Need-To-Know News on Hepatitis C Treatment – Dec 2014

Introduction
Hepatitis C treatment continues to develop at a rapid pace, so we’ve updated our fact sheet again to help you make well-informed decisions about your treatment plan. You can download a copy at www.hepatitisaustralia.com

Please bear in mind, the information and comments we’ve presented here are not intended as a substitute for professional medical advice. Always refer to your GP, liver specialist or hepatology (liver) nurse for expert advice on the type of treatment that is best suited to your individual situation.

Hepatitis C Treatment: An overview
For many years, hepatitis C has been treated with pegylated interferon and ribavirin, both of which cause significant side-effects. But with groundbreaking new treatments becoming available, we anticipate that over the next few years at least 9 out of 10 people could be cured of hepatitis C by taking a short course of tablets with very few side effects. This is provided the new medicines are made available on the Pharmaceutical Benefits Scheme (PBS). The cost of the new medicines is a significant issue which may delay PBS listing.

We’ve already seen improvements in treatment since the first direct acting antiviral medicines (DAAs) were subsidised by the government in April 2013, through the PBS for people with hepatitis C genotype 1. The improvements are going to keep on coming.

With more clinical trials in the pipeline, we expect new medicines to be subsidised through the PBS. Initially, these are likely to be shorter treatments, using a combination of pegylated interferon and DAAs to drive the cure rate higher.

Eventually, we’ll see combinations of interferon-free oral medicines become available. These will have far fewer side-effects than current treatments and result in a very high cure rate for the vast majority of people. We also anticipate that these treatments will substantially improve the cure rate for people living with compensated cirrhosis, co-infections and also people who didn’t previously respond well to treatment.

What’s the current treatment for hepatitis C in Australia?
Treatment at the moment is tailored according to the particular genotype or strain of hepatitis C that you have. In Australia, the most common are genotype 1 (54%) and genotype 3 (37%). Collectively, genotypes 2, 4, 5 and 6 have less than 5% prevalence in Australia. The information provided below is therefore focused on treatment options for people with genotype 1 and genotype 3 infection.

Treating hepatitis C genotype 1
In December 2014, the treatment for genotype 1 changed to include weekly pegylated interferon injections, with twice-a-day ribavirin tablets, and a once-a-day tablet of simeprevir (brand name Olysio, a second generation protease inhibitor).
Simeprevir replaces previous treatment regimens using boceprevir or telaprevir. Compared to boceprevir or telaprevir it is easier to take (no fatty food requirements), better tolerated (fewer side effects) and safer (few complications).

The treatment regime begins with triple therapy of simeprevir, ribavirin and pegylated interferon for the first 12 weeks. This is followed by ribavirin and pegylated interferon for an additional 12 or 36 weeks. Your length of treatment will be determined by your doctor. Prior treatment responses and/or how quickly the virus responds to treatment this time will be considered. If the virus doesn’t respond well to treatment it may be stopped.

Simeprevir is not recommended for use if you have previously been treated with pegylated interferon and ribavirin and either boceprevir or telaprevir, as there is no data to suggest that there would be a clinical benefit.

**Treating hepatitis C genotype 3**

For hepatitis C genotype 3, treatment has remained unchanged for many years and includes a combination of weekly pegylated interferon injections and daily ribavirin tablets over a period of 26 weeks.

**What are the side-effects of current treatments?**

The side-effects of pegylated interferon and ribavirin can be significant, which is one reason why treatment rates remain so low in Australia.

**Possible side-effects from pegylated interferon and ribavirin include:**
- Mild to severe mood disturbances
- Anaemia
- Slow blood-clotting
- Fatigue

**Flu-like symptoms**
- Dry skin
- Rash
- Insomnia
- Decreased appetite
- Weight loss
- Hair loss.

Ribavirin can also cause birth defects and is therefore not suitable for women who are pregnant or trying to get pregnant.

**Additional possible side-effects related to simeprevir include:**
- Skin rashes or itchy skin
- Skin sensitivity to sunlight
- Constipation
- Nausea.

Often, the body’s tolerance of treatment is reduced the longer the treatment lasts. Therefore, for most people, shortening the duration of treatment can result in higher tolerance and fewer/lesser side-effects.

If you experience side-effects, the earlier you seek advice from your doctor, the better. Early intervention and careful monitoring can often minimise side-effects.

In rare cases, treatment may be stopped to avoid progression of significant life-threatening side-effects.

**Mixing other medicines with hepatitis C treatments**

Mixing your medications can be dangerous, if you need to take other prescription or over-the-counter medicines during your treatment, always check with your specialist first. This includes herbal medicines such as St. John’s wort or milk thistle, which should not be taken with simeprevir.
What are my chances of being cured with current treatments?
On average, there is a 70% to 80% success rate with current treatments. However, there are many personal factors that influence treatment outcomes for individuals. To get a better understanding of how well you’re likely to respond to current treatments, make an appointment with your doctor.

The success of your treatment can be improved by taking your prescribed medicines regularly, so be sure to follow your doctor’s instructions consistently.

How will my response to treatment be monitored?
Your response to treatment is monitored by taking blood tests at intervals to measure the amount of virus in your blood. What your doctor will be looking for is a Sustained Virological Response (SVR). This means that the virus drops to undetectable levels while you are undergoing treatment and remains undetectable for six months after you complete the treatment. In a word, it means you’re cured.

What if treatment doesn’t work for me?
If your treatment doesn’t result in a cure this time, remember there is hope in the form of new medicines that might be suitable for you. Stay in touch with your doctor for regular liver health checks and updates on the release of new treatments offering higher cure rates.

What’s the next step in hepatitis C treatment?
An application was made to the July 2014 meeting of the Pharmaceutical Benefits Advisory Committee for Sofosbuvir to be recommended for listing on the PBS. This application was rejected.

The agenda for the March 2015 meeting of the Pharmaceutical Benefits Advisory Committee indicates that the following medicines are to be considered:

- **Asunaprevir** (BMS) – for treatment of chronic genotype 1b hepatitis virus infection
- **Daclatasvir** (BMS) – for treatment of hepatitis C
- **Ledipasvir with Sofosbuvir** (Gilead) – for treatment of chronic hepatitis C genotype 1
- **Sofosbuvir** (Gilead) – for treatment of hepatitis C
- **Ribavirin** (Clinect) – for treatment of hepatitis C genotype 2 and 3 in combination with Sofosbuvir

Abbvie’s **Viekira Pak** (ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets) to treat chronic hepatitis C virus genotype 1 infection, including those with cirrhosis has recently been approved by the United States Food and Drug Administration (FDA) and it is anticipated that an application will be made to the Pharmaceutical Benefits Advisory Committee at some point in 2015.

MSD also has two new medicines (MK-5172 and MK-8742) currently in clinical trials; however the timing of a Pharmaceutical Benefits Advisory Committee application is unknown at this stage.
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When will new treatments be available in Australia?
The new hepatitis C medicines are very expensive and will be subject to a rigorous process of expert assessment to establish safety and cost-effectiveness. Once a recