

# Factsheet: Treatments for hepatitis C



**For more information about anything in this factsheet, phone the Hepatitis Infoline on 1800 803 990 or go to [www.hep.org.au](http://www.hep.org.au)**

The information in this factsheet will be amended as new information emerges. In particular, the administrative details concerning prescription arrangements for GPs and other doctors still need to be established. New treatment consensus guidelines also are being developed. The purpose of this factsheet is to provide as much information about the new treatments as is currently known.

## Introduction

New direct acting antiviral treatment drugs were listed on the Pharmaceutical Benefits Scheme (PBS) on 1 March 2016. This factsheet relates primarily to these hepatitis C treatment combinations:

- Harvoni (sofosbuvir/ledipasvir) two drugs combined in one pill, taken once per day
- Sovaldi and Daklinza (sofosbuvir and daclatasvir) in 1 pill of each, taken once per day
- Sovaldi and Ibavyr (sofosbuvir and ribavirin) in 3 or more separate pills, taken daily
- VIEKIRA PAK (paritaprevir/ritonavir/ombitasvir and dasabuvir) in 4 separate pills, taken daily.
- VIEKIRA PAK plus ribavirin (paritaprevir/ritonavir/ombitasvir and dasabuvir and ribavirin) in 6 or more pills taken per day.

Other new drugs for treating hepatitis C are currently in different stages of development and/or approval. Over time, these new drugs will also likely be PBS listed and funded, and this factsheet will be amended accordingly.

## Success rates of the new treatments

Genotype 1: sofosbuvir/ledipasvir; sofosbuvir and daclatasvir; or VIEKIRA PAK (with or without ribavirin) achieve cure rates in excess of 95-97%, depending on pre-treatment variables such as the presence of cirrhosis, prior therapy, etc.

Genotype 2: sofosbuvir and ribavirin achieves cure rates of around 95% depending on pre-treatment variables such as the presence of cirrhosis, prior therapy, etc.

Genotype 3: sofosbuvir and daclatasvir achieves cure rates of around 95% depending on pre-treatment variables such as the presence of cirrhosis, prior therapy, etc.

Genotypes 4-6: People with genotypes 4 or 6 remain limited to sofosbuvir taken with pegylated interferon and ribavirin treatment. They enjoy a greater than 90% chance of cure.

The above cure rates relate to people's hepatitis C genotype and treatment history. Treating doctors will advise which treatment options are suitable for individual people.

## Treatments and genotypes

- If you have hep C genotype 1, you'll be offered Harvoni (on its own), or you'll be offered Sovaldi plus Daklinza (taken together).
- If you have hep C genotype 1a, you might be offered VIEKIRA PAK plus ribavirin (taken together)
- If you have hep C genotype 1b, you might be offered VIEKIRA PAK.
- If you have hep C genotype 2, you'll be offered Sovaldi plus Ibavyr (taken together).

- If you have hep C genotype 3, you'll be offered Sovaldi plus Daklinza (taken together).
- If you have hep C genotypes 4 or 6, you remain limited to Sovaldi taken with pegylated interferon injections plus ribavirin pills.

Other drug combinations are approved and available but those mentioned above are the ones with best response and tolerability.

## Treatment durations

Sofosbuvir/ledipasvir = 8 weeks for people with no prior treatment, no cirrhosis and viral load less than 6 million IU/mL

= 12 weeks for people with no prior treatment, no cirrhosis and viral load more than 6 million IU/mL

= 12 weeks for people with no prior treatment and cirrhosis

= 24 weeks for people with prior treatment and cirrhosis

Sofosbuvir and daclatasvir = 12 weeks (although likely longer for people with cirrhosis)

= 24 weeks for people with genotype 3 and cirrhosis

Sofosbuvir and ribavirin = 12 weeks for people with genotype 2

Sofosbuvir and daclatasvir and ribavirin = 12 weeks for people with genotype 1 and cirrhosis.

VIEKIRA PAK = 12 weeks for people with genotype 1b, no cirrhosis

= 12 weeks for people with genotype 1b, compensated cirrhosis

VIEKIRA PAK plus ribavirin pack = 12 weeks for people with genotype 1a, no cirrhosis

= 12 weeks for people with genotype 1a, with cirrhosis

= 24 weeks for people with genotype 1a, cirrhosis and prior null response to treatment

There are a range of different treatment regimens. People will be offered treatment on the basis of their genotype, level of liver damage and treatment history.

## Are new treatments taken with ribavirin or interferon injections?

As listed above, sofosbuvir is sometimes taken with ribavirin. Also, sofosbuvir and daclatasvir may additionally be taken with ribavirin for those people who have genotype 3 and cirrhosis. VIEKIRA PAK may be taken with ribavirin for people with genotype 1a.

Importantly, all the new treatments are taken as tablets (pills) and none involve interferon injections.

(Treatment for people with genotypes 4 or 6, involves sofosbuvir taken with pegylated interferon injections and ribavirin tablets.)

## Treatment side effects

Sofosbuvir/ledipasvir is well tolerated with only minor side effects.

Sofosbuvir and daclatasvir are well tolerated with only minor side effects.

Sofosbuvir and ribavirin are well tolerated (the most common adverse events of ribavirin are anaemia, fatigue, headache, skin irritation and insomnia).

VIEKIRA PAK is well tolerated with only minor side effects. When taken with ribavirin, it is well tolerated but may be associated with anaemia, fatigue, headache, skin irritation and insomnia.

Sofosbuvir/peginterferon/ribavirin combination treatment involves side effects including fatigue, headache, throwing up, sleep problems, itching and crawling of the skin, and anaemia (low blood platelets). Pregnancy must be strictly avoided by both men and women (during treatment and for 24 weeks after). This is because ribavirin has been shown to cause birth defects.

## Treatment contraindications

There are some drug-to-drug interaction issues, including the drug amiodarone (used for heart problems), but most issues will be able to be handled with changing accompanying medications, or through careful monitoring.

VIEKIRA PAK includes ritonavir which can lead to significant drug-drug interactions. All medications should be checked before prescribing with any hepatitis C medications.

Pregnancy must be strictly avoided by both men and women treated with Ibvavir (ribavirin) in any of the previously mentioned treatment combinations (during treatment and for 24 weeks after). Pregnancy must also be avoided with Daklinza (during treatment and for 5 weeks after). Talk to your doctor about treatment with Harvoni in pregnancy.

Your doctor or specialist will advise which treatments would be suitable (or not suitable) for you, depending on your past and present medical conditions and any other medications you are taking.

## Does treatment interfere with other drugs I am taking?

Sometimes one medicine we take interferes with other medicines, or with recreational drugs (including alcohol). A useful website that lists all these interactions is based at University of Liverpool (UK). Of course, it is really important to talk about these issues with your treatment doctor or nurses.

<http://www.hep-druginteractions.org/>

## No treatment restrictions

All Australian adults who have been diagnosed with chronic hepatitis C (genotypes 1, 2 and 3) and who hold a Medicare Card will be eligible to access the new DAA treatments, regardless of their stage of disease.

There will be no restrictions applied for people who inject drugs. If people are denied access or experience limited access to treatment and believe it is because of their status as a person who injects drugs, they can call either the *Hepatitis Infoline* on 1800 803 990 or the NSW Users and AIDS Association on 02 8354 7300 for information.

The Federal Government has also agreed to fund the new treatments for prisoners (see far below).

## Treatment access

The new medicines are available through Medicare (PBS) to all adults who hold a Medicare Card.

Currently, doctors and specialists working at hospital liver clinics and some specially trained GPs (doctors) are handling most people seeking treatment.

But soon, many more GPs will be able to manage hep C treatment. This will really expand your access to treatment, especially if you live in a rural area.

See [www.hep.org.au/services-directory/](http://www.hep.org.au/services-directory/) for a listing of GP across NSW. This list is updated on a regular basis.

For more information about the above directory, or to have one of our workers do a search for you, please call the Hepatitis Infoline on 1800 803 990.

Sofosbuvir/peginterferon/ribavirin combination treatment remains available via liver clinics and specialists.

## Preparing for treatment

People with hepatitis C have an initial GP or specialist assessment. This involves full blood testing and assessment of fibrosis stage, via Fibroscan<sup>®</sup> or APRI test. People with cirrhosis are referred for specialist

care and treatment. People with cirrhosis require long term monitoring for complications including liver cancer.

See [www.hep.org.au/services-directory/](http://www.hep.org.au/services-directory/) for a listing of Fibroscan® availability across NSW.

