data from START substudies over the coming years. As with the earlier SMART trial of CD4-guided treatment interruption, a study that some experts also thought was ill-advised, there is more we can learn from START. Although I was a naysayer, I'm glad to have the SMART data to support the guidelines I contributed to, as well as my own clinical practice. More importantly, I'm optimistic about the influence these data will have on the treatment of HIV infection globally.

PARTICIPANTS IN START'S EARLY TREATMENT ARM HAD A

53%

LOWER RISK

OF AN AIDS-RELATED ILLNESS, SERIOUS NON-AIDS ILLNESS, OR DEATH COMPARED TO THOSE WHO DELAYED TREATMENT.

EDITOR'S NOTE: For another great summary plus Q&A about the START study, including an excellent community perspective by Simon Collins, go to i-base.info/i-base-qa-on-the-start-study-results.

JOEL GALLANT is Medical Director of Specialty Services at Southwest CARE Center in Santa Fe, New Mexico, adjunct professor of medicine at the Johns Hopkins School of Medicine, and clinical professor of medicine at the University of New Mexico. He treats patients and conducts clinical trials on the treatment of HIV infection. He is Immediate Past-Chair of the HIV Medicine Association and is on the Board of Directors of the IAS-USA. He is a member of the IAS-USA Antiretroviral Guidelines panel and the IDSA/HIVMA HIV Primary Care Guidelines panel. He authored *100 Questions and Answers about HIV and AIDS* and has an interactive question and answer blog at hivforum.tumblr.com.

TRIUMEQ is a once-a-day pill used to treat HIV-1. TRIUMEQ should not be used by itself in some people. Take TRIUMEQ exactly as your healthcare provider tells you.

Is it time for you? Ask your doctor.

APPROVED USES

TRIUMEQ is a prescription medicine used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. HIV-1 is the virus that causes AIDS. It is not known if TRIUMEQ is safe or effective in children under the age of 18. TRIUMEQ is not for use by itself in people who have or have had resistance to abacavir, dolutegravir, or lamivudine.

TRIUMEQ does not cure HIV-1 or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illness.

IMPORTANT SAFETY INFORMATION

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

- **Serious allergic reaction (hypersensitivity reaction).** TRIUMEQ contains abacavir. Patients taking TRIUMEQ may have a serious allergic reaction to abacavir that can cause death. Your risk is much higher if you have a gene variation called HLA-B*5701. Your healthcare provider can determine with a blood test if you have this gene variation. **If you get symptoms from 2 or more of the following groups while taking TRIUMEQ, call your healthcare provider right away: 1. fever; 2. rash; 3. nausea, vomiting, diarrhea, or stomach pain; 4. generally ill feeling, extreme tiredness, or achiness; 5. shortness of breath, cough, or sore throat.** Your pharmacist will give you a Warning Card with a list of these symptoms. **Carry this Warning Card with you at all times.**

  If you stop taking TRIUMEQ because of an allergic reaction, never take TRIUMEQ or any other medicine that contains abacavir or dolutegravir again. If you take TRIUMEQ or any other abacavir-containing medicine again after you have had an allergic reaction, **within hours** you may get **life-threatening symptoms** that may include **very low blood pressure** or **death**. If you stop TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ, talk with your healthcare provider before taking it again. Taking TRIUMEQ again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before. **If your healthcare provider tells you that you can take TRIUMEQ again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.**
- **A buildup of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take TRIUMEQ. This serious medical emergency can cause death. Call your healthcare provider right away if you feel very weak or tired; have unusual muscle pain; have trouble breathing; have stomach pain with nausea and vomiting; feel cold, especially in your arms and legs; feel dizzy/light-headed; or have a fast/irregular heartbeat.
- **Severe liver problems.** Severe liver problems can happen in people who take TRIUMEQ. In some cases, these severe liver problems can lead to death. You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight, or have been taking nucleoside analogue medicines for a long time. Call your healthcare provider right away if you get any of the following signs or symptoms:
  - yellow skin, or the white part of the eyes turns yellow; dark urine; light-colored stools; nausea; itching; or stomach-area pain.
- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 and hepatitis B virus infections, your hepatitis virus infection may get worse if you stop taking TRIUMEQ. Do not stop taking TRIUMEQ without first talking to your healthcare provider, so he or she can monitor your health.
- **Resistant hepatitis B virus.** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIUMEQ and become harder to treat (resistant).
- **Use with interferon and ribavirin-based regimens.** If you're taking TRIUMEQ and interferon, with or without ribavirin, tell your healthcare provider about any new symptoms. Liver disease might get worse in patients who are taking HIV-1 medicines and interferon.

Who should not take TRIUMEQ?

- **Do not take TRIUMEQ if you:**
  - have the HLA-B*5701 gene variation
  - have ever had an allergic reaction to abacavir, dolutegravir, or lamivudine
  - take dofetilide (Tikosyn®)
  - have certain liver problems

What are other possible side effects of TRIUMEQ?

- People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with TRIUMEQ. Your healthcare provider may do tests to check your liver function before and during treatment with TRIUMEQ.
- When you start taking HIV-1 medicines, your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- Changes in body fat can happen in people who take HIV-1 medicines.
- Some HIV-1 medicines, including TRIUMEQ, may increase your risk of heart attack.

The most common side effects of TRIUMEQ include: trouble sleeping, headache, and tiredness.

These are not all the possible side effects of TRIUMEQ. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Important Safety Information continued on next page.

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 brief summary of Prescribing Information for TRIUMEQ on the following pages.

ViiV Healthcare

If you don't have prescription coverage and can't afford your medicines, visit GSKforYou.com or call the ViiV Healthcare Response Center 1-877-844-8872

ViiV for you Healthcare

Printed in USA. DTR045R0 November 2014

"I have the Courage to start HIV treatment. It's Time."

Not an actual patient. Testimonial is based on a collection of real patient experiences.

What should I tell my healthcare provider before taking TRIUMEQ?

- **Before you take TRIUMEQ, tell your healthcare provider if you:**
  - have been tested and know whether or not you have a gene variation called HLA-B*5701.
  - have or had liver problems, including hepatitis B or C infection; have kidney problems; have heart problems, smoke, or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes; drink alcoholic beverages; or have any other medical condition.
  - are pregnant or plan to become pregnant. It is not known if TRIUMEQ will harm your unborn baby.
  - are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ.
- **You should not take TRIUMEQ if you also take:**
  - abacavir (EPZICOM, TRIZIVIR, or ZIAGEN)
  - lamivudine (COMBIVIR®, EPIVIR, EPIVIR-HBV®, EPZICOM, or TRIZIVIR)
  - emtricitabine (EMTRIVA®, ATRIPLA®, COMPLERA®, STRIBILD®, TRUVADA®)
- **Tell your healthcare provider about all the medicines you take,** including prescription and nonprescription medicines (for example, antacids; laxatives; vitamins such as iron or calcium supplements; anti-seizure medicines; other medicines to treat HIV-1, hepatitis, or tuberculosis; metformin; and methadone) and herbal supplements (for example, St. John's wort). TRIUMEQ may affect the way they work, and they may affect how TRIUMEQ works.

Triumeq®

abacavir 600 mg/dolutegravir 50 mg/ lamivudine 300 mg tablets

It's Time.

BRIEF SUMMARY

TRIUMEQ® (TRI-u-meck)

(abacavir 600 mg/dolutegravir 50 mg/lamivudine 300 mg) tablets

Read this Medication Guide before you start taking TRIUMEQ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. Be sure to carry your TRIUMEQ Warning Card with you at all times.

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

- **Serious allergic reaction (hypersensitivity reaction).** TRIUMEQ contains abacavir (also contained in EPZICOM®, TRIZIVIR®, and ZIAGEN®). Patients taking TRIUMEQ may have a serious allergic reaction (hypersensitivity reaction) that can cause death. Your risk of this allergic reaction to abacavir is much higher if you have a gene variation called HLA-B*5701. Your healthcare provider can determine with a blood test if you have this gene variation.

  If you get a symptom from 2 or more of the following groups while taking TRIUMEQ, call your healthcare provider right away to find out if you should stop taking TRIUMEQ.

	Symptom(s)
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness, or achiness
Group 5	Shortness of breath, cough, sore throat

  A list of these symptoms is on the Warning Card your pharmacist gives you. **Carry this Warning Card with you at all times.**

  If you stop TRIUMEQ because of an allergic reaction, never take TRIUMEQ or any other medicines that contain abacavir or dolutegravir (EPZICOM, ZIAGEN, TRIZIVIR, or TIVICAY®) again. If you take TRIUMEQ or any other abacavir-containing medicine again after you have had an allergic reaction, **within hours** you may get **life-threatening symptoms** that may include **very low blood pressure** or **death**. If you stop TRIUMEQ for any other reason, even for a few days, and you are not allergic to TRIUMEQ, talk with your healthcare provider before taking it again. Taking TRIUMEQ again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

  If your healthcare provider tells you that you can take TRIUMEQ again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take TRIUMEQ. Lactic acidosis is a serious medical emergency that can lead to death.

  Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems.

  Call your healthcare provider right away if you get the following symptoms that could be signs of lactic acidosis:
  - feel very weak or tired
  - have unusual (not normal) muscle pain
  - have trouble breathing
  - have stomach pain with nausea and vomiting
  - feel cold, especially in your arms and legs
  - feel dizzy or light-headed
  - have a fast or irregular heartbeat

- **Severe liver problems.** Severe liver problems can happen in people who take TRIUMEQ. In some cases these severe liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis).

  Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:
  - your skin or the white part of your eyes turns yellow
  - dark "tea-colored" urine
  - light colored stools (bowel movements)
  - nausea
  - itching
  - stomach-area pain

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

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 and hepatitis B virus infections, your hepatitis virus infection may get worse if you stop taking TRIUMEQ. To help avoid this: Take TRIUMEQ exactly as prescribed.
  - Do not run out of TRIUMEQ.
  - Do not stop TRIUMEQ without talking to your healthcare provider.
  - Your healthcare provider should monitor your health and do regular blood tests to check your liver for at least several months if you stop taking TRIUMEQ.

- **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with TRIUMEQ and become harder to treat (resistant).

- **Use with interferon and ribavirin-based regimens.** Worsening of liver disease has happened in people infected with HIV-1 and hepatitis C virus who are taking anti-HIV medicines and are also being treated for hepatitis C with interferon with or without ribavirin. If you are taking TRIUMEQ and interferon with or without ribavirin, tell your healthcare provider if you have any new symptoms.

What is TRIUMEQ?

TRIUMEQ is a prescription medicine used to treat HIV-1 (Human Immunodeficiency Virus-type 1) infection. TRIUMEQ contains 3 prescription medicines: abacavir (ZIAGEN), dolutegravir (TIVICAY), and lamivudine (EPIVIR®).

- TRIUMEQ is not for use by itself in people who have or have had resistance to abacavir, dolutegravir, or lamivudine.

It is not known if TRIUMEQ is safe and effective in children.

TRIUMEQ may help:
- reduce the amount of HIV-1 in your blood. This is called "viral load".
- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

TRIUMEQ does not cure HIV-1 infection or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.
- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

(continued on the next page)

BRIEF SUMMARY (cont'd)
TRIUMEQ® (abacavir, dolutegravir, and lamivudine) tablets

Who should not take TRIUMEQ?

Do not take TRIUMEQ if you:

- have a certain type of gene variation called the HLA-B*5701 allele. Your healthcare provider will test you for this before prescribing treatment with TRIUMEQ.
- have ever had an allergic reaction to abacavir, dolutegravir, or lamivudine
- take dofetilide (TIKOSYN®). Taking TRIUMEQ and dofetilide (TIKOSYN) can cause side effects that may be life-threatening.
- have certain liver problems

What should I tell my healthcare provider before taking TRIUMEQ?

Before you take TRIUMEQ, tell your healthcare provider if you:

- have been tested and know whether or not you have a particular gene variation called HLA-B*5701
- have or had liver problems, including hepatitis B or C virus infection
- have kidney problems
- have heart problems, smoke, or have diseases that increase your risk of heart disease such as high blood pressure, high cholesterol, or diabetes
- drink alcoholic beverages
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if TRIUMEQ will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking TRIUMEQ.
  Pregnancy Registry. There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- **are breastfeeding or plan to breastfeed. Do not breastfeed if you take TRIUMEQ.** You should not breastfeed because of the risk of passing HIV-1 to your baby. It is not known if abacavir or dolutegravir passes into your breast milk. Lamivudine can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRIUMEQ may affect the way other medicines work, and other medicines may affect how TRIUMEQ works.

You should not take TRIUMEQ if you also take:

- abacavir (EPZICOM, TRIZIVIR, or ZIAGEN)
- lamivudine (COMBIVIR®, EPIVIR, EPIVIR-HBV®, EPZICOM, or TRIZIVIR)
- emtricitabine (EMTRIVA®, ATRIPLA®, COMPLERA®, STRIBILD®, TRUVADA®)

Tell your healthcare provider if you take:

- antacids, laxatives, or other medicines that contain aluminum, magnesium, sucralfate (CARAFATE®), or buffered medicines. TRIUMEQ should be taken at least 2 hours before or 6 hours after you take these medicines.
- anti-seizure medicines:
  - oxcarbazepine (TRILEPTAL®)
  - phenytoin (DILANTIN®, DILANTIN®-125, PHENYTEK®)
  - phenobarbital
  - carbamazepine (CARBATROL®, EQUETRO®, TEGRETOL®, TEGRETOL®-XR, TERIL®, EPITOL®)
- any other medicine to treat HIV-1
- iron or calcium supplements taken by mouth. Supplements containing calcium or iron may be taken at the same time with TRIUMEQ if taken with food. Otherwise, TRIUMEQ should be taken at least 2 hours before or 6 hours after you take these medicines.
- medicines used to treat hepatitis virus infections, such as interferon or ribavirin
- a medicine that contains metformin
- methadone
- rifampin (RIFATER®, RIFAMATE®, RIMACTANE®, RIFADIN®)
- St. John's wort (*Hypericum perforatum*)

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider and pharmacist when you get a new medicine. Ask your healthcare provider or pharmacist if you are not sure if you take one of the medicines listed above.

How should I take TRIUMEQ?

- **Take TRIUMEQ exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking TRIUMEQ without talking with your healthcare provider.
- Stay under the care of a healthcare provider while taking TRIUMEQ.
- You can take TRIUMEQ with or without food.
- If you miss a dose of TRIUMEQ, take it as soon as you remember. If it is within 4 hours of your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.
- Do not run out of TRIUMEQ. The virus in your blood may become resistant to other HIV-1 medicines if TRIUMEQ is stopped for even a short time. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much TRIUMEQ, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TRIUMEQ?

TRIUMEQ can cause serious side effects including:

- **See "What is the most important information I should know about TRIUMEQ?"**
- **Changes in liver tests.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with TRIUMEQ. Your healthcare provider may do tests to check your liver function before and during treatment with TRIUMEQ.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Changes in body fat (fat redistribution)** can happen in people who take HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.
- **Heart attack (myocardial infarction).** Some HIV medicines including TRIUMEQ may increase your risk of heart attack.

