

Accessing new medicines for hepatitis C: What you need to know.

Introduction

A new generation of direct-acting antiviral medications are now available to Australians living with chronic hepatitis C. They are more effective, easier to take and have fewer side-effects than the older medications. The Australian Government has listed these new medicines on the Pharmaceutical Benefits Scheme (PBS), ensuring they are accessible and affordable to people with hepatitis C. This is a leap forward in the management and treatment of hepatitis C and positions Australia as a world leader in publicly-funded access to these new, highly effective medicines.

What are the new medicines?

The new, direct-acting antiviral (DAA) medicines available on the PBS from 1 May 2016 include:

Daklinza®	daclatasvir
Harvoni®	sofosbuvir + ledipasvir
Ibavyr®	ribavirin
Sovaldi®	sofosbuvir
Viekira Pak®	paritaprevir + ritonavir + ombitasvir + dasabuvir
Viekira Pak RBV®	As above + ribavirin

Following a clinical assessment, these medicines are used independently or in combination with other medicines depending on the person's particular situation. For most people, this will mean treatment without the need to use interferon.

Are the new medicines better than the previous ones?

Yes, the new DAA medicines are:

- more effective, resulting in a cure for 90-95% of people
- taken as tablets only, and have very few side-effects
- taken for as little as 8-12 weeks in most cases,
- provide interferon-free treatment options for all common genotypes in Australia.

Are the new medicines available for all people with hepatitis C?

Yes, treatment using the new DAA medicines is available through the PBS for all people living with hepatitis C over the age of 18 and who have a Medicare Card. However, the particular combination of medicines used will depend on a range of individual factors including genotype, prior treatment experience and whether or not you have developed cirrhosis (liver scarring).

What about people who currently inject drugs?

There are no restrictions applied to people who inject drugs as they are a priority population for hepatitis C treatment. Whether or not a person currently injects drugs should not be used as criteria for restricting access to the new medicines.

Can people in prison access the new medicines?

Yes, people in prison are a priority population for hepatitis C treatment. The Australian Government has ensured the new medicines will be funded for people in prison.

Are there interferon-free options available for all genotypes?

Currently, interferon-free treatment options are only available for genotypes 1, 2 and 3 – these are the most common genotypes in Australia. For now, treatment for people with genotypes 4, 5 and 6 will still require taking a combination of one of the new medicines in conjunction with pegylated interferon and ribavirin, but for a shorter duration than before.

Other new DAA medicines in development are likely to be considered by the Government for listing on the PBS. Also, as new data becomes available the use of current medicines may be broadened to include other genotypes.

Hepatitis Australia will provide further information about interferon-free options for genotypes 4, 5 and 6 as it becomes available.

What information will the doctor need to know about your health before treatment can be prescribed?

There are a number of tests the doctor will do and information you will be asked to provide before treatment can be prescribed. These include:

- undergoing blood tests to confirm you have active hepatitis C infection
- undergoing tests to determine the genotype (strain) you have
- undergoing an assessment to see if you have developed cirrhosis (liver scarring)
- discussing any previous treatments for hepatitis C you may have taken,
- identifying any other illnesses or health complaints you have, and;
- discussing any other prescription medications, over-the-counter medications or substances you are taking. This is important to avoid any possible drug interactions.

It is very important that medicines are taken as instructed, so the doctor or nurse may also talk with you about your readiness to start treatment and discuss things that may impact on your ability to take the medicine regularly, as prescribed.

What does treatment with the new medicines involve?

The treatment regimens for the new DAA medicines range between 8 and 24 weeks for a complete course of treatment, depending on your genotype, treatment history, whether you have cirrhosis and the combination of medicines used. *(Refer to the table at the end)*

Some treatments require only 1 to 2 tablets once or twice a day. For some treatment regimens, more medicines may be required to be used together. Depending on treatment history and genotype, some people may still need to include an injection (of peg-interferon) as well as taking tablets. Your doctor will explain the options available to you in more detail.

Will you need to have more tests during treatment?

Yes, the doctor will need to do blood tests to monitor how your body is responding to the medicines. This means checking if the medicine is working effectively against the hepatitis C virus

and that it is not negatively affecting your overall health.

Can General Practitioners (GPs) prescribe treatment for hepatitis C?

Yes, GPs in Australia can prescribe the new medicines. Before prescribing any medicines, your GP will be required to collect information and conduct tests (see above) to establish which combination of medicines will be the most effective for you. Based on that information, the GP will then consult with a specialist before prescribing the medicine for you. This means it is likely you will need a couple of appointments before receiving a prescription. In some cases, where there are other significant health factors to consider, the GP may refer you to a specialist before treatment is commenced.

Can you still see your specialist to access the new medicines?

Yes, gastroenterologists, hepatologists or infectious diseases physicians experienced in the treatment of chronic hepatitis C will continue to prescribe the new medicines. These specialists will also provide advice to GPs prescribing the new medicines, so you may consider seeing your GP if this is more convenient for you.

Where can you get your prescription filled?

This will depend on the type of prescription you receive and the doctor will provide more details. There are two types of prescriptions known as either s100 or s85.

Most people will receive the s85 prescription, which can usually be filled by your local pharmacy. However, it is important to note that some pharmacies may not have the medicines in stock and you may need to wait up to 72hrs to collect them. This is due to the very high cost the pharmacies have to outlay to keep the medicines in stock. If a pharmacy cannot fill your prescription, ask them for a referral to a pharmacy that can, or contact a local [hepatitis organisation](#) for assistance. This situation should improve over time as more people start accessing treatment.

Some people accessing specialists may receive the s100 type of prescription. These prescriptions can only be filled through hospital-based pharmacies and not local, community-based pharmacies. *(continued next page)*

As well as some initial delays, some prescriptions may only allow you to collect 4 weeks' supply of medicine at a time. So it is important to plan ahead so you don't run out of medicine.

How much do the medicines cost you?

You will be charged the usual co-payment price you pay for the dispensing fee of **each** prescription. This is currently \$38.30 for general patients and \$6.20 for concessional patients. This fee is reviewed each year.

Remember, as these medicines are PBS 'Authority required' the doctor can only prescribe one medicine on each prescription. This means you may be required to pay the dispensing fee for each medicine.

What if treatment is not effective for you?

For most people it is highly likely the new DAA medicine will be effective. If the new treatment does not work for you, your doctor will refer you to a specialist for further assessment prior to commencing any further treatment.

Where can you get further information?

You can talk to your GP, specialist, and clinic nurse or call the National Hepatitis Information line on:

1800 437 222.

Treatment Options available on the PBS from 1 May 2016

The treatment options below are based on the ['Australian recommendations for the management of hepatitis C virus infection: a consensus statement 2016'](http://www.gesa.org.au) (www.gesa.org.au).

Some variations to these regimens may be required depending on a person's individual clinical history or health status and Interferon containing regimens are only shown where there are no other PBS option is currently approved. For more detailed information you can discuss options with your doctor.

Genotype	No Previous Treatment (naïve)		Previously Received Treatment (experienced)	
	No cirrhosis	With cirrhosis	No cirrhosis	With cirrhosis
1 a/b	Ledipasvir/sofosbuvir [8 or 12 weeks]	Ledipasvir/sofosbuvir [12 weeks] or Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]	Ledipasvir/sofosbuvir [12 weeks] or Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]	Ledipasvir/sofosbuvir [24 weeks] or Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]
1 a/b	Daclatasvir and sofosbuvir [12 weeks]	Daclatasvir and sofosbuvir and ribavirin [12 weeks] or Daclatasvir and sofosbuvir [24 weeks]	Daclatasvir and sofosbuvir [12 or 24 weeks]	Daclatasvir and sofosbuvir and ribavirin [12 weeks] or Daclatasvir and sofosbuvir [24 weeks]*
1a	Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 weeks)	Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 weeks)	Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 weeks)	Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 or 24 weeks)
1b*	Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)	Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)	Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)	Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)
2	Sofosbuvir and ribavirin [12 weeks]	Sofosbuvir and ribavirin [12 weeks]	Sofosbuvir and ribavirin [12 weeks]	Sofosbuvir and ribavirin [12 weeks]
3	Daclatasvir and sofosbuvir [12 weeks] or Sofosbuvir and ribavirin [24 weeks]	Daclatasvir and sofosbuvir [24 weeks] or Sofosbuvir and ribavirin [24 weeks]	Daclatasvir and sofosbuvir [12 weeks] or Sofosbuvir and ribavirin [24 weeks]	Daclatasvir and sofosbuvir [24 weeks] or Sofosbuvir and ribavirin [24 weeks]
4, 5, 6	Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]	Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]	Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]	Sofosbuvir and Peg-Interferon alfa-2a/ribavirin [12 weeks]

* As per the Australian approved label for Viekira Pak-RBV: GTb patients with cirrhosis should receive ombitasvir, paritaprevir, ritonavir and dasabuvir and ribavirin.