

HOLD THE INTERFERON: HCV TREATMENT IN THE ERA OF DIRECT ACTING ANTIVIRALS

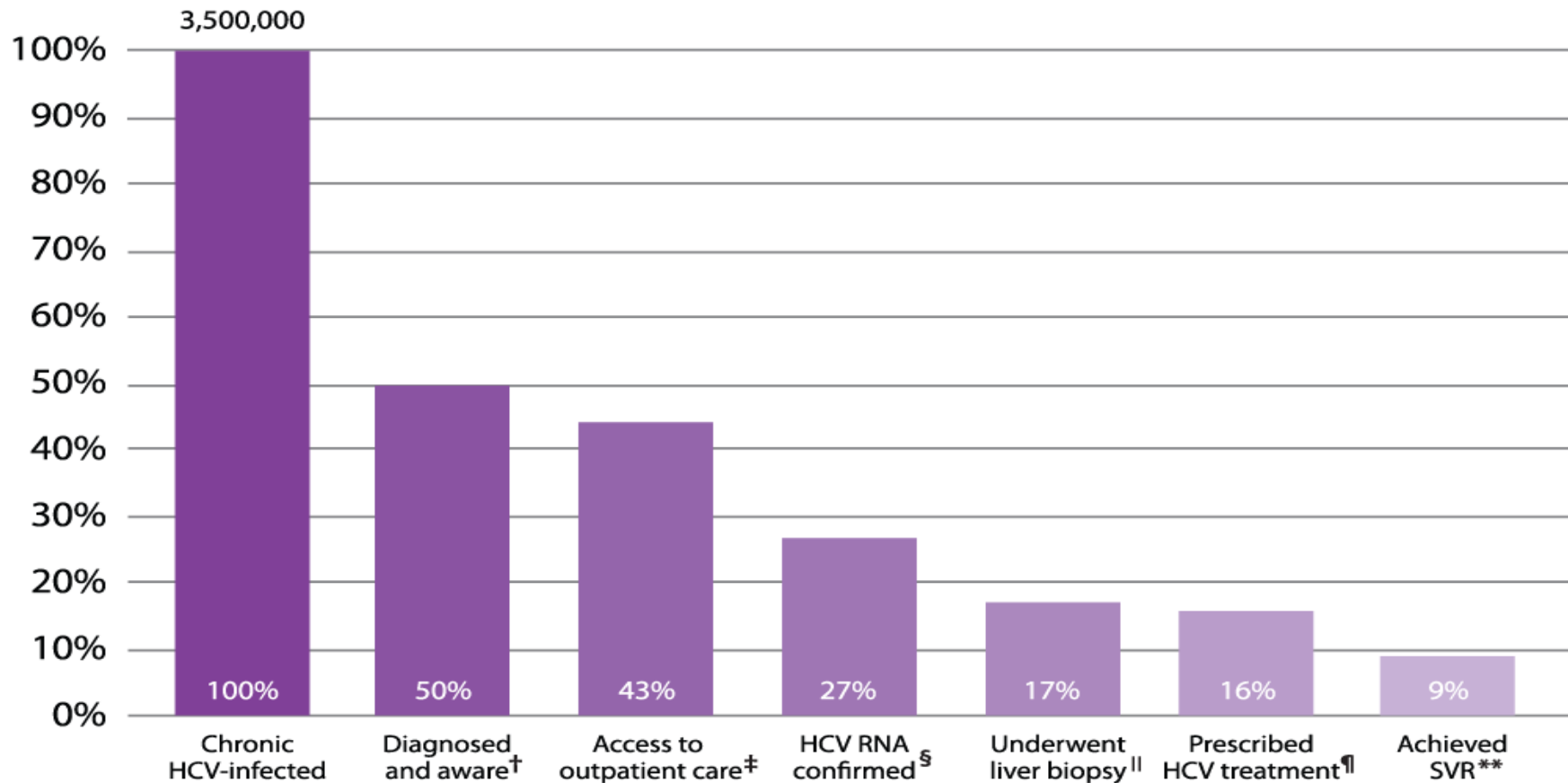
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Project Inform

Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis

PEOPLE WITH HEPATITIS C IN THE US



PEOPLE LIVING WITH HEPATITIS C WHO ENGAGED IN HCV CARE

www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0101554

[†] Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.

[‡] Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage with access to outpatient care (86.9%); n=1,514,667.

[§] Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.

^{||} Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.

[¶] Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=555,883.

^{**} Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.

Note: only non-VA studies are included in the above HCV treatment cascade.

2014: The Interferon-Free Era is Here

- Began in late 2013, but limited
- HCV genotype 1, 2, 3, and 4 can be treated without interferon
- Some with GT1 can even go without ribavirin

List of FDA Approved or Late Stage Daas for treatment of HCV

HCV Drugs Approved or on the Horizon				
NS3/NS4A Protease Inhibitors	NS5A Replication Complex Inhibitors	NS5B Nucleoside/tide Polymerase Inhibitors	NS5B Nonnucleoside Polymerase Inhibitors	Cyclophillin Inhibitors
<ol style="list-style-type: none"> 1. Boceprevir* 2. Telaprevir*# 3. Simeprevir* 4. Asunaprevir 5. ABT-450 6. Danoprevir 7. Sovaprevir 8. GS-9451 9. MK-5172 	<ol style="list-style-type: none"> 1. Daclatasvir 2. Ledipasvir 3. Samatasvir 4. Ombitasvir (ABT-267) 5. GS-8516 6. MK8742 7. JNJ56914845 	<ol style="list-style-type: none"> 1. Sofosbuvir* 2. Meracitabine 	<ol style="list-style-type: none"> 1. Dasabuvir (ABT-333) 2. BMS-791325 3. GS-9669 4. TMC647055 	<ol style="list-style-type: none"> Alisporivir SCY-635

All Oral DAA Treatment: Available Now

Generic Name	Brand Name
Sofosbuvir + ribavirin	Sovaldi + (several brand names)
Sofosbuvir + simeprevir	Sovaldi + Olysio
Sofosbuvir + ledipasvir	Harvoni
Paritaprevir/ritonavir + dasabuvir + ombitasvir (with or without ribavirin)	Viekira Pack

HCV Drugs No Longer Recommended

- Pegylated interferon
- Telaprevir (Incivek): No longer sold in the U.S.
- Boceprevir (Victrelis)

I'm genotype 1, never been on treatment, and my liver is healthy...What should I take?

Regimen	Length of Treatment	Clinical Trial SVR Rates
Harvoni (HCV viral load, less than 6 million)	8 weeks	97%
Harvoni (HCV viral load, greater than 6 million)	12 weeks	95%
Viekira Pak (genotype 1a) + ribavirin	12 weeks	97%
Viekira Pak (genotype 1b)	12 weeks	99.5%
Sovaldi + Olysio	12 weeks	95%

I'm genotype 1, never been on treatment, and I have cirrhosis...What should I take?

Regimen	Length of Treatment	Clinical Trial SVR Rate
Harvoni	12 weeks	97%
Viekira Pak + Ribavirin	12 weeks	94%
Sovaldi + Olysio	24 weeks	100%

I'm genotype 1, treatment was unsuccessful, and my liver is healthy...What should I take?

Regimen	Length of Treatment	Clinical Trial SVR Rate
Harvoni	12 weeks	95%
Viekira Pak + ribavirin	12 weeks	95%
Sovaldi + Olysio	12 weeks	95%

I'm genotype 1, treatment was unsuccessful, and I have cirrhosis...What should I take?

Regimen	Length of Treatment	Clinical Trial SVR Rates
Harvoni	24 weeks	100%
Viekira Pak (genotype 1a) + ribavirin	12 weeks	89%
Viekira Pak (genotype 1a) + ribavirin	24 weeks	94%
Viekira Pak (genotype 1b) + ribavirin	12 weeks	99%
Viekira Pak (genotype 1b) + ribavirin	24 weeks	100%
Sovaldi + Olysio	24 weeks	100%

I'm genotype 2...What should I take?

Regimen	Treatment Length	Clinical Trial SVR Rate
Sovaldi + ribavirin	12 weeks	Tx Naïve: 98% (91% with cirrhosis);
	16 weeks (with cirrhosis or if prior treatment did not work)	Tx Experienced: 96% (60% with cirrhosis)

I'm genotype 3...What should I take?

Regimen	Treatment Length	Clinical Trial SVR Rate
Sovaldi + ribavirin	24 weeks	Tx Naïve: 93% (92% with cirrhosis); Tx Experienced: 85% (60% with cirrhosis)

I'm genotype 4...What should I take?

Regimen	Treatment Length	Clinical Trial SVR Rate
Sovaldi + ribavirin	24 weeks	93% (both Tx naïve and experienced)

I am HIV/HCV coinfecting...

What should I take?

- All regimens can be taken in HIV/HCV coinfecting
- Very similar response rates as HCV mono-infected
- Sovaldi and Viekira are FDA approved;
- Olysio and Harvoni are not FDA approved, but have been studied in coinfecting patients; off-label prescribing is possible
- Must be mindful of drug-drug interactions

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EVERYONE HAS A REASON. **SAVE FOR YOURS.**

PERSONAL SAVINGS



Robert Glatter, MD

PHARMA & HEALTHCARE | 6/28/2014 @ 5:53PM | 4,990 views

Bitter Pill To Swallow: Can The US Market Bear The Cost Of Sovaldi?

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27 comments

\$1,000-a-pill hepatitis C drug \$ care system

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Jun 20, 2014, 1:22pm PDT

Should Medicaid cover \$1,000-a-pill hepatitis-C drug Sovaldi? (Poll)

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We listen, explain and work together with you and your loved ones.

JOHN MU HEALTH



The Apothecary

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OPINION | 6/17/2014 @ 8:46AM | 12,284 views

The Sovaldi Tax: Gilead Can't Justify The Price It's Asking For Hepatitis C Therapy

Avik Roy, Forbes Staff

U.S. Senate probes pricing of Hepatitis C drug Sovaldi

By Lori Sandoval, Tech Times | July 13, 10:02 PM

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HCV Medications: Medi-Cal Access

- Burdensome, restrictive, limiting!
- Patients must have advanced liver disease (METAVIR F3-F4 or equivalent)
 - Restrictive to women of child-bearing age
 - Facilitates rapid progression of HCV in HIV/HCV co-infected persons
- People must have 6 months of documented abstinence from all drugs and alcohol

If you wait until somebody had cirrhosis to treat their HCV, you now have two diseases to deal with, one of which cannot be cured and leads to lifelong complications including heightened risk of liver cancer.

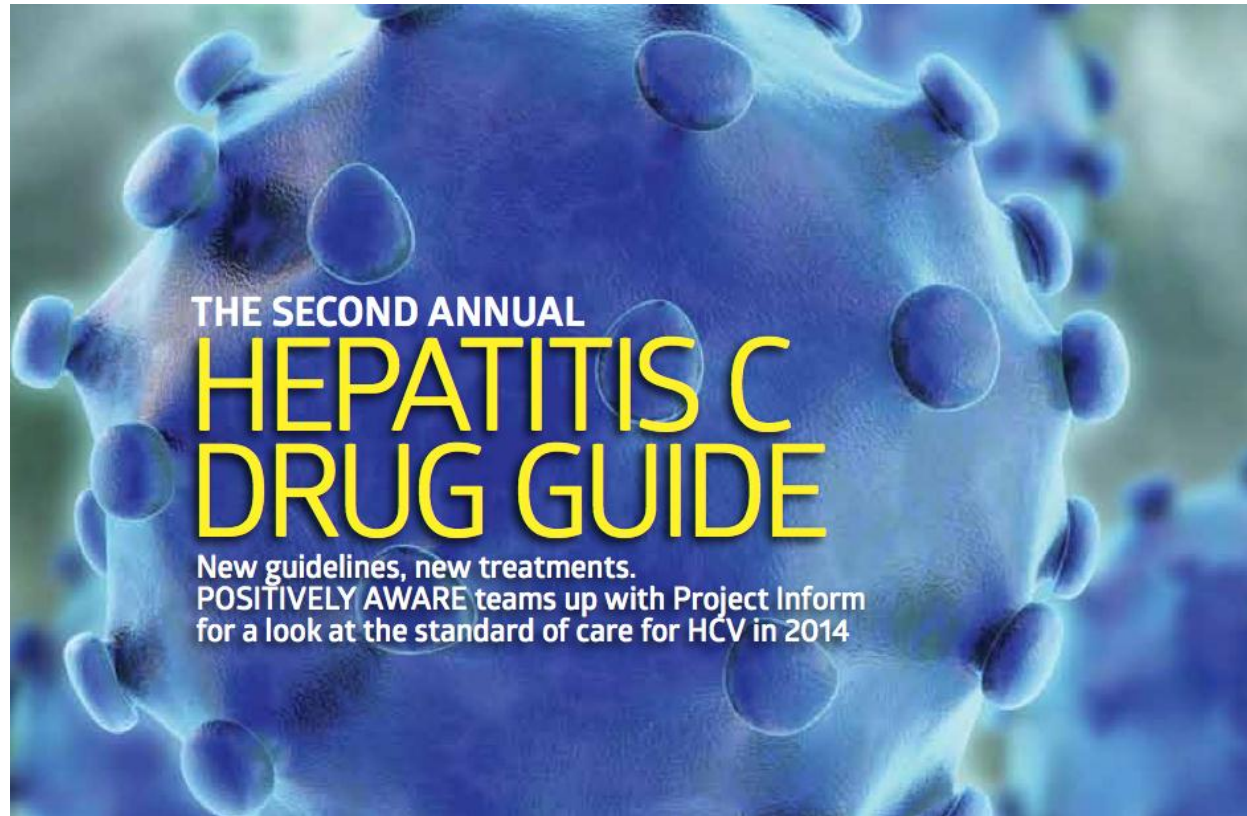
HCV Medications: Patient Assistance Programs

- Sovaldi (sofosbuvir) and Harvoni: 855-769-7284;
www.mysupportpath.com
- Viekira Pak: 1-844-277-6233;
www.viekira.com/proceed-program
- Olysio (simeprevir): 855-565-9746; www.olsio.com
- HarborPath: www.harborpath.com (one-stop shopping for all PAPs for HIV and HCV)
- Patient Access Network Foundation: 866-316-7263;
www.panfoundation.org (offers up to \$7000 in co-pay assistance)

Information and Support for People with HCV

- Find HCV support groups in your area; if none exist, think about starting one
- Call The Support Partnership's national HCV support line: 1-877-HELP-4-HEP
- HCV Advocate: www.hcvadvocate.org
- Contact me!

HCV Treatments Approved & in Pipeline



- <http://positivelyaware.com/2014/july-issue.pdf>

Project Inform www.projectinform.org

Project Inform fights the HIV & hepatitis C epidemics by assuring the development of effective treatments and a cure; supporting individuals to make informed choices about their health; advocating for quality, affordable health care; and promoting medical strategies that prevent new infections.

The screenshot shows the Project Inform website homepage. At the top, the Project Inform logo is on the left, and the tagline "Information, Inspiration and Advocacy for People with HIV/AIDS and Hepatitis C" is in the center. Below the tagline is a navigation menu with links for HOME, ABOUT US, AIDS WALK, INFORMATION, HELP LINES, and SUPPORT US, along with social media icons for Facebook, Twitter, and RSS. On the left side, there is a "DONATE NOW" button and a sign-up form for the e-newsletter. Below that is a list of categories: HIV cure advocacy, HIV care & treatment, HIV prevention, HIV policy, Hepatitis C care & treatment, Hepatitis C policy, and Health care reform. A "CONTRIBUTORS" section is also visible. The main content area features a large purple banner with the text "we inform people about how to avoid infection with HIV and/or hepatitis C." and the Project Inform logo. Below the banner is a section titled "what's in a name?" with a pagination indicator showing 1, 2, 3, 4, 5. Two articles are listed: "Ending hepatitis C in the United States: The role of screening" dated July 4, 2014, and "FREE WEBINAR: Scaling Up Risk Based Hepatitis C Screening in the US" dated July 3, 2014. The first article includes a thumbnail image of a human torso with the liver highlighted in red. The second article includes a "ReadyTalk" logo and text about a webinar on July 23, 2014. At the bottom left, there is a "Project Inform" logo with a "Like" button and a notification that "2,298 people like Project Inform."

Closing

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