The most common side effects of TRIUMEQ include:

- trouble sleeping
- headache
- tiredness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TRIUMEQ. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

(continued on the next page)

BRIEF SUMMARY (cont'd)
TRIUMEQ® (abacavir, dolutegravir, and lamivudine) tablets

How should I store TRIUMEQ?

- Store TRIUMEQ at room temperature between 68°F to 77°F (20°C to 25°C).
- Store TRIUMEQ in the original bottle.
- Keep the bottle of TRIUMEQ tightly closed and protect from moisture.
- The bottle of TRIUMEQ contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. Do not remove the desiccant packet.

Keep TRIUMEQ and all medicines out of the reach of children.

General information about the safe and effective use of TRIUMEQ

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRIUMEQ for a condition for which it was not prescribed. Do not give TRIUMEQ to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about TRIUMEQ. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TRIUMEQ that is written for health professionals.

For more information go to www.TRIUMEQ.com or call 1-877-844-8872.

What are the ingredients in TRIUMEQ?

Active ingredients: abacavir, dolutegravir, and lamivudine

Inactive ingredients: D-mannitol, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. The tablet film-coating contains iron oxide black, iron oxide red, macrogol/PEG, polyvinyl alcohol–part hydrolyzed, talc, and titanium oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:

ViiV Healthcare
Research Triangle Park, NC 27709

by:

GlaxoSmithKline
Research Triangle Park, NC 27709

Lamivudine is manufactured under agreement from
Shire Pharmaceuticals Group plc
Basingstoke, UK

Issued: August 2014
TRM:1MG

MY SUMMER READING LIST TO FIGHT AIDS

PROGRESS IN THE FIGHT AGAINST HIV DEPENDS ON COMPELLING IDEAS. HERE ARE A FEW WORTH READING

BY **DAVID ERNESTO MUNAR**

PHOTO © YURI/ISTOCKPHOTO.COM

SUCCESSFUL AIDS ADVOCATES study the epidemic and the many developments and approaches designed to interrupt its cycles. To make a difference, AIDS advocates need curiosity, passion, knowledge, and tenacity to effect meaningful change.

Keeping up-to-date on a constellation of AIDS-related news and topics is admittedly difficult. Thankfully, advocacy organizations produce a steady stream of thought-provoking recommendations and analysis to fuel advocacy work.

That's why I've compiled my summer reading list. Below are just some of the wonky reports I plan to peruse or re-read between my growing pile of magazines and books for leisure this summer. Like any good list, this one is certainly incomplete and hardly representative of all there is to learn and know about the AIDS fight. Use mine or make your own. Between picnics and pool

parties, broaden your horizons this season for the hard work ahead!

1. **New York State's Blueprint to End AIDS:** Tenacious advocacy persuaded New York Governor Andrew Cuomo to commission a planning process and report to "get to zero" new AIDS cases.

   "The end of the AIDS epidemic in New York State will occur when the total number of new HIV infections has fallen below the number of HIV-related deaths," Gov. Cuomo says in the report. Members of the governor's End AIDS Task Force advanced several recommendations, including new financial investments, to go even further than the blueprint in truly striving for zero new infections and HIV-related deaths by 2020. The Blueprint articulates three driving goals: (1) provide testing and linkage to care for people with unknown HIV infection; (2) Link and retain in care those who do know their HIV-positive diagnosis; and (3) facilitate access to PrEP and PEP (pre-exposure prophylaxis and non-occupational post-exposure prophylaxis) to prevent HIV acquisition. Treatment Access Group and Housing Works have modelled the new financial investments needed, and offsetting cost-savings produced, to launch the plan with massive scale-up of testing, linkage, and delivery of care, prevention, and other vital services. Learn more about this exciting statewide effort here: health.ny.gov/diseases/aids/ending_the_epidemic/#blueprint. **Projected Fiscal Impact:** treatmentactiongroup.org/sites/g/files/g450272/f/201504/NYS%20ETE%20Fiscal%20Impact%20v4.pdf.

2. **UNAIDS's 90-90-90 Plan** The New York plan might be considered a municipal version of a similar strategy initiated by UNAIDS to marshal global progress against the epidemic. The plan aims to achieve the following targets:

   - By 2020, 90% of all people living with HIV will know their HIV status
   - By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy
   - By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression

   Elegant and persuasive, the plan nonetheless underscores the challenges ahead to meet the defined target. For example, UNAIDS estimates that only 37% of people living with HIV were receiving HIV treatment as of December 2013, leaving more than 22 million people with HIV without treatment. 90-90-90 articulates not only a path forward but the economic and societal benefits of doing so. Download it at unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf.

3. The just-released **CDC Prevention Strategic Plan Through 2020** (cdc.gov/nchhstp/docs/NCHHSTP-Strategic-Plan-through-2020-508.pdf), which describes CDC's high-impact prevention framework, pledges CDC resources to better document dynamics fueling health disparities among men who have sex with men, transgender people, injection drug users, youth, and heterosexuals. CDC further agrees to expand communications with stakeholders on progress toward established goals, better utilize surveillance and program data for planning and decision making, and strengthen collaborations with Medicaid and Medicare.

   The new CDC plan defers to the National HIV/AIDS Strategy, which merits a re-reading (aids.gov/federal-resources/national-hiv-aids-strategy/overview). Unveiled by President Obama in 2010, the plan established meager and yet unrealized goals through 2015. As the White House assesses progress and entertains a possible extension, readers should review recommendations to embolden the nation's HIV/AIDS response plan (see: treatmentactiongroup.org/sites/tagone.drupalgardens.com/files/201304/RevitalizeNHASMeetingReport.pdf).

4. **Back of the Line: The State of AIDS Among Black Gay Men in America** (blackaids.org/images/reports/back.pdf) by the Black AIDS Institute documents the devastating HIV disparities experienced by black gay men in the U.S. At rates rivaling the most affected quarters of the world, the report calls on all sectors to prioritize anti-HIV work with Black gay men; large-scale, targeted awareness, testing, and link-to-care initiatives to reach the population; greater promotion of antiretroviral therapy and adherence; intensive national efforts to reduce other sexually transmitted infections; and scale-up of proven-effective HIV prevention strategies, including PrEP, capacity development for Black gay men's institutions, and policy to mitigate stigma and discrimination suffered by Black gay men.

   NMAC's report entitled **RISE Proud: Combating HIV Among Black Gay and Bisexual Men** (nmac.org/wp-content/uploads/2013/06/Action-Plan_6.4.13.pdf) delves into similar topics such as the role of mass incarceration, trauma, sex work for survival, and HIV criminalization statutes that must be reformed in order to mitigate the HIV crisis within this community.

5. **Transgender Health and HIV** (sfaf.org/hiv-info/hot-topics/beta/beta_2009_sum-fall_transgender2.pdf), a 2009 article by the San Francisco AIDS Foundation, provides a comprehensive and user-friendly guide to transgender healthcare topics important to people living with HIV/AIDS.

   Taking a global perspective, amfAR's issue brief on the **Trans Population and HIV: Time to End the Neglect** (amfar.org/End-the-Neglect) recommends greater leadership, funding, research, healthcare capacity, and structural interventions to mitigate the stigma, discrimination, and HIV-related health disparities suffered by transgender people.

6. **From Treatment to Healing: The Promise of Trauma-Informed Primary Care** (whijournal.com/article/S1049-3867%2815%2900033-X/fulltext) advocates for the adoption of strategies designed to address the effects of trauma on health outcomes among women and other patient populations harmed by current or past traumatic events. As stated in the article, the authors "reviewed patient deaths at the Women's HIV Program (WHP) at the University of California, San Francisco, and revealed that most were not from

HIV, but rather from trauma—directly through murders and indirectly through depression, suicide, and addiction. These deaths occurred in a clinic that already had integrated medical, mental health, and social services. Positive Women's Network—USA (PWN-USA) had also noted the pervasive impact of trauma among its national network of women living with HIV. Together, we looked for ways to address trauma in a clinic setting and found that, despite national calls to action, there was a lack of guidance about the core components of a practical approach to addressing recent and past traumatic experiences within adult primary health care settings."

7. **Prevention on the Line** (avac.org/report2014-15), AVAC's 2014-15 Report, analyzes how national and international target-setting on HIV prevention has led to new investments and achievements reducing new HIV infections in diverse settings around the world. AVAC Executive Director Mitchell Warren summarizes the report in this YouTube video: youtube.com/watch?v=gVsZUrEq_Rg&feature=youtu.be.

   A series of multilingual educational videos by the International Rectal Microbicide Advocates (youtube.com/user/IRMAadvocacy/videos) describe the urgent need for continued scientific focus toward development of a safe and effective gel, lubricant, or suppository formulated with HIV prevention properties. To bolster outcomes, the Black AIDS Institute shines a light on the persistent knowledge gap in HIV sciences and treatment literacy among the HIV/AIDS workforce in the U.S. The report, **When We Know Better, We Do Better** (blackaids.org/images/reports/15-know.pdf), calls for greater education and training for those on the frontlines of the fight against HIV/AIDS.

8. **15 Ways HIV Criminalization Laws Harm Us All** by Lambda Legal (lambdalegal.org/sites/default/files/publications/downloads/15-ways-hiv-criminalization-laws-harm-us-all.pdf) makes a compelling argument for reform of state-based laws that unjustly incarcerate people with HIV for alleged HIV non-disclosure and/or intimate contact with consenting adults, including contact not capable of transmitting HIV.

   Equally powerful is the video **HIV is Not a Crime** by the Sero Project (youtube.com/watch?v=iB-6blJjbjc), which also hosted the first national conference on criminalization advocacy and reform initiatives last year. See the conference report here: seroproject.com/wp-content/uploads/2014/07/Conference_Report_Final_forwebsite.pdf.

   Finally, the Center for HIV Law & Policy's Positive Justice Project published this helpful **Guiding Principles for Eliminating Disease-Specific Criminal Laws** (hivlawandpolicy.org/resources/guiding-principles-eliminating-disease-specific-criminal-laws-positive-justice-project).

9. The Southern HIV/AIDS Strategy Initiative (SASI)'s 2015 report called **One Size Does Not Fit All: What Does High Impact Prevention Funding Mean for Community-Based Organizations in the Deep South?** (southernaids.files.wordpress.com/2015/04/cdc-cbo-funding-paper-one-size-does-not-fit-all-3-final.pdf) makes a cogent argument for additional resources for rural and suburban areas in the southeastern U.S., which bears the brunt of the country's HIV/AIDS crisis.

   Supplementing SASI's analysis, the Latino Commission on AIDS published **The State of Latinos in The Deep South: Being Visible by Piercing the Stigma Veil** (latinoaids.org/publications/DeepSouthReport2015.pdf). As the Latino population grows in the region, the infrastructure and cultural competency needed to meet an array of health, wellness, and psychosocial needs is not in place, which is exacerbating rates of HIV/AIDS among Latino men and women across the region.

10. How healthcare services are financed and delivered for people with and at risk of HIV/AIDS is quickly shifting thanks to the reforms established by the Affordable Care Act (ACA). Mapping changes and helping advocates navigate health policy and law in the new ACA landscape is the focus of HIVHealthReform.org, which offers free monthly webinars, an active blog, and collaborative advocacy opportunities.

    The Kaiser Family Foundation has an HIV specific portal on the ACA and resources such as this article on payer reform: iasusa.org/sites/default/files/tam/21-4-138.pdf.

    The Ryan White safety-net is being deployed in unique ways across the country to fill gaps around the ACA. Kaiser and Georgetown University wrote about ways Ryan White services may be repositioned to drive better care outcomes (kff.org/hivaids/report/updating-the-ryan-white-hivaids-program-for-a-new-era-key-issues-and-questions-for-the-future). Fact sheets on the ACA and Ryan White are also available from AIDS United (ACA: aidsunited.org/data/files/Site_18/AW2015-ACA_Web.pdf and Ryan White: aidsunited.org/data/files/Site_18/AW2015-RWP_Web.pdf).

Yes, learning can be fun—I promise! Becoming an informed AIDS advocate serves the greater good, and what could be more rewarding. Whatever resources you review, these reports demonstrate that better outcomes are not only possible but also achievable, heightening the tragedy of persistent HIV health disparities.

Keep reading, keep learning, and keep contributing to the discourse. As RuPaul reminds us, reading is fundamental. PA

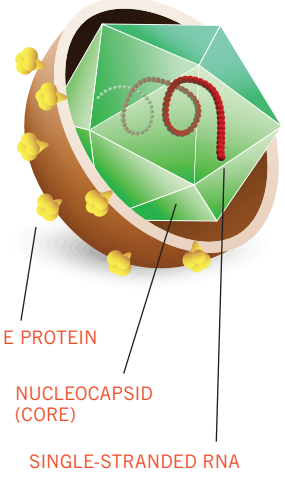
DAVID ERNESTO MUNAR is the President and CEO of the Howard Brown Health Center (HBHC), Chicago's LGBTQ community health center. He joined HBHC in 2014 after a 23-year career at the AIDS Foundation of Chicago, where he served as President and CEO from 2011 to 2014. Munar devoted his entire professional career to building comprehensive systems of care and prevention that meet the needs of vulnerable populations. He is Colombian-American, a gay man, and a person living with HIV.

THE VALUE OF AN HCV CURE

CURING HCV BENEFITS THE INDIVIDUAL—AND SOCIETY

BY **ANDREW REYNOLDS, PROJECT INFORM**

In the Direct Acting Antiviral (DAA) era, treatments for hepatitis C virus (HCV) are easier to take, with fewer side effects, and for a shorter duration, yet the high cost of drugs and insurance companies' unwillingness to pay for treatment keeps the hope of cure out of reach for most living with HCV. This article explores the many benefits of curing HCV, and makes a case that people living with this disease should reap the benefits of cure.



The hepatitis C virus (HCV), above, needs to infect a liver cell in order to reproduce. After attaching to a cell, HCV uses that cell's replication cycle to make hundreds to thousands of copies of itself. Direct acting antivirals (DAAs) target the HCV life cycle at several points, preventing the virus from reproducing and eventually eradicating all virus from the body and achieving cure. Take DAAs as prescribed to maximize chance of cure.

Hepatitis C virus (HCV) is chronic progressive liver disease.

TO BE MORE PRECISE, HCV is chronic progressive liver disease that can be cured.

Without a cure, up to 20% of people with HCV will develop cirrhosis (scarring that damages the liver, causing it to not function properly) in 20–30 years. There are several additional factors, such as alcohol consumption or HIV/HCV co-infection, that can both increase the risk of developing, and speed up this rate of, cirrhosis. Among those patients with cirrhosis, there is a 1–5% annual risk of developing liver cancer, and a 3–6% annual risk of hepatic decompensation (disease progression requiring a liver transplant). Once people are diagnosed with a decompensated liver, their risk of death in the next year runs between 15–20%.[1]

Early treatment and cure of hepatitis C can virtually eliminate all of these long-term complications.

Although a minority opinion, it has been argued that not everyone progresses to cirrhosis and end-stage liver disease, making HCV treatment and cure not valuable or cost effective.[2] Tell that to a person who is infected with HCV and lives with the daily stress that comes from living with a chronic disease and the uncertainty of knowing if they will be one of those who will develop cirrhosis. Tell that to the woman of child-bearing age who would like to treated and cured before becoming pregnant and starting a family. Tell that to a person who does not want to transmit HCV to their sexual or drug-using partner.

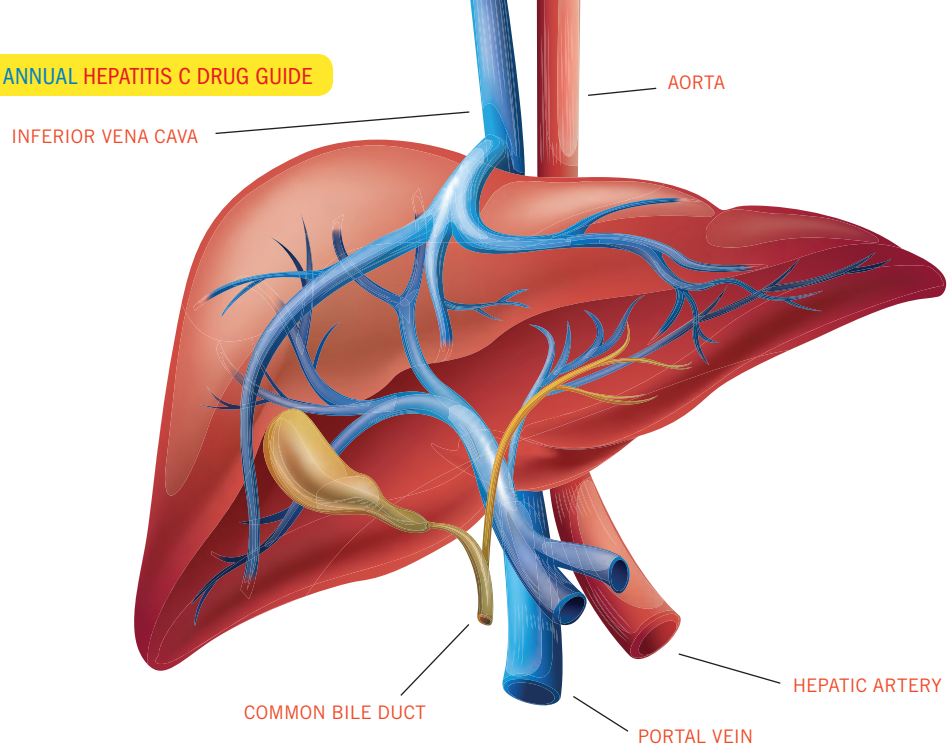
People with HCV want to be cured, and we have effective treatments that can cure them. And yet, we have large numbers of patients who cannot access HCV treatment due to the refusal of insurance companies or Medicaid programs to pay for them for a variety of reasons including, but not limited to, active or recent substance use, livers that are deemed too healthy, or restrictions on the number of times a person can be treated. None of these excuses are based on clinical evidence or public health concerns, and expert medical opinion calls for the treatment of all people with HCV.[3]

Even before the DAA era, we had evidence of the benefits that come from curing HCV.[4] Today, we are now seeing more and more people cured of HCV. With this comes increased knowledge about the clinical value of a cure, as well as the more subjective improved quality of life experienced by those who are cured. Consequently, there has been a flood of research that demonstrates the benefits of an HCV cure for the individual, the public health, and society.

What is an HCV cure?

THE TERM *sustained virologic response*, or *SVR*, is used to describe a cure for HCV. When HCV treatment is successful, a person will have an undetectable HCV viral load. This person is followed for 12 weeks (with periodic viral load tests to look for a return of the virus). If a person has no virus and remains undetectable after 12 weeks, they achieve an SVR12, which is considered a virologic cure—and in most cases they will remain undetectable after they finish their treatment.

The term "undetectable" can sometimes lead to confusion. Patients will often ask: Does this mean the virus is completely gone? The answer is yes. HCV is



The liver is the largest organ in the human body, responsible for over 500 vital functions, including filtering toxins and transporting nutrients. The PORTAL VEIN, where approximately 75% of the blood passes, is the major blood vessel responsible for a healthy, functioning liver. These functions are dependent upon a liver whose shape is unchanged with little to no scarring to serve as a barrier to blood flow. On average, HCV progresses slowly over a period of time that can last 20–30 years, with small amounts of scar tissue building, changing the shape of the liver, and stressing the portal vein. Portal hypertension, a condition where the pressure on the portal vein restricts blood flow and can lead to a host of serious and potentially life-threatening conditions such as ascites (fluid retention), hepatic encephalopathy (mental confusion), or esophageal varices (enlarged, and sometimes bleeding, veins in the esophagus). Many of these conditions can be managed, but are very challenging. With cure, comes a reversal of some, or in some cases all, scarring and improvement in functioning as the liver regains its original shape and there is less pressure on the portal vein.

no longer found in the blood or in the liver. A patient could not undergo an HCV genotype test because there is no virus to test. *The virus is gone*.

But is the cure permanent? HCV recurrence after 12 weeks of SVR is extremely rare: Less than 1% of cured patients experience a late relapse.[5]

People who have been cured of hepatitis C will always test positive for HCV antibodies, but they no longer have virus in their body doing damage to their liver, nor do they have any virus to infect others. If a person is exposed to HCV at a later date, re-infection can happen, making prevention health education and the provision of tools such as clean syringes and other injecting supplies, and improved access to substance use and behavioral health services, an extremely important part of any HCV treatment program. But an SVR is a cure, and the liver starts to heal and function better once the virus is gone.

Personal benefits of a cure

TO THE PERSON living with HCV, the benefits of getting cured are many. It is worth noting that these benefits are found not only in HCV mono-infected persons, but also people living with HIV/HCV co-infection and in people following a liver transplant.

Once cure is achieved, most people experience an improvement in liver functioning, and many experience a reversal of fibrosis (mild scarring) over time. Even patients who have cirrhosis (severe scarring) experience improved liver function and a reduction in the risk of developing end-stage liver complications. There is evidence that even cirrhosis can be reversed once SVR is achieved. In reviews that have looked at changes in the liver over time, the shape of the liver can slowly return to normal, as do many of its functions. Liver enzymes improve, as do platelet counts of cured patients.[6]

This reduction in fibrosis and return to normal liver function comes with a host of other longer-term benefits, not the least of which is extension of life. Cured patients live longer than people who are not. A cure improves the life expectancy of people with HCV, including those with cirrhosis.

With cure from HCV comes a clinical improvement in a variety of medical conditions that occur outside the liver (extrahepatic). Conditions such as cryoglobulinemia or porphyria cutenea tarda clinically improve, or in some cases disappear. Curing HCV also reduces the risk of developing diabetes.

In addition to the clinical benefits of HCV cure, there is an additional body of literature that looks at the more subjective, personal experience, called "patient-reported outcomes" (PROs). PROs are measurements about a person's health and well-being that come from a survey or questionnaire that comes directly from the patient.[7] Reviews of PROs for people with HCV show that with cure comes reduction in fatigue, depression, insomnia, and chronic pain. People report reductions in anxiety and worry. In every aspect of quality of life, people cured of HCV report improvements. As one patient stated, "I had no idea how sick I was until I got cured of HCV."

Public health and societal benefits of a cure

FOR ALL THE personal benefits of cure, there are societal benefits, too. Both in terms of public health (reduced HCV transmission) and cost-effectiveness (utilization of fewer health resources and increased productivity in the workforce), the benefits run deep.

As with HIV, HCV treatment and reducing viral load to undetectable levels can dramatically reduce the risk of transmitting the virus to others. With HCV cure, there is no virus left, so the risk of transmission is not only reduced, it's eliminated: A cured patient cannot transmit HCV to anyone else. In a model looking at the impact of increased screening and treatment in a variety of

HCV TREATMENT AND CURE PUTS AN END TO THE DOWNWARD SPIRAL OF DIMINISHING PRODUCTIVITY.

BENEFITS OF HCV CURE

- Negative HCV viral load for life.
- Disappearance of HCV from the liver.
- Normalization of AST, ALT, and GGT (liver function enzymes).
- Platelet increase in patients with thrombocytopenia.
- Reduced risk of developing cirrhosis.
- Reversal of fibrosis and, in some cases, cirrhosis.
- Disappearance of varices (enlarged blood vessels in the esophagus, which may burst).
- Reduced risk of progression to liver cancer.
- Reduced risk of decompensated liver disease.
- Reduced risk of progression to liver failure and liver transplant.
- Eliminates risk of transmission to drug using or sexual partners.
- Eliminates risk of mother-to-child transmission.
- Improved quality of life.
- Reduction of psychological distress (anxiety, depression, etc.).
- Elimination of HCV-related stigma.
- Lessens healthcare utilization and costs.
- Return to the workforce, improved productivity.

SOURCE:
RUI MARINHO, 2014

countries, researchers found that even a small increase in HCV screening and treatment can have an enormous impact on the burden of HCV. A treatment rate of 10% could lead to near-elimination of HCV overall.[8]

Treatment, or cure as prevention, can have an even greater impact on populations that are most affected by HCV, such as people who inject drugs (PWIDs) and HIV-positive MSM (men who have sex with men) at risk of sexual transmission. In a mathematical model looking at the prevention impact that comes from treating PWIDs, HCV prevention expert Natasha Martin, PhD, found that even if a small number of PWIDs were treated, there would be a 25% reduction in HCV in this population, and this benefit increases the more treatment that is provided.[9] Although we do not have models or research studies assessing the impact of HCV cure as prevention in HIV/HCV co-infected persons at risk through sexual transmission, a prediction would seem to follow logically that routine HCV screening and treatment of patients who are co-infected with HIV would lead to similar reductions of new infections.

Cost effectiveness of HCV treatment

IN SPITE OF studies that have demonstrated the cost-effectiveness of these new HCV treatments, the dominant narrative in the media and policy discussions revolve around the high cost. As Dr. John Bartlett stated, "What does it mean when a drug can be cost effective, but no one can afford to take it?"

There has been much research on the cost-effectiveness of HCV treatment. Cost effectiveness is a complex subject. It is a mathematical model that looks at both the quantity (how long one lives with or without treatment), and the quality of life (either with or without treatment), accounting for the burden of disease that comes with living with symptoms such as fatigue or chronic pain.

In a sweeping review of both the clinical and financial value of HCV treatments, the California Technology Assessment Forum (CTAF) found that while treating all patients regardless of liver disease severity was expensive, it met the benchmark for cost-effectiveness in terms of the benefits gained.[10]

A number of other cost effectiveness studies have found similar results, with the economic benefits increasing as the cost of HCV medications go down.[11]

All cost effectiveness studies find that waiting to treat for more advanced liver disease significantly increases cost, and Dr. Sammy Saab and colleagues have shown that the cost per cure is lower for both treatment-naïve and non-cirrhotic patients, providing further evidence for the effectiveness of an early HCV treatment strategy.[12]

This strategy was further strengthened by a review of HCV treatments, where researchers found it to be a cost-effective option for patients across the spectrum of liver disease, with both short- and long-term health and economic benefits.[13]

Another area of HCV that has received little attention, but has significant benefits to both individuals and society, is worker productivity. It has been found that people with HCV miss more days from work, and are less productive when at work, primarily due to HCV-associated fatigue. The effect gets worse as HCV disease progresses and liver function worsens.

Further, this has a domino-like effect, as decreased worker productivity also affects the HCV patient's caregiver, often a partner or family member, whose productivity also worsens as they miss work to take care of their loved one.

HCV treatment and cure puts an end to the downward spiral of diminishing productivity. Recent research indicates that people are able to work while on DAAs, and once cure is achieved, their absenteeism is reduced and their productivity increases dramatically.[14]

Treating and curing HCV lowers healthcare costs for all patients, including those with end-stage liver disease. In a review of 33,309 patients with HCV, 4,111 of whom received treatment, it was found that those who were treated and cured of HCV had significantly lower medical expenses than those who were not.[14] These savings increased as the severity of HCV disease increased. The average monthly healthcare costs of those with no or little fibrosis was $885 for the treated group and $1,370 in the untreated, while those with cirrhosis had costs of $1,369 (treated) versus $1,802 (untreated). Lastly, the costs of treated versus untreated patients in end-stage liver disease saw a significant increase in monthly cost of $3,547 and $5,137 respectively.[15] Other studies have come to similar findings and have highlighted the long-term cost savings associated with curing HCV, further cementing the rationale for treating all people with HCV.

In short: Treating people *now* saves money *later.*

CONCLUSIONS

THE BENEFITS of curing HCV far outweigh the costs. The high cost of HCV drugs is often cited as a reason to defer or refuse treatment, a rationale that does not hold up to the scrutiny of cost effectiveness analyses. That said, regardless of affordability, these drugs have value. They cure people, extend life, eliminate risk of transmission, reduce suffering, and save money in the long run while improving worker productivity. They should be available to all people living with HCV.

THERE IS NO CLINICAL REASON TO MAKE A BLANKET DENIAL OF TREATMENT BASED SOLELY ON A PERSON'S CURRENT OR PAST SUBSTANCE USE.

TREATING PEOPLE WHO USE DRUGS

IN 2001, Brian Edlin and colleagues wrote an opinion piece in the *New England Journal of Medicine* titled, "Is it justifiable to withhold treatment for hepatitis C from illicit drug users?"[1] At the time, withholding treatment was indeed the standard set by the National Institutes of Health (NIH) in a consensus statement on managing HCV, which called for at least six months of abstinence from alcohol or drugs before initiating treatment. Back then, HCV treatment consisted of 6–12 months of interferon and ribavirin, and was extremely difficult to take. It is true that some people who used drugs were not able to successfully complete treatment. It's equally true people who did not use drugs were not able to complete treatment. Whether one used drugs or not, these medications were hard to take.

Regardless, the NIH recommendations served as a barrier to care and treatment of people who used drugs. Edlin and his co-authors identified four reasons used to withhold HCV treatment in people who use drugs (PWUDs)—poor adherence to treatment, inability to cope with side effects, high risk of reinfection with HCV following cure, and the lack of urgency to start treatment overall—and they provided evidence to refute these assumptions and recommendations to overcome them. This influential article helped change these recommendations so that by the end of 2002, the NIH consensus statement was changed to allow for treatment decisions for people who use drugs to be made on a case-by-case basis.

The stigma of drug use and the belief that drug users could not be treated remained, however, and many providers held onto the earlier recommendations, and refused to treat patients who were using substances. Similarly, patients who used drugs would self-select and not seek treatment, assuming that they would not get it.

Fast forward to 2015, and much has changed in the treatment world. These changes eliminate many of the earlier arguments for denying treatment to PWUDs. As stated earlier, shorter durations, simplified regimens with no interferon injections, and minimal side effects have simplified treatment and improved adherence. Re-infection is still possible, and studies have demonstrated that it does happen, but at low rates—0.8 to 4.7 per 100 person years.[2] Further, with a robust harm reduction program of clean syringes and injection supplies, access to drug treatment and opiate-substitution (methadone or buprenorphone) therapy and other prevention interventions, re-infection can be reduced further. The ease of treatment and benefits that come with cure can and should be available to all people who have HCV, including those who use drugs. Yet it is not.

The lack of urgency to treat PWUDs remains, as does the stigma and discrimination toward PWUDs.

THAT SAID, we know that PWUDs can and have been treated and cured. Even in days of pegylated interferon and ribavirin, adherence rates and treatment outcomes were similar to those of their non-drug using counterparts. With newer treatments, there is no clinical reason to make a blanket denial of treatment based solely on a person's current or past substance use. The treatments work in the same way and cure at the same rates among PWUDs as they do in those who do not use substances. Treatment decisions should be made on a case by case basis between the patient and medical provider. In some cases, extra support around medication adherence, mental health issues, and other medical aspects of managing HCV may be needed, but these are problems that may affect non-drug users as well and are not unique to PWUDs. Drug use alone should not be a discriminatory factor in preventing cure. Indeed, as we will see in the accompanying article, treating and curing PWUDs has larger public health implications, as it will reduce or eliminate new infections.

As the AASLD/IDSA/IAS-USA HCV Guidelines state, "Recent and active injection drug use should not be seen as an absolute contraindication to HCV therapy. Scale up of HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the United States and globally."[3]

—ANDREW REYNOLDS

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.

FOOTNOTES TO THIS ARTICLE CAN BE FOUND AT POSITIVELYAWARE.COM.

HOW TO USE THIS GUIDE

BY **ANDREW REYNOLDS**

THE HCV DRUG GUIDE includes medications that are FDA approved, expected to be approved this year, or are likely to be approved through June of 2016. The information provided on FDA-approved drugs comes from the package labels, as well as other sources such as conference presentations and medical journals. For the drugs not yet approved, the information comes from conference presentations and medical journals.

All current HCV medications must be taken in combination with other medications (with the exception of Harvoni and Viekira Pak). Pegylated interferon is injected, but all other HCV medications are taken as pills. HCV treatment may comprise two or more medications taken together, but there are also fixed-dose combination (FDC) pills which contain two medications from different classes.

HCV IN A NEW LIGHT:
LIVER CELLS UNDER A LIGHT MICROSCOPE.

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 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

Just as HIV medications are divided into several different drug classes, the "DAA" (direct acting antiviral) era of HCV treatment has seen the development of several different classes as well. Currently, there are six classes of HCV drugs, and two multi-class combination options:

- NS3/4A protease inhibitors
- Nucleoside and nucleotide NS5B polymerase inhibitors
- NS5A inhibitors
- Non-nucleoside NS5B polymerase inhibitors
- Multi-class combination drugs
- Pegylated interferon alfa (no longer recommended)
- Nucleoside analogs

GENOTYPE

Genotype (GT) refers to the strain or variation 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). Different genotypes can play a role in disease progression or severity, but it is especially important to know one's genotype to determine the correct treatment. Some genotypes can be treated for a shorter amount of time and do not need interferon or even ribavirin. We will list the genotype(s) that the specific HCV medication works against, both those for which there is FDA approval as well as those with enough evidence for "off-label" use.

APPROVED FOR HIV/HCV CO-INFECTION

Information about the HCV drugs for use in HIV/HCV co-infected patients will appear in this section, both those that are FDA approved as well as those for off-label use.

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 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 they pay for 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 have a general idea of 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. We provide a list of HCV drug patient assistance and co-pay programs on page 51.

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 would 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 such as anemia (low red blood cell count) or neutropenia (low white blood cell count).

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 the most important ones for drugs that are commonly used by people living with HCV. 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 general information that does not fit in any of the above sections, but is still important for you to know, including opinions from treatment advocates.

What's new in 2015?

We have seen several changes since last year's publication of the HCV Drug Guide: Victrelis and Incivek, two first-generation HCV protease inhibitors, have been discontinued and are no longer available in the United States. These have been removed from this year's guide, but are still available for review on the PA website. We saw the FDA approval of the drugs that comprise Harvoni and Viekira Pak, and the withdrawal of the FDA submission for the approval of asunaprevir. Daclatasvir has been resubmitted for approval in genotypes 1 and 3 (used with the already approved Sovaldi), as has the Merck FDC, grazoprevir and elbasvir. Stay tuned to POSITIVELY AWARE (positivelyaware.com) and Project Inform (projectinform.org) for updates and news on hepatitis C medications, prevention, and treatments.

POSITIVELY AWARE

THE POSITIVELY AWARE 2015 HEPATITIS C DRUG CHART

Each drug is recommended for use in combination with other HCV drugs (except Harvoni and Viekira Pak). See drug page or package insert for complete information on dosage requirements. Drug chart information is current as of June 10, 2015. To review the complete POSITIVELY AWARE 2015 HCV Drug Guide online, go to positivelyaware.com.

Harvoni

ledipasvir/sofosbuvir, or LDV/SOF
One ledipasvir 90 mg/sofobuvir 400 mg tablet once daily, with or without food.
GENOTYPE 1 (OFF-LABEL USE IN GT4.)
FDA APPROVED FOR MONO-INFECTION. OFF-LABEL USE POSSIBLE FOR HIV/HCV CO-INFECTION.

Sovaldi

sofosbuvir, SOF, or SOV
One 400 mg tablet once daily, with or without food.
GENOTYPE 1 2 3 4 5 6
FDA APPROVED FOR HIV/HCV CO-INFECTION.

Viekira Pak

ombitasvir/paritaprevir/ritonavir and dasabuvir, or OMB/PTV-R + DAS
Two ombitasvir 12.5 mg/paritaprevir 75 mg/ritonavir 50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily, with a meal.
GENOTYPE 1 (OFF-LABEL USE IN GT4.)
FDA APPROVED FOR HIV/HCV CO-INFECTION.

Olysio

simeprevir, or SMV
One 150 mg capsule once daily, with food. Do not crush or dissolve the capsule.
GENOTYPE 1
FDA APPROVED FOR MONO-INFECTION. OFF-LABEL USE MAY occur FOR HIV/HCV CO-INFECTION.

Copegus; Rebetol; Ribasphere

ribavirin, or RBV
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.
GENOTYPE 1 2 3 4 5 6
FDA APPROVED FOR HIV/HCV CO-INFECTION.

PegIntron; Pegasys

peginterferon alfa-2b; peginterferon alfa-2a
or rPEG; PEG IFN; IFN; pegylated interferon; interferon
Administer one injection once a week with or without food; must be taken in combination with ribavirin and other HCV drugs. Interferon should never be taken by itself.
GENOTYPE 1 2 3 4 5 6
FDA APPROVED FOR HIV/HCV CO-INFECTION.

daclatasvir, or DCV

NOT YET APPROVED. Take one 60 mg tablet once daily with or without food; 30 mg tablets are sold in Europe and may be available in U.S. upon approval.
GENOTYPE 1 3 4
LIKELY TO BE APPROVED FOR HIV/HCV CO-INFECTION.

grazoprevir/elbasvir, or GZR/EBR

formerly MK-5172, MK-8742
NOT YET APPROVED. Studied as a fixed-dose combination of grazoprevir 100 mg/elbasvir 50 mg.
GENOTYPE 1 4 6
LIKELY TO BE APPROVED FOR HIV/HCV CO-INFECTION.

ISENTRESS®
raltegravir film-coated tablets 400 mg

HIV Positive Model

Hey Birthday! It's always great to see you.

I wanted to know more about my HIV treatment options. So I spoke with my doctor and we chose ISENTRESS as part of my HIV regimen. My doctor told me it could fight my HIV and may fit my needs and lifestyle.

I have so many plans for what's next.

ISENTRESS® (raltegravir) has been available to help people manage their HIV since 2007 and has been tested in long-term clinical trials.

- ISENTRESS has been available for previously treated patients since 2007 and for first-time patients since 2009
- A long-term clinical study lasting more than 4 years (240 weeks) of patients being treated with HIV medicine for the first time showed that ISENTRESS plus *Truvada* may help:
  - Lower viral load to undetectable
  - Raise CD4 cell counts

ISENTRESS may not have these effects in all patients.

INDICATION

ISENTRESS is a prescription HIV-1 medicine used with other antiretroviral medicines to treat human immunodeficiency virus (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age.

The use of other medicines active against HIV-1 in combination with ISENTRESS may increase your ability to fight HIV.

ISENTRESS does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

IMPORTANT RISK INFORMATION

Some people who take ISENTRESS develop serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead to death. If you develop a rash with any of the following symptoms, stop using ISENTRESS and call your doctor right away: fever, generally ill feeling, extreme tiredness, muscle or joint aches, blisters or sores in mouth, blisters or peeling of skin, redness or swelling of the eyes, swelling of the mouth or face, problems breathing.

Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems: yellowing of your skin or whites of your eyes, dark or tea-colored urine, pale-colored stools (bowel movements), nausea or vomiting, loss of appetite, pain, aching or tenderness on the right side of your stomach area.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

People taking ISENTRESS may still develop infections or other conditions associated with HIV infections.

The most common side effects of ISENTRESS include: trouble sleeping, headache, dizziness, nausea, and tiredness. Less common side effects include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.

Tell your doctor before you take ISENTRESS if you have a history of a muscle disorder called rhabdomyolysis or myopathy or increased levels of creatine kinase in your blood.

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. These may be signs of a rare serious muscle problem that can lead to kidney problems.

These are not all the possible side effects of ISENTRESS. For more information, ask your doctor or pharmacists. Tell your doctor if you have any side effect that bothers you or that does not go away.

Tell your doctor about all your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. ISENTRESS is not recommended for use during pregnancy. **Do not breastfeed if you take ISENTRESS.** Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take ISENTRESS with those other medicines.

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

Please read the adjacent Patient Information for ISENTRESS and discuss it with your doctor.

Merck Helps™ | Having trouble paying for your Merck medicine? Merck may be able to help. www.merckhelps.com

Talk to your healthcare professional about ISENTRESS and visit isentress.com.

MERCK

Patient Information
ISENTRESS® (eye **sen** tris) (raltegravir) film-coated tablets

ISENTRESS raltegravir film-coated tablets 400 mg

Read this Patient Information before you start taking ISENTRESS and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS?
ISENTRESS is a prescription HIV medicine used with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV-1) infection in people 4 weeks of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if ISENTRESS is safe and effective in babies under 4 weeks of age.

When used with other HIV medicines to treat HIV-1 infection, ISENTRESS may help:
- reduce the amount of HIV in your blood. This is called " viral load".
- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.
- reduce the amount of HIV-1 and increase the CD4+ (T) cells in your blood, which may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

ISENTRESS does not cure HIV-1 infection or AIDS.

You must stay on continuous HIV therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:
- Do not share needles or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

What should I tell my doctor before taking ISENTRESS?
Before taking ISENTRESS, tell your doctor if you:
- have liver problems
- have a history of a muscle disorder called rhabdomyolysis or myopathy
- have increased levels of creatine kinase in your blood
- have phenylketonuria (PKU). ISENTRESS chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ISENTRESS can harm your unborn baby.
  Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take ISENTRESS.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS. Keep a list of your medicines to show your doctor and pharmacist.

- You can ask your doctor or pharmacist for a list of medicines that interact with ISENTRESS.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take ISENTRESS with other medicines.

How should I take ISENTRESS?
- Take ISENTRESS exactly as prescribed by your doctor.
- **Do not** change your dose of ISENTRESS or stop your treatment without talking with your doctor first.
- Stay under the care of your doctor while taking ISENTRESS.
- ISENTRESS film-coated tablets must be swallowed whole.
- ISENTRESS chewable tablets may be chewed or swallowed whole.
- ISENTRESS for oral suspension should be given to your child within 30 minutes of mixing. **See the detailed Instructions for Use that comes with ISENTRESS for oral suspension**, for information about the correct way to mix and give a dose of ISENTRESS for oral suspension. If you have questions about how to mix or give ISENTRESS for oral suspension, talk to your doctor or pharmacist.
- **Do not switch between the film-coated tablet, the chewable tablet, or the oral suspension without talking with your doctor first.**
- **Do not** run out of ISENTRESS. Get a refill of your ISENTRESS from your doctor or pharmacy before you run out.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not double your next dose or take more ISENTRESS than prescribed.
- If you take too much ISENTRESS, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of ISENTRESS?

ISENTRESS can cause serious side effects including:
- **Serious skin reactions and allergic reactions.** Some people who take ISENTRESS develop serious skin reactions and allergic reactions that can be severe, and may be life-threatening or lead to death. If you develop a rash with any of the following symptoms, stop using ISENTRESS and contact your doctor right away:
  - fever
  - generally ill feeling
  - extreme tiredness
  - muscle or joint aches
  - blisters or sores in mouth
  - blisters or peeling of the skin
  - redness or swelling of the eyes
  - swelling of the mouth or face
  - problems breathing

Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems:
  - yellowing of the skin or whites of your eyes
  - dark or tea colored urine
  - pale colored stools (bowel movements)
  - nausea or vomiting
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of ISENTRESS include:
- trouble sleeping
- headache
- dizziness
- nausea
- tiredness

Less common side effects include:
- depression
- hepatitis
- genital herpes
- herpes zoster including shingles
- kidney failure
- kidney stones
- indigestion or stomach area pain
- vomiting
- suicidal thoughts and actions
- weakness

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. These may be signs of a rare serious muscle problem that can lead to kidney problems.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ISENTRESS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ISENTRESS?

Film-Coated Tablets:
- Store ISENTRESS Film-Coated Tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ISENTRESS and all medicines out of the reach of children.

General information about ISENTRESS

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use ISENTRESS for a condition for which it was not prescribed. Do not give ISENTRESS to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about ISENTRESS that is written for health professionals.

For more information go to www.ISENTRESS.com or call 1-800-622-4477.

What are the ingredients in ISENTRESS?

ISENTRESS film-coated tablets:

Active ingredient: raltegravir
Inactive ingredients: calcium phosphate dibasic anhydrous, hypromellose 2208, lactose monohydrate, magnesium stearate, microcrystalline cellulose, poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant), sodium stearyl fumarate.
The film coating contains: black iron oxide, polyethylene glycol 3350, polyvinyl alcohol, red iron oxide, talc and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

usppi-mk0518-mf-1502r026

Issued: 02/2015

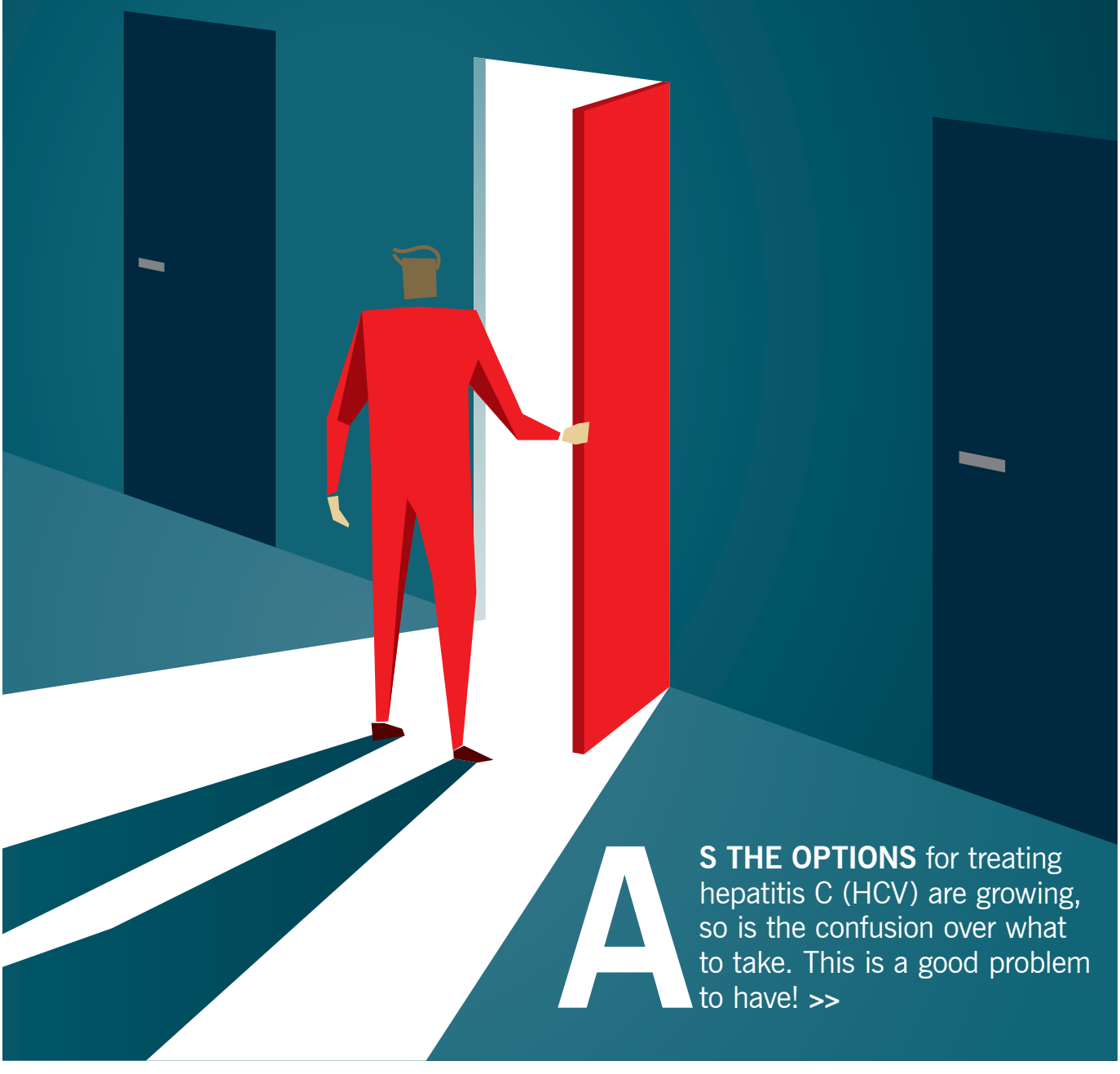
INFC-1141321-0000 03/15

MERCK

WHICH TREATMENT IS RIGHT FOR ME?

A QUICK GUIDE TO HEPATITIS C TREATMENT OPTIONS

BY **ANDREW REYNOLDS**



AS THE OPTIONS for treating hepatitis C (HCV) are growing, so is the confusion over what to take. This is a good problem to have! >>

HCV TREATMENT GUIDELINES

With more treatment options come more opportunities for a cure for people with various HCV genotypes (GT), treatment histories, and levels of cirrhosis. With these many options comes confusion about which regimen is right for which genotype or treatment history and so on.

The American Association for the Study of Liver Disease (AASLD), Infectious Diseases Society of American (IDSA), and International AIDS Society-USA (IAS-USA) have collaborated to provide medical providers with expert guidance on screening, managing, and treating HCV. This brief article provides you with a listing of the treatments that are approved or "off-label" (that is, not FDA approved for a particular use but shown to be effective for that condition or population) for people with HCV, the length of treatment, the clinical trial name, and the sustained virologic response rates (SVR, or cure) from each of these trials.

As you will see here, treatments are shorter and more effective than ever before. You will also see that pegylated interferon—a once-weekly injected medication that has a host of challenging side effects—is nowhere to be found. As such, these treatments have the added benefit of being better tolerated with fewer side effects.

This list is not exhaustive: We cover the first-line recommendations for genotypes 1, 2, 3, and 4 only. 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.

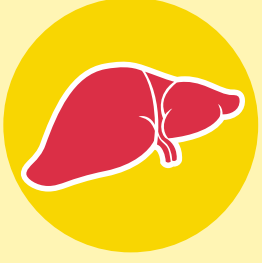
HIV/HCV-co-infected persons should be treated and retreated the same as persons without HIV infection, according to U.S. hep C treatment guidelines. Thus, all the regimens listed in this article can be taken by co-infected people, and clinical trials show similar response rates as people living with HCV alone.

MY GENOTYPE, MY

SVR=SUSTAINED VIROLOGIC RESPONSE, OR CURE

I HAVE GENOTYPE 1, have never been on treatment, and do not have cirrhosis. What can I take?

REGIMEN	TREATMENT LENGTH	STUDY	STUDY SVR
Harvoni (VIRAL LOAD OF LESS THAN 6 MILLION)	8 WEEKS	ION-3	**94%**
Harvoni (VIRAL LOAD OF 6 MILLION OR MORE)	12 WEEKS	ION-1	**99%**
Viekira Pak + ribavirin GT1A	12 WEEKS	SAPPHIRE-I; PEARL-IV	**97%**
Viekira Pak GT1B	12 WEEKS	PEARL-III	**100%**
Sovaldi + Olysio	12 WEEKS	COSMOS	**95%**



I HAVE GENOTYPE 1, I took treatment before but it didn't work, and I don't have cirrhosis. What can I take?

Harvoni
ION-2 STUDY
12 WEEKS
94% SVR

Viekira Pak + ribavirin
SAPPHIRE STUDY
12 WEEKS
96% SVR

Sovaldi + Olysio
COSMOS STUDY
12 WEEKS
95% SVR

I HAVE GENOTYPE 2, have never been on treatment and I do not have cirrhosis. What should I take?

Sovaldi + ribavirin
VALENCE STUDY
12 WEEKS
97% SVR

I HAVE GENOTYPE 2, have either been on treatment but it didn't work and/or I have cirrhosis. What should I take?

Sovaldi + ribavirin
16 WEEKS
VALENCE STUDY
TREATMENT-EXPERIENCED: **90% SVR**
THOSE WHO HAD CIRRHOSIS: **88% SVR**

I HAVE GENOTYPE 3, have never been on treatment, and I do not have cirrhosis. What should I take?

Sovaldi + ribavirin
VALENCE STUDY
24 WEEKS
93% SVR

OPTIONS

I HAVE GENOTYPE 1, and have never been on treatment, but I do have cirrhosis. What can I take?

Harvoni

ION-1 STUDY
12 WEEKS
94% SVR

Viekira Pak + ribavirin

TURQUOISE-II STUDY
12 WEEKS
GT1a **92% SVR**
GT1b **100% SVR**

Sovaldi + Olysio

COSMOS STUDY
24 WEEKS
96% SVR

I HAVE GENOTYPE 1, I took treatment before but it didn't work, and I do have cirrhosis. What can I take?

Harvoni

ION-2
24 WEEKS
99% SVR

Viekira Pak + ribavirin
GT 1A
TURQUOISE-II
24 WEEKS
95% SVR

Viekira Pak + ribavirin
GT 1B
TURQUOISE-II
12 WEEKS
99% SVR

Sovaldi + Olysio

COSMOS
24 WEEKS
96% SVR

I HAVE GENOTYPE 3, have either been on treatment but it didn't work and I have cirrhosis. What should I take?

Sovaldi + ribavirin

VALENCE STUDY
24 WEEKS
TREATMENT-EXPERIENCED: **85% SVR**
TREATMENT-EXPERIENCED WITH CIRRHOSIS: **60% SVR**

I HAVE GENOTYPE 4. What should I take?
(NOTE: RESULTS FOR BOTH TREATMENT-NAÏVE AND -EXPERIENCED WERE THE SAME.)

Harvoni

SYNERGY STUDY
12 WEEKS
95% SVR

Viekira Pak

PEARL-I STUDY
12 WEEKS
100% SVR

Sovaldi + ribavirin

(UNNAMED STUDY)
12 WEEKS
89% SVR

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. Any switch in your HIV medications should be done in collaboration with your HIV care provider.

At the time of publication, Sovaldi and Viekira Pak are FDA approved for HCV treatment in people living with HIV as well, but Olysio and Harvoni have not been. (Harvoni tablets contain Solvadi—generic name sofosbuvir—along with another hep C medication, ledipasvir.) It is likely Harvoni will be submitted for approval for use in co-infected persons by the end of 2015. That said, both Olysio and Harvoni have been studied in people living with co-infection, and off-label use of these treatments is possible.

WHAT ABOUT TREATMENT OPTIONS FOR PEOPLE WITH OTHER CO-MORBIDITIES (DECOMPENSATED LIVER DISEASE, KIDNEY [RENAL] DISEASE, OR POST-TRANSPLANT)?

Regardless of genotype, patients who have decompensated cirrhosis, kidney disease, or are post-transplant with HCV have treatment options that may mirror these recommendations, but should be done with more 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 here are a snapshot of the options, but there are many considerations such as side effects, other co-morbidities, and other matters to consider before making a treatment decision. Gather the help you need to make that decision. Speak with your medical provider, pharmacist, or nurse. 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 (877) HELP-4-HEP, or (877) 435-7443, to speak with a trained counselor about your treatment options. Read the guidelines at hcvguidelines.org.

HCV medications BY DRUG CLASS

DRUG CLASS	GENERIC AND COMMON NAMES	BRAND NAME	STATUS	GENOTYPE (FDA AND OFF-LABEL)	IFN-FREE?	APPROVED FOR HIV/HCV CO-INFECTION?	MANUFACTURER	FIND IT ON PAGE
Nucleotide NS5B polymerase inhibitor	sofosbuvir SOF, SOV	**Sovaldi** ALSO FOUND IN **Harvoni**	APPROVED	1 2 3 4 5 6	**YES,** FOR GT 2 AND 3; IN SOME CASES FOR GT 1 (IN COMBINATION WITH OTHER DRUGS)	YES	Gilead Sciences	36
Non-nucleoside NS5B polymerase inhibitor	dasabuvir (ABT-333)	FOUND IN **Viekira Pak**	APPROVED	1	YES	YES	AbbVie	37
NS5A inhibitor	daclatasvir, DCV	N/A	SUBMITTED FOR APPROVAL	1 3 and 4	YES	**TBD**	Bristol-Myers Squibb	41
NS5A inhibitor	elbasvir, EBR (MK-8742)	**N/A**	SUBMITTED FOR APPROVAL	1 4 and 6	YES	**TBD**	Merck	42
NS5A inhibitor	ombitasvir, (ABT-267)	FOUND IN **Viekira Pak**	APPROVED	1	YES	YES	AbbVie	37
NS5A inhibitor/ nucleotide NS5B polymerase inhibitor	ledipasvir, LDV plus sofosbuvir, SOF	**Harvoni**	APPROVED	1	YES	**NO,** BUT LIKELY TO BE APPROVED FOR CO-INFECTION BY END OF 2015	Gilead Sciences	35
NS3/4A protease inhibitor	grazoprevir, GZR (MK-5172)	NA	SUBMITTED FOR APPROVAL	1 4 and 6	YES	**TBD**	Merck	42
NS3/4A protease inhibitor	paritaprevir ABT-450/r	FOUND IN **Viekira Pak**	APPROVED	1	YES	YES	AbbVie	37
NS3/4A protease inhibitor	simeprevir, SMV	**Olysio**	APPROVED	1	**NO,** UNLESS TAKEN WITH SOVALDI	**NO**	Janssen	38
Nucleoside analog	ribavirin, RBV	**Copegus**	APPROVED	1 2 3 4 5 6	**YES,** WITH SEVERAL OTHER HCV DRUGS ONLY	YES	Genentech	39
Nucleoside analog	ribavirin, RBV	**Rebetol**	APPROVED	1 2 3 4 5 6	**YES,** WITH SEVERAL OTHER HCV DRUGS ONLY	YES	Merck	39
Nucleoside analog	ribavirin, RBV	**Ribasphere**	APPROVED	1 2 3 4 5 6	**YES,** WITH SEVERAL OTHER HCV DRUGS ONLY	YES	Kadmon	39
Pegylated interferon	Peginterferon alfa-2a PEG-IFN	**Pegasys**	APPROVED	1 2 3 4 5 6	**N/A**	YES	Genentech	40
Pegylated interferon	Peginterferon alfa-2b PEG-IFN	**PegIntron**	APPROVED	1 2 3 4 5 6	**N/A**	YES	Merck	40

Harvoni

COMMON NAMES: ledipasvir/sofosbuvir, LDV/SOF

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

FDA STATUS

FDA APPROVED, BUT NOT FOR USE IN HIV/HCV CO-INFECTION. OFF-LABEL USE IS POSSIBLE—SEE BELOW FOR MORE DETAILS (LIKELY TO BE APPROVED FOR USE IN CO-INFECTION BY THE END OF 2015).

GENOTYPE 1

(Has been shown to be effective in GT4, though not FDA approved for this use.)

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 for duration indications.

MANUFACTURER

Gilead Sciences

AWP

$9,450 per week

SVR12 RATES OF THE 335 PATIENTS IN THE ION-4 PHASE 3 STUDY

OVERALL RESULTS	96%
150 PATIENTS WERE **TREATMENT NAÏVE**	95%
185 PATIENTS WERE **TREATMENT EXPERIENCED**	97%
268 PATIENTS HAD **NO CIRRHOSIS**	96%
67 PATIENTS **HAD CIRRHOSIS**	94%

AN HCV CURE IN AS LITTLE AS 8, 12, OR 24 WEEKS

TREATMENT-NAÏVE WITHOUT CIRRHOSIS AND A VIRAL LOAD LESS THAN 6 MILLION	8 WEEKS
TREATMENT-NAÏVE WITH OR WITHOUT CIRRHOSIS	12 WEEKS
TREATMENT-EXPERIENCED WITHOUT CIRRHOSIS	12 WEEKS
TREATMENT-EXPERIENCED WITH CIRRHOSIS	24 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.

After FDA approval, several cases of symptomatic bradycardia, and cases of fatal heart attacks or cases requiring a pacemaker, have been associated with the use of Harvoni with amiodarone. Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these occur. The mechanism for this is unclear, but no sofosbuvir-based HCV regimens are to be used with amiodarone.

Harvoni should not be taken within four hours of antacids. Do not take with the HIV antiretrovirals Aptivus/Norvir (tipranavir/ritonavir), Vitekta (elvitegravir, found in Stribild), Tybost (cobicistat, found in EvoTaz, Prezcobix, and Stribild), Emtriva (emtricitabine, found in Truvada), or Viread (tenofovir DF, found in Atripla, Complera, Truvada, and Stribild). 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, and 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

This combination marks an exciting development for treating HCV GT 1: One pill, once daily potentially curing HCV in as little as 8, 12, or 24 weeks with minimal side effects is an astounding achievement. The treatment durations can be found in the chart.

Although not yet approved for use in HIV/HCV co-infected persons, we have very compelling evidence that this treatment is safe and effective in this patient group. An early NIH study, ERADICATE, treated 50 non-cirrhotic co-infected patients with Harvoni, and achieved an SVR12 in 98% (49 of 50). This small study was exciting, but we needed larger numbers with a more varied patient population to demonstrate its effectiveness more broadly. Results from ION-4, a Phase 3 study of 335 co-infected patients, demonstrated an SVR12 of 96%, offering compelling evidence that co-infected persons with GT1 can be treated for HCV with this regimen. The breakdown by patient characteristic can be found in the chart.

Sovaldi

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

FDA STATUS
APPROVED FOR HIV/HCV CO-INFECTION.

GENOTYPE
1 2 3 4 5 6

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 below 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, Inc.

AWP
$8,400 per week

APPROVED TREATMENT DURATIONS FOR SOVALDI
HCV MONO-INFECTED AND HIV/HCV CO-INFECTED

GENOTYPE 1* and 4
Sovaldi + ribavirin + pegylated interferon
12 WEEKS

GENOTYPE 2
Sovaldi + ribavirin
12 WEEKS
(16 WEEKS FOR PATIENTS WITH CIRRHOSIS CAN BE CONSIDERED)

GENOTYPE 3
Sovaldi + ribavirin
24 WEEKS

GENOTYPE 3
Sovaldi + ribavirin + pegylated interferon
24 WEEKS

* PER FDA RECOMMENDATIONS, Sovaldi in combination with ribavirin for 24 weeks can be considered for patients who cannot take pegylated interferon. However this combination is not recommended by the AASLD/IDSA/IAS-USA hepatitis C guidance as it is a sub-optimal regimen when compared to newer DAA options such as Harvoni or Viekira Pak (see each respective drug page for more details.)

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

When Sovaldi is taken with pegylated interferon and ribavirin or ribavirin alone, the most common side effects reported by people taking this regimen are related to those two medications: fatigue, headaches, nausea, fever, chills, and arthralgia (joint pain). For more information on the side effects of each of these medications, see their respective drug pages. Pegylated interferon has been associated with depression, anxiety, and in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HCV treatment if it contains interferon (it does not mean you can't take HCV treatment, you just want to watch for signs and be able to take preventative actions ahead of time). When Sovaldi is used with ribavirin, pregnant women or women who are trying to become pregnant cannot take it; women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

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.

Sovaldi cannot be taken with the antiarrhythmic medication amiodarone: Several cases of serious symptomatic bradycardia have occurred with this combination. 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. Given the history of HCV treatment and the desire for regimens that are easier to take, along with its treatment effectiveness and the fact that it can be used without interferon for GT 2 and 3 (and in some cases, even 1), and its use and effectiveness in co-infected people, it's no wonder it was so widely used so quickly. Sovaldi has also been approved for use with ribavirin in people who have hepatocellular carcinoma (liver cancer) and are awaiting a liver transplant. The combination of Sovaldi and Olysio with or without ribavirin received FDA approval in late 2014. There is also Harvoni, the fixed-dose combination of Sovaldi and ledipasvir for the treatment of genotype 1 (see drug page for more information on this combination). The approval of the BMS drug daclatasvir (see page 41), a drug that has also been shown to be highly effective when used with Sovaldi, will also create 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.

Viekira Pak

COMMON NAMES: ombitasvir (ABT-267); paritaprevir (ABT-450/r); and dasabuvir (ABT-333) , 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 FOR HIV/HCV CO-INFECTION.

GENOTYPE 1
(Off label use in genotype 4.)

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
$8,331 per week

GENOTYPE 1A, NO CIRRHOSIS	GENOTYPE 1A, WITH CIRRHOSIS	GENOTYPE 1B, NO CIRRHOSIS	GENOTYPE 1B, WITH CIRRHOSIS
Viekira Pak + ribavirin	Viekira Pak + ribavirin	Viekira Pak	Viekira Pak + ribavirin
12 WEEKS	24 WEEKS	12 WEEKS	12 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, 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 39. 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 are recommended.

POTENTIAL DRUG INTERACTIONS

Viekira Pak interacts with many 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. For a complete listing, refer to the package insert. Do not take with St. John's wort. Do not take with the HIV medications Edurant (rilpivirine, also found in Complera), Kaletra (lopinavir/ritonavir), Norvir-boosted Prezista (darunavir/ritonavir), or Sustiva (efavirenz, found in Atripla). Boosted Reyataz (atazanavir/ritonavir) 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 the sedatives triazolam or midazolam. Do not take with lovastatin. Women taking ethinyl estradiol-containing medications should monitor for ALT elevations (see side effects). 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 both treatment-naïve and -experienced, HIV/HCV co-infected, with renal disease, or post-transplant, but is not recommended for people with decompensated cirrhosis.

Olysio

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

FDA STATUS
FDA APPROVED, BUT NOT FOR USE IN HIV/HCV CO-INFECTION. OFF-LABEL USE IS POSSIBLE.

GENOTYPE 1

DOSAGE
Take one 150 mg capsule once daily with food; must be taken in combination with Sovaldi or with pegylated interferon/ribavirin (see below for more details). 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 focuses on the Olysio + Sovaldi combination, as Olysio taken with interferon and ribavirin is not recommended by AASLD/IDSA/IAS-USA HCV guidance.

MANUFACTURER
Janssen Therapeutics

AWP
$6,648 per week

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. When 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

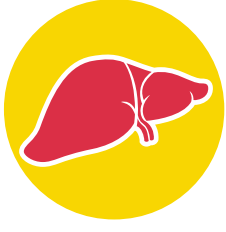
Talk to your medical provider and/or pharmacist about any and all medications you are taking whether they're prescribed, over-the-counter, or illicit. Olysio interacts with many other medications, and this is not a complete list. For a more detailed review of drug interactions, see the package insert.

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) or Viramune (nevirapine); or Intelence (etravarine); or with Tybost (cobicistat) and cobicistat-boosted regimens (Stribild) or medications (EvoTaz and Prezcobix). Olysio can be taken with Edurant (rilpivirine), Isentress (raltegravir), Tivicay (dolutegravir), and the nucleoside reverse transcriptase inhibitors, including Truvada, Ziagen (abacavir), Emtriva (emtricitabine), Epivir (lamivudine), Epzicom, and Viread (tenofovir). Olysio boosts the levels of erectile dysfunction 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

It is not likely that Olysio is used on its own in combination with pegylated interferon + ribavirin: The SVR rates don't stand up to the interferon-free regimens, to say nothing of the severity of side effects and length of treatment. That said, the combination of Olysio plus Sovaldi with or without ribavirin, which received FDA approval for the treatment of GT1 in November 2014, may still be used by some. 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 (cure) rates and minimal side effects for both treatment-naïve and prior non-responders. It is also listed as an off-label, alternative regimen for people with genotype 4.



APPROVED TREATMENT DURATIONS FOR OLYSIO WITH SOFOSBUVIR

PATIENT TREATMENT HISTORY	REGIMEN	DURATION
TREATMENT-NAÏVE WITHOUT CIRRHOSIS	Olysio + Sovaldi	12 WEEKS
TREATMENT-EXPERIENCED WITHOUT CIRRHOSIS	Olysio + Sovaldi	12 WEEKS
TREATMENT-NAÏVE WITH CIRRHOSIS	Olysio + Sovaldi	24 WEEKS
TREATMENT-EXPERIENCED WITH CIRRHOSIS	Olysio + Sovaldi	24 WEEKS

Copegus; Rebetol; Ribasphere

COMMON NAMES: ribavirin, RBV
DRUG CLASS: Nucleoside analog

FDA STATUS
APPROVED FOR HIV/HCV CO-INFECTION

GENOTYPE
1 2 3 4 5 6

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
Copegus: **Genentech**
Rebetol: **Merck**
Ribasphere: **Kadmon**

AWP
$347 per week, based on 1,200 mg/day

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

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

POTENTIAL DRUG INTERACTIONS

Ribavirin cannot be taken with the rarely-used HIV medication didanosine (Videx-EC, Videx, ddI) as this combination can lead to potentially fatal levels of ddI; similarly, azathioprine (an immunosuppressant) 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. There are some scenarios where ribavirin is not needed for the treatment of genotype 1, but it's still a component of treatment for all HCV genotypes. 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 for it early in your treatment (within the first four weeks). Some people who are taking ribavirin experience what is popularly called "riba-rage", that is they get easily irritated and become 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, there is a desire among many patients, advocates, and medical providers for ribavirin-free treatments in the near 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 10^3/mm^3)	Usually none, but regular or unusual infections may indicate this condition
Thrombocytopenia	**Platelets**	150–399 (x 10^3/mm^3)	Easy or excessive bleeding, spontaneous nosebleeds or bleeding gums, unusually heavy menstrual flows, and/or blood in urine or stools

PegIntron; Pegasys

COMMON NAMES: PEG-IFN; pegylated interferon
DRUG CLASS: Interferon (interferon alfa-2a, interferon alfa-2b)

FDA STATUS
APPROVED FOR HIV/HCV CO-INFECTION.

GENOTYPE
1 2 3 4 5 6

DOSAGE
Administer one injection once a week with or without food; must be taken in combination with ribavirin and other HCV drugs (see below for more details). Interferon should never be taken by itself. Take your missed dose as soon as possible on the same day or the next day and then continue on your regular dosing schedule; if multiple days are missed, check with your medical provider about what to do; never double dose or take doses too close together.

MANUFACTURER
PegIntron: **Merck**
Pegasys: **Genentech (Roche)**

AWP
$1,039 per week for four 180 mcg syringes

BOSON SVR12 RESULTS FOR GENOTYPE 3:
SOFOSBUVIR + PEGYLATED INTERFERON + RIBAVIRIN

71 PATIENTS	23 PATIENTS	52 PATIENTS	35 PATIENTS
TREATMENT NAÏVE, NO CIRRHOSIS	TREATMENT NAÏVE, WITH CIRRHOSIS	TREATMENT EXPERIENCED, NO CIRRHOSIS	TREATMENT EXPERIENCED, WITH CIRRHOSIS
96% SVR	91% SVR	94% SVR	86% SVR

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

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

POTENTIAL DRUG INTERACTIONS

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

MORE INFORMATION

People living with HCV long for the day when the words "pegylated" and "interferon" are no longer a part of the hepatitis C treatment lexicon. It is the oldest HCV drug we have, and the one that no one wants nor should have to take. In the past, most of the severe side effects that people experienced while on HCV treatment were caused by interferon, and the fact that it is an injectable drug made it even less desirable to people. The DAA era has essentially made this drug obsolete, but there may still be a role for select patients: A recent report from EASL (the European liver conference) from the BOSON Study found that some patients with genotype 3 benefited from the addition of interferon, and the patients in this trial reported better tolerance of side effects than one might expect (see chart above for SVR results). It is worth noting, however, that there are still interferon-free regimens that can be used—see the daclatasvir drug page for more details. In the United States, there really is no clinical reason to use interferon. However, many insurance programs, public and private alike, are requiring their patients to start with an interferon-based regimen and if they fail it, they can be moved to an interferon-free DAA one. This is merely a cost-savings move. There also may be medical providers who aren't as up-to-date on the treatment guidelines who mistakenly prescribe it. In the year 2015, with all of the HCV medications we have at our disposal, with few exceptions, no one should be prescribed interferon. If it is offered to you, or your insurance will only cover it as a first line of treatment, ask to see if there are other options available to you.

COMMON NAMES: daclatasvir, DCV

BRAND NAME: Yet to be determined (Daklinza in Europe)
DRUG CLASS: NS5A replication complex inhibitor

FDA STATUS
SUBMITTED FOR APPROVAL. RULING EXPECTED AUGUST 2015.

HIV/HCV CO-INFECTION
To be determined; clinical trial data shows very high SVR rates in HIV/HCV co-infection when used in combination with sofosbuvir.

GENOTYPE 1 3 and possibly 4.

DOSAGE
Take one 60 mg tablet once daily with or without food; 30 mg tablets are sold in Europe and may be available in U.S. upon approval. Check package insert for complete dosing details. Must be taken in combination with Sovaldi (sofosbuvir); ribavirin may be included for some genotypes, treatment-experienced patients, or for those with cirrhosis.

MANUFACTURER
Bristol-Myers Squibb

ALLY-2: SVR12 FOR DACLATASVIR + SOFOSBUVIR
FOR 12 WEEKS IN HIV/HCV CO-INFECTED PERSONS

GENOTYPE 1A	GENOTYPE 1B	GENOTYPE 2	GENOTYPE 3	GENOTYPE 4
TREATMENT NAÏVE: **96%** SVR	TREATMENT NAÏVE: **100%** SVR	TREATMENT NAÏVE: **100%** SVR	TREATMENT NAÏVE: **100%** SVR	TREATMENT NAÏVE: **100%** SVR
TREATMENT EXPERIENCED: **97%** SVR	TREATMENT EXPERIENCED: **100%** SVR	TREATMENT EXPERIENCED: **100%** SVR	TREATMENT EXPERIENCED: **100%** SVR	TREATMENT EXPERIENCED: **100%** SVR

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
Side effect data reported here comes from the package insert for the European approved daclatasvir (brand name Daklinza in Europe). 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, 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
As daclatasvir has been approved elsewhere, we have very detailed information on drug interactions; upon FDA approval, you can then refer to the package insert for a listing of interactions with other medications. Daclatasvir may interact with other medications. 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.

The following cannot be taken with daclatasvir: The anti-seizure medications phenytoin, carbamazepine, oxcarbazepine, or phenobarbital; anti-tuberculosis medications rifampicin, rifabutin, or rifapentine; the steroid dexamethasone; and St. John's wort. All of these medications weaken daclatasvir's effectiveness and the treatment will not work. Daclatasvir is safe to use with Edurant (rilpivirine, also found in Complera), Isentress (raltegravir), Kaletra (lopinavir/ritonavir), boosted Prezista (darunavir/ritonavir), Tivicay (dolutegravir, found in Triumeq), and Viread (tenofovir DF, found in Atripla, Complera, Truvada, and Stribild). Dose adjustments of daclatasvir may be required when used with EvoTaz (atazanavir/cobicistat), Norvir-boosted Reyataz (atazanavir/ritonavir), Sustiva (efavirenz, found in Atripla), and Tybost (cobicistat, found in Stribild). Safe to take with immunosuppressants cyclosporine, tacrolimus, sirolimus, and mycophenolate mofetil. No interactions with methadone, buprenorphine, or naloxone.

MORE INFORMATION
Daclatasvir has been approved in Europe (under the brand name Daclinza), as well as Japan and Brazil, but not yet in the U.S. It was submitted for FDA approval last year with a drug called asunaprevir, but that submission was pulled by BMS as the regimen was not as effective as some of the currently available ones and thus was not likely to be used much. As such, we have lots of information about the effectiveness of daclatasvir in the real world: Although it's been submitted to the FDA for treatment in GT3, it will be interesting to see how it's used once approved. 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.

COMMON NAMES: grazoprevir, GZR, formerly MK-5172; and elbasvir, EBR, formerly MK-8742

BRAND NAME: Yet to be determined

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

FDA STATUS

SUBMITTED FOR FDA APPROVAL; HAS RECEIVED "BREAKTHROUGH" STATUS FROM FDA; EXPECTED TO BE REVIEWED IN FALL 2015 OR EARLY 2016.

HIV/HCV CO-INFECTION

To be determined, but clinical trial results showed very high SVR rates which suggests that it will be available for this population.

GENOTYPE 1 4 and 6

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. In some cases, the addition of ribavirin may be recommended. Treatment duration will likely be 12 weeks, with 16 weeks a potential option for treatment-experienced patients.

MANUFACTURER

Merck

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

As this drug combination has not yet been FDA approved, side effect data come from conference presentations and peer-reviewed scientific papers published in medical journals. A complete listing of side effects will be included in the package insert. The combination of grazoprevir/elbasvir is very well tolerated overall. The most commonly reported side effects are headache, fatigue, nausea, arthralgia (joint pain), and asthenia (weakness); less commonly reported side effects were insomnia, dizziness, and diarrhea. In clinical trials, very few people—around 1%—have 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

There is limited data on the drug interactions with either grazoprevir or elbasvir. More detailed information will be available upon FDA approval, and you can then refer to the package insert for a listing of interactions. Grazoprevir/elbasvir may interact with other medications. 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 this FDC with atazanavir/ritonavir, Kaletra (lopinavir/ritonavir), Norvir-boosted Reyataz (atazanavir/ritonavir), Norvir-boosted Prezista (darunavir/ritonavir), or Sustiva (efavirenz, found in Atripla). No dose adjustments needed when taken with Isentress (raltegravir), Norvir (ritonavir), or Viread (tenofovir DF); other HIV medications to be determined. No dose adjustments needed when taken with buprenorphine, methadone, or naloxone. Safe to use with oral contraceptives. Further data is needed on interactions with rifampin, so avoid co-administration for the time being.

MORE INFORMATION

Merck is getting into the HCV treatment scene behind several other pharmaceutical companies, but their medications look to be as good and in some cases perform better for certain populations than their competitors'. One area where Merck should be commended is in the breadth and depth of their clinical trial work in populations that are heavily affected by HCV: HIV co-infected patients, patients with renal (kidney) disease, active substance users and those on methadone, and patients with more advanced liver damage. As such, there will be a rich array of data for the FDA to make recommendations from, and this medication is likely to be approved for patients with complicated conditions who face treatment challenges with today's regimens. Of particular importance: This regimen looks to be especially effective in patients with kidney disease, including those on hemodialysis, with 99% achieving an SVR12. This regimen was given "breakthrough" designation by the FDA, which speeds up the development and approval process for new drugs that are deemed to be significantly better than currently available options. As such, if approved, this regimen will become available by the end of 2015.

SVR12 RESULTS FROM SELECT CLINICAL TRIALS

C-EDGE
316 PATIENTS
HCV TREATMENT-NAÏVE

95% SVR
12 WEEKS

C-EDGE CO-INFECTION
218 PATIENTS
HIV/HCV CO-INFECTED

95% SVR
12 WEEKS

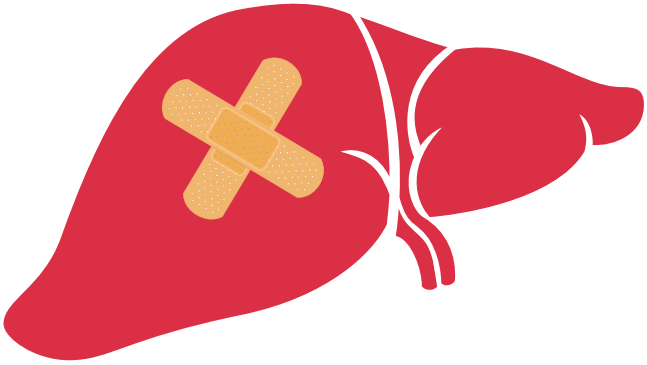
C-EDGE TE
105 PATIENTS
TREATMENT-EXPERIENCED
(NO RIBAVIRIN)

92% SVR
12 WEEKS

104 PATIENTS
WITH RIBAVIRIN
94% SVR
12 WEEKS

C-SURFER
116 PATIENTS
WITH KIDNEY DISEASE

99% SVR
12 WEEKS



AFTER THE CURE

A GUIDE TO POST-TREATMENT CARE

After patients achieve a sustained virologic response (SVR) and are cured of HCV, the AASLD/IDSA/IAS-USA HCV Guidelines recommend the following:

- If you have been cured with little to no fibrosis (F0 to F2), you should receive the same standard follow-up as if you never had HCV.
- HCV recurrence is exceedingly rare, but re-infection can happen. If you do not have on-going risk for HCV (for example, injection drug use), you don't need to screen for HCV routinely. If you do 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 (you will always test positive for antibodies) to look for a new infection.
- If you were cured after developing more advanced liver disease (F3 or F4), you should be screened for hepatocellular carcinoma (HCC, or liver cancer) with twice-yearly ultrasound testing.
- If you were cured after developing cirrhosis, you should get an endoscopy to check for varices (enlarged veins in the torso, which can burst). If they should find varices, they will be treated appropriately and you will not likely have them again (it's rare for them to return after getting cured).

Other important considerations:

ALCOHOL USE: Without the virus, it is common to wonder if it's safe to drink alcohol again. We know that alcohol, even drinking 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 is no research to help us make an informed recommendation on this subject. If you have cirrhosis, you cannot drink alcohol. For everyone else, it's an important question to ask your medical provider, as she/he will know your liver health, the amount of fibrosis you have, and other complications that may help determine if you can or cannot drink alcohol.

HCV TRANSMISSION AND RE-INFECTION: Once you're cured of HCV, you have no virus to transmit to others. This applies to sharing injection drug using equipment, sexual transmission, or other less risky forms of transmission such as sharing razors or toothbrushes. You can, however, get re-infected if you're exposed to HCV again. If you use drugs, don't share injecting equipment (anything: syringes, cookers, water, cotton, and so on), straws for snorting, or pipes for smoking. If you're HIV-positive, be mindful of sexual transmission of HCV (HIV-negative people are at low risk of sexual transmission), and use condoms and other practices to minimize risk of blood exposure during sex.

TALK WITH YOUR MEDICAL PROVIDER about any other important lab tests or follow-up that she or he recommends for your unique needs.

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

—**ANDREW REYNOLDS**

WHAT IS PREZCOBIX™?

- PREZCOBIX™ is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX™ contains the prescription medicines PREZISTA® (darunavir) and TYBOST® (cobicistat).
- It is not known if PREZCOBIX™ is safe and effective in children under 18 years of age.
- **When used with other antiretroviral medicines to treat HIV-1 infection, PREZCOBIX™ may help:**
  - reduce the amount of HIV-1 in your blood. This is called "viral load."
  - increase the number of CD4+ (T) cells in your blood that help fight off other infections.
- PREZCOBIX™ is always taken in combination with other HIV medications for the treatment of HIV-1 infection in adults. PREZCOBIX™ should be taken once daily with food.
- PREZCOBIX™ does not cure HIV-1 infection or AIDS, and you may still experience illnesses associated with HIV-1 infection. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.
- **Please read the Important Safety Information below and talk to your healthcare provider to learn if PREZCOBIX™ is right for you.**

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZCOBIX™?

- **PREZCOBIX™ may cause liver problems.** Some people taking PREZCOBIX™ may develop liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX™.
  - Chronic hepatitis B or C infection may increase your chance of developing liver problems. Your healthcare provider should check your blood tests more often.
  - Signs and symptoms of liver problems include dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale-colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite. Tell your healthcare provider if you develop any of these symptoms.
- **PREZCOBIX™ may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash.
  - **Stop taking PREZCOBIX™** and call your healthcare provider right away if you develop any skin changes with symptoms such as fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes like "pink eye" (conjunctivitis).
- **PREZCOBIX,™ when taken with certain other medicines, can cause new or worse kidney problems, including kidney failure.** Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX™.

Who should not take PREZCOBIX™?

- **Do not take PREZCOBIX™** with any of the following medicines: alfuzosin (Uroxatral®), cisapride (Propulsid,® Propulsid® Quicksolv), colchicine (Colcrys,® Mitigare,® if you have liver or kidney problems), dronedarone (Multaq®), dihydroergotamine (D.H.E.45,® Embolex,® Migranal®), ergotamine tartrate (Cafergot,® Ergomar,® Ergostat,® Medihaler,® Migergot,® Wigraine,® Wigrettes®), methylergonovine (Methergine®), lovastatin or a product that contains lovastatin (Altoprev,® Advicor,® Mevacor®), lurasidone (Latuda®), oral midazolam (Versed®), pimozide (Orap®), ranolazine (Ranexa®), rifampin (Rifadin,® Rifater,® Rifamate,® Rimactane®), sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin (Simcor,® Vytorin,® Zocor®), St. John's Wort (*Hypericum perforatum*) or a product that contains St. John's Wort, or triazolam (Halcion®).
- Serious problems can happen if you take any of these medicines with PREZCOBIX™.

What should I tell my healthcare provider before taking PREZCOBIX™?

- **About all health problems.** Tell your healthcare provider if you have liver problems, including hepatitis B or hepatitis C, have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition, are pregnant, breastfeeding, or plan to become pregnant or breastfeed. Tell your healthcare provider if you become pregnant while taking PREZCOBIX™.
- **About all medicines you take.** Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX™. **Keep a list of your medicines to show your healthcare provider and pharmacist. Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PREZCOBIX™ with other medicines.

What are the possible side effects of PREZCOBIX™?

- **The most common side effects of darunavir, one of the medicines in PREZCOBIX,™ include** diarrhea, nausea, rash, headache, stomach area (abdominal) pain, and vomiting.
- **Other possible side effects include:**
  - **High blood sugar, diabetes or worsening diabetes, and increased bleeding in people with hemophilia** have been reported in patients taking protease inhibitor medicines, including PREZCOBIX™.
  - **Changes in body fat can happen in people who take HIV-1 medicines.** The exact cause and long-term health effects of these changes are not known.
  - **Changes in your immune system** (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time.

These are not all of the possible side effects of PREZCOBIX™. For more information, ask your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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.

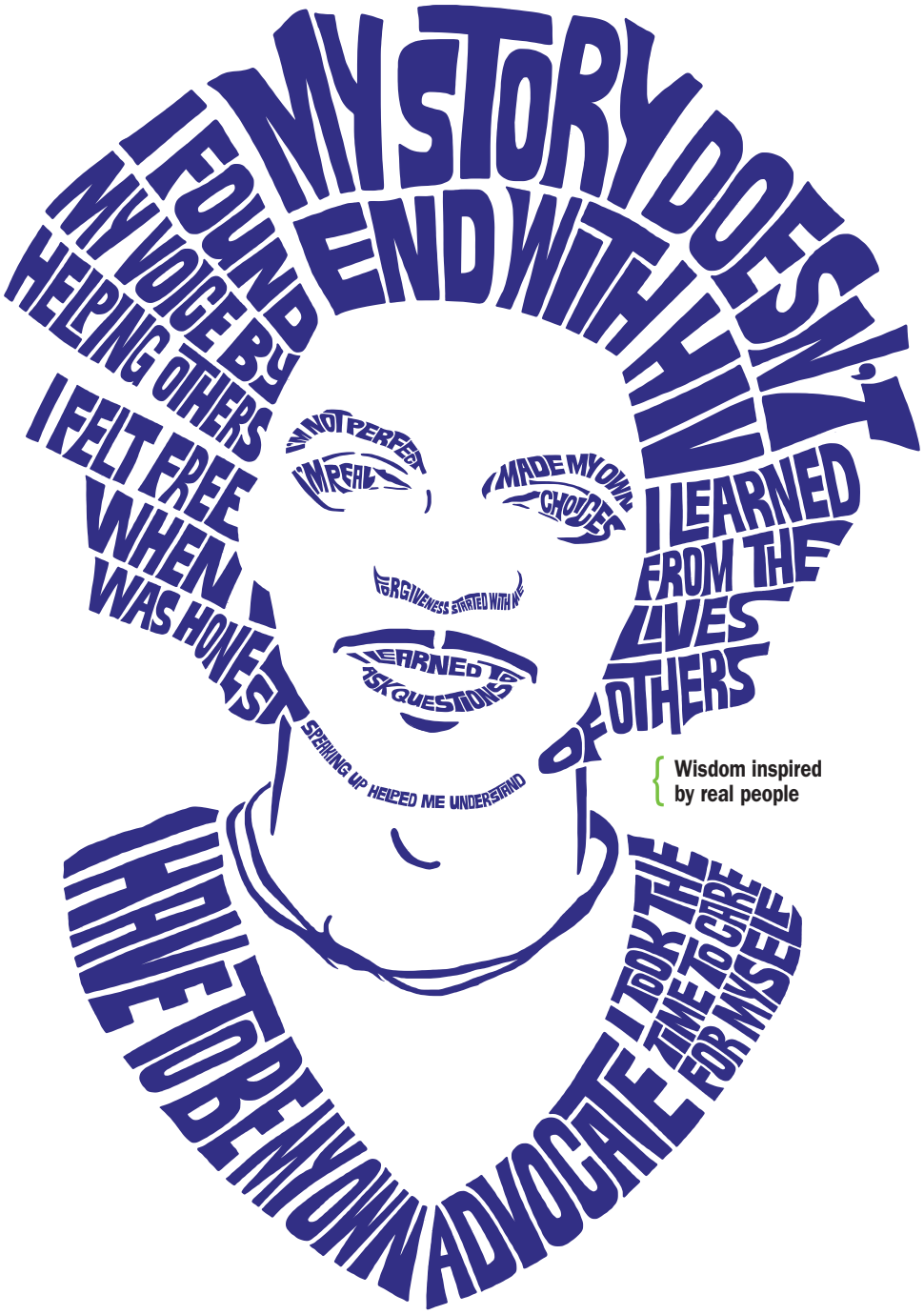
Please see accompanying full Product Information for more details.

Janssen Therapeutics,
Division of Janssen Products, LP

janssen

01/15 008417-140113

027409-150108



Wisdom inspired by real people

DISCOVER YOUR WISDOM WITHIN

Visit **PREZCOBIX.com** to hear wisdom inspired by experts and people like you living with HIV.

Ask your provider if Once-Daily* PREZCOBIX™ is right for you.

PREZCOBIX™
(darunavir 800 mg/
cobicistat 150 mg) tablets

PREZCOBIX.com

*PREZCOBIX™ is taken in combination with other HIV medications for the treatment of HIV-1 infection in adults.

IMPORTANT PATIENT INFORMATION

PATIENT INFORMATION
PREZCOBIX (prez-koe-bix)
(darunavir and cobicistat)
tablets

Please read this information before you start taking PREZCOBIX and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. **What is the most important information I should know about PREZCOBIX?**

- **PREZCOBIX may cause liver problems.** Some people taking PREZCOBIX may develop liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.

  Tell your healthcare provider if you have any of the below signs and symptoms of liver problems.
  - dark (tea colored) urine
  - yellowing of your skin or whites of your eyes
  - pale colored stools (bowel movements)
  - nausea
  - vomiting
  - pain or tenderness on your right side below your ribs
  - loss of appetite
- **PREZCOBIX may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash. **Stop taking PREZCOBIX** and call your healthcare provider right away if you develop any skin changes with symptoms below:
  - fever
  - tiredness
  - muscle or joint pain
  - blisters or skin lesions
  - mouth sores or ulcers
  - red or inflamed eyes, like "pink eye" (conjunctivitis)
- **PREZCOBIX when taken with certain other medicines can cause new or worse kidney problems, including kidney failure.** Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX.

See **"What are the possible side effects of PREZCOBIX?"** for more information about side effects.

What is PREZCOBIX?

PREZCOBIX is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

PREZCOBIX contains the prescription medicines PREZISTA (darunavir) and TYBOST (cobicistat).

It is not known if PREZCOBIX is safe and effective in children under 18 years of age.

When used with other antiretroviral medicines to treat HIV-1 infection, PREZCOBIX may help:

- reduce the amount of HIV-1 in your blood. This is called "viral load".
- increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

PREZCOBIX does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

Who should not take PREZCOBIX?

Do not take PREZCOBIX with any of the following medicines:

- alfuzosin (Uroxatral®)
- cisapride (Propulside®, Propulsid® Quicksolv)
- colchicine (Colcrys®, Mitigare®), if you have liver or kidney problems
- dronedarone (Multaq®)
- ergot-containing medicines:
  - dihydroergotamine (D.H.E. 45®, Embolex®, Migranal®)
  - ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®, Migergot®, Wigraine®, Wigrettes®)
  - methylergonovine (Methergine®)
- lovastatin or a product that contains lovastatin (Altoprev®, Advicor®, Mevacor®)
- lurasidone (Latuda®)
- midazolam (Versed®), when taken by mouth
- pimozide (Orap®)
- ranolazine (Ranexa®)
- rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
- sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension (PAH)
- simvastatin or a product that contains simvastatin (Simcor®, Vytorin®, Zocor®)
- St. John's Wort (*Hypericum perforatum*), or a product that contains St. John's Wort
- triazolam (Halcion®)

Serious problems can happen if you take any of these medicines with PREZCOBIX.

What should I tell my healthcare provider before taking PREZCOBIX?

Before taking PREZCOBIX, tell your healthcare provider if you:

- have liver problems, including hepatitis B or hepatitis C
- have kidney problems
- are allergic to sulfa (sulfonamide)
- have diabetes
- have hemophilia
- have any other medical condition

- are pregnant or plan to become pregnant. It is not known if PREZCOBIX will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking PREZCOBIX.
  - **Pregnancy Registry:** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZCOBIX.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV to your baby.
  - It is not known if PREZCOBIX can pass into your breast milk.
  - Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PREZCOBIX.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PREZCOBIX with other medicines.

How should I take PREZCOBIX?

- Take PREZCOBIX exactly as your healthcare provider tells you.
- Do not change your dose or stop taking PREZCOBIX without talking to your healthcare provider.
- Take PREZCOBIX 1 time a day with food.
- If you miss a dose of PREZCOBIX by less than 12 hours, take your missed dose of PREZCOBIX right away. Then take your next dose of PREZCOBIX at your regularly scheduled time.
- If you miss a dose of PREZCOBIX by more than 12 hours, wait and then take the next dose of PREZCOBIX at your regularly scheduled time.
- If a dose of PREZCOBIX is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZCOBIX at any one time.
- If you take too much PREZCOBIX, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of PREZCOBIX?

PREZCOBIX may cause serious side effects including:

- See **"What is the most important information I should know about PREZCOBIX?"**
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including PREZCOBIX can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking PREZCOBIX.
- **Changes in body fat can happen in people who take HIV-1 medications.** The changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including PREZCOBIX.

The most common side effects of darunavir, one of the medicines in PREZCOBIX, include:

- diarrhea
- nausea
- rash
- headache
- stomach area (abdominal) pain
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PREZCOBIX. For more information, ask your health care provider.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PREZCOBIX?

- Store PREZCOBIX tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep PREZCOBIX and all medicines out of reach of children.

General information about PREZCOBIX

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PREZCOBIX for a condition for which it was not prescribed. Do not give PREZCOBIX to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about PREZCOBIX that is written for health professionals.

For more information call 1-800-526-7736.

What are the ingredients in PREZCOBIX?

Active ingredients: darunavir and cobicistat

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, and silicified microcrystalline cellulose. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

Manufactured by:
Janssen Ortho LLC, Gurabo, PR 00778

Manufactured for:
Janssen Therapeutics, Division of Janssen Products, LP, Titusville NJ 08560

Issued: January 2015

027415-150108

HCV RESOURCES, SERVICES, AND INFORMATION

HELP-4-HEP
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, 9 am–7 pm EST.

HIV Health InfoLine
800-822-7422 toll-free
Staffed by trained Project Inform operators and staff, many of whom also live with or are affected by HIV. Call-back service Monday–Friday, 10 am–4 pm PST.

AIDS/HIV Nightline
800-628-9240 toll-free
Operates 5 pm–5 am and is run by the San Francisco Suicide Prevention hotline. Very strong on offering emotional support and health education.

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

The Hepatitis C Mentor and Support Group, Inc.
www.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
www.hepeducation.org
Based in Seattle, Washington, HEP provides an array of services for people in the Seattle area, but also has a host of information and resources for all people living with HCV.

Caring Ambassadors
hepcchallenge.org
Array of services and advocacy around HCV. They also publish *Hepatitis C Choices*.

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

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

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

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

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

Call 877-HELP-4-HEP

And get the most important thing of all... Someone to talk to about Hepatitis C.

You can talk to us.

We're Help-4-Hep, and one of our phone counselors is ready to help you meet the challenges of hepatitis C head-on ... where to get tested, how to get treatment, or help paying for lab work and medicines. All from someone who's had hepatitis C touch their own life.

TAKE YOUR BEST SHOT AGAINST HIV...

ON A DAY WITH HIV.

WE'RE ALL AFFECTED BY HIV AND ITS STIGMA.
BUT THERE'S SOMETHING WE CAN DO ABOUT IT.

A DAY WITH HIV is Sept. 22, 2015.
On that day, use your smartphone or digital camera to capture a moment of your day, and share your story with the world.

Upload your picture to adaywithhiv.com or email it to photo@adaywithhiv.com, along with your caption, the time and place you took it, and your inspiring story behind your picture. Select high-resolution images will appear in the November+December 2015 issue of POSITIVELY AWARE.

TAKE YOUR BEST SHOT AGAINST HIV ON

9/22/2015

SPREAD THE WORD

#adaywithhiv
adaywithhiv.com

A DAY WITH HIV

FINDING HELP TO PAY FOR TREATMENT

Like HIV, treatment for HCV is 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	MANUFACTURER	CONTACT INFO
Harvoni and **Sovaldi**	Gilead	(855) 769-7284; mysupportpath.com; harvoni.com; sovaldi.com
Viekira Pak	AbbVie	(844) 277-6233; viekira.com; viekira.com/proceed-program
Olysio	Janssen Pharmaceuticals	(855) 565-9746; janssenprescriptionassistance.com/olysio-cost-assistance; olysio.com
Copegus	Genentech	(888) 941-3331; genentech-access.com
Ribasphere RibaPak	Kadmon	(888) 668-3393; pparx.org
Pegasys	Genentech	(888) 941-3331; pegasysaccesssolutions.com; pegasys.com
PegIntron	Merck	(866) 939-4372; merckhelps.com; pegintron.com

ADDITIONAL PROGRAMS

Harbor Path
harborpath.org
Provides a single site for all patient assistance program applications for both HIV and HCV medications.

HealthWell Foundation
healthwellfoundation.org
Assists patients with chronic and life-altering diseases in paying prescription drug co-pays, deductibles, and insurance premiums.

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.

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

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

CUTS THAT REALLY HURT

I MEET WITH NEW CLIENTS almost weekly who are moving to the greater Chicago area because health care services in their "red states," such as Indiana, have been dramatically cut or perhaps never existed in the first place. Cities like Chicago, New York, and Los Angeles are also experiencing budget cuts, but at least these cuts are not examples of public health systems that are absolutely devastated, such as what we're experiencing right next door in Indiana. Illinois, like other blue states that still have existing HIV services, is definitely feeling the pinch of the cuts, but bad as they may be, we can work with cuts.

By 'exploring' the success of a needle exchange program, all Indiana governor Mike Pence will do is increase his state's numbers of HIV cases.

We tighten our belts and figure out a way to keep programs active; however, we can't work with gaping, bleeding wounds.

This is what the state of Indiana is experiencing by the latest response of its governor, Mike Pence, a Republican in a very red state with an increasing mini-HIV-epidemic. I met a new patient in January who told me that he was unable to access health care services in the Miami area, and would rather move to Chicago and freeze here, than die of AIDS while basking in the sun.

I find it interesting that Governor Pence was recently quoted as saying: "Outside of the United States, China represents the largest economy in the world. Today we see immense potential for the creation of more great jobs for Hoosiers through the strengthening of ties with our Chinese partners." After criticizing President Obama for speaking with China to continue fostering working relationships with China, he turns around and does the same thing. It would be helpful if he would now follow President Obama and fully implement the Affordable Care Act (ACA) in Indiana. He could also link with an agency like the Chicago Recovery Alliance (CRA) which has provided a free needle exchange program in Chicago for decades, effectively curbing the spread of HIV and more recently hepatitis C.

Illinois is now under the governance of our very own Republican governor, Bruce Rauner, who's cutting our programs and everything else that helps poor people, including HIV/AIDS services, like his plan to cut ADAP (AIDS Drug Assistance Program). Rauner indicated that Illinois' funding for ADAP can be cut since so many people with HIV/AIDS in Illinois are now covered by the ACA. Now I don't know when the last time was that Bruce Rauner went to his local pharmacy to pick up his HIV medication, but many people who are now insured either by the ACA or traditional marketplace insurance companies have such high co-pays for their medications (as high as $300 to $500 per prescription) that they still need ADAP to cover their treatment. I'm not insinuating that our governor is HIV-positive, but merely being snarky as I explain that he as well as Indiana's governor can probably afford the co-pays since they have some serious money, but our patients cannot.

By "exploring" the success of a needle exchange program and by extending it another 30 days as he was last quoted before this writing, all Pence will do is increase his state's numbers of HIV cases. Perhaps the governor could meet with people working in public health in places like Chicago, New York, or Los Angeles and query them on how well their services work when they "try them out" or "extend" them for a ridiculous amount of time like a month! Someone needs to train this man on how addiction works and how needle exchange programs have been scientifically proven to be effective in reducing transmission, while not encouraging drug use. If his Scott County has 149 confirmed HIV cases, I guesstimate the real numbers to be somewhere upwards of 300 to 500 or more because people travel while they use, and while they travel they also have sex.

He could also compare the implementation of public health programs for a short period of time to ongoing programs that help curb outbreaks of public health diseases. If he were to suddenly reduce Indiana's LIHEAP, WIC, or SNAP programs down to 30 days, would the beneficiaries of these programs stop turning on their lights or stop feeding their children? Of course not, so why would he continue to fund the Scott County needle exchange program for just another month? What he will eventually accomplish will be another spike in his state's HIV cases. The people who are currently using the needle exchanges will continue to inject their drug of choice with or without the program, doing what they have done and will continue to do to feel better.

This is not a moral, political, or religious issue; this is a public health issue and the CDC (Centers for Disease Control), has enough published data on HIV/AIDS services and programs, like needle exchange, that have been proven as effective strategies to curb HIV and hepatitis C, that should convince Governor Pence, providing he listens.

The fact that he signed the Religious Freedom Restoration Act (RFRA) also doesn't help the state's already tarnished image. Regardless of his caveat that this is not a law that will discriminate against target populations such as people impacted by HIV/AIDS, a pharmacist could, by citing this law refuse to provide needles, condoms, or HIV medications to anyone based on where that pharmacist sits his or her ass on a Sunday!

PHOTO: CHRIS KNIGHT | INDIANA FLAG: © CHRISTOPHE BOISSON/ISTOCKPHOTO

Saturday, August 15, 2015

dance for life
CHICAGO

5pm Hilton Chicago's Grand Ballroom | **7:30pm** Auditorium Theatre of Roosevelt University

PERFORMANCES BY Giordano Dance Chicago, Hubbard Street Dance Chicago, Joffrey Ballet, River North Dance Chicago, Chicago Human Rhythm Project, Same Planet Different World, C5 presenting a world premiere, and choreographer Randy Duncan's highly acclaimed work STAND BY ME with special music arrangement by Ira Antelis

EMCEES Joey Bland and Tim Mason of The Second City

BENEFICIARIES AIDS Foundation of Chicago and The Dancers' Fund

GALA LEVEL TICKETS $250-$600 | **PERFORMANCE LEVEL TICKETS** $15-$75

www.DanceforLifeChicago.org | 312-922-5812

/DanceForLifeChicago @danceforlifeChi

ATHLETICO PHYSICAL THERAPY · AUDITORIUM THEATRE of ROOSEVELT UNIVERSITY · BELLLITHO inc. · CHICAGO · GILEAD Advancing Therapeutics. Improving Lives. · Hilton CHICAGO · HMS MEDIA · JEWELL EVENTS · CATERING

BARBARA LEVY KIPPER · mb financial bank · MERCK Be well · MICHIGAN AVENUE MAGAZINE · N·I·H·B FOUNDATION · PALOMAR CHICAGO · PaternoGroup PRINT & MEDIA DESIGN · pci Public Communications Inc. serving clients since 1982 · Walgreens AT THE CORNER OF HAPPY & HEALTHY

MEDIA PARTNERS a&u · dancers.org · CHICAGO PRIDE.COM · GC MAGAZINE · GRAB · PA · See Chicago Dance .com · WINDY CITY TIMES

PHOTOGRAPHY Sandro | DANCERS Jason Hortin, Hubbard Street Dance Chicago & Derrick Agnoletti, Joffrey Ballet

WE KNOW HIV/AIDS medication therapy

But we also know you want a pharmacy that cares for you and the *community.*

From participating in AIDS walks to offering education and free HIV testing in select stores nationwide, Walgreens is committed to giving back to the local groups and organizations that bring people together and bring us closer to new treatments, avenues of support—and a cure.

To learn more, visit **HIV.Walgreens.com.**

Walgreens AT THE CORNER OF HAPPY & HEALTHY®