## Filling of prescriptions

Scripts are usually filled for a month at a time. S100 scripts are written as public hospital items and need to be dispensed in the public hospital pharmacy. Hospital pharmacies will usually be able to fill scripts on the day.

The new S85 (General Schedule streamlined approval) scripts are written by GPs or specialists and are dispensed at community pharmacies. Community pharmacies will probably not have the capacity to carry stocks of the DAA medicines, but will be able to order them in – usually within 72 hours. It is important to remind the community pharmacy to order in the next month's supply of medications about a week before the medications are due to be collected.

For more information, please call the *Hepatitis Infoline* on 1800 803 990.

## Online pharmacies

The new hepatitis C treatment drugs can also be ordered from online pharmacies. While this might not be as secure as customers picking up their treatment drugs from a local pharmacy, it will be very helpful for people who live in parts of NSW with no pharmacies that fill these scripts.

Consumers are required to

- fill in their details online
- phone the pharmacy
- post the prescription to the address provided on the website.

The pharmacy must first receive the prescription. Once they receive the script, they will place the order for the medicine, which may arrive within 1-2 days and then the medicine is delivered through Australia Post.

Try the following online pharmacies...

<https://www.chemistwarehouse.com.au/>

<https://www.epharmacy.com.au>

<https://www.pharmacyonline.com.au>

<http://www.pharmacydirect.com.au/>

<http://www.yourchemistshop.com.au/>

<http://www.royyoungchemist.com.au/>

If the treatment drugs don't appear in their 'search' option, people should call the online pharmacy. They can take orders over the phone (generally, a medicine doesn't go live on their site until it's ordered previously). Further, online pharmacies prefer to receive a call about the script beforehand so they can explain to the consumer the process.

## Treatment costs

Once the PBS listing takes effect on 1 March 2016, people will be charged only the usual monthly co-payment paid for a prescription. This is currently \$38.30 per month for general patients and \$6.20 per month for concessional patients.

## Treatment monitoring and follow up

The Australian Consensus Statement recommends that the virus is not checked while people are on treatment, as the result does not affect the treatment duration. Only liver enzymes, kidney function and

full blood count are checked at week 4 of treatment. If ribavirin is required in the treatment, then most people will have blood tests every month of treatment.

Some hospital clinics may use different monitoring protocols based on whether or not people have other illnesses and the complexity and severity of their hepatitis C disease.

All people will require a PCR viral load test 12 weeks after treatment finishes to check if they are cured.

## Defining cure

“Cure” or “SVR” (Sustained Virological Response) means that someone has cleared hepatitis C virus from their body. If someone has a PCR viral load test which shows undetectable (no virus) at 12 weeks after treatment finished they are considered to be cured.

If hepatitis C has caused significant liver damage, clearing the virus (cure) might not mean that someone is healthy again all of a sudden. In particular, if someone has cirrhosis, they still need specialist care and monitoring. People with cirrhosis still have a potential risk of developing liver cancer, even after being cured of hepatitis C.

People should talk to their treating doctor about what “cure” should mean for them.

## Treatment inside NSW jails

The Federal Government has agreed to fund the new treatments for prisoners under the current S100 scheme. On this basis, NSW adult prisoners will have access to the new DAA treatments for hep C after 1 March 2016.

People with hep C in NSW jails will be assessed and treatment delivered under Justice Health and Forensic Mental Health Network’s (JH&FMHN) Nurse-Led Model of Care.

There are 31 JH&FMHN Health Centres across NSW and most will be able to initiate and manage the new hep C treatments. To talk about accessing treatment while you are in custody, prisoners should first talk to the Health Centre Nurse.

For more information about hep C including treatment, please call the Hepatitis Infoline by dialling 3 on the Common Calls list. This is a free service.

## Children and treatment

The PBS listing of new direct acting antivirals (1 March 2016) is for Australian adults only. Children with hepatitis C should be seen and assessed by a paediatrician experienced in viral hepatitis. To find out more about monitoring and treating hepatitis C in children, contact the gastroenterology unit at The Children’s Hospital at Westmead (02 9845 3989).

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This factsheet was developed by Hepatitis NSW. It was reviewed by the Hepatitis NSW Medical and Research Advisory Panel with special input from Prof Gregory Dore and A/Prof Simone Strasser.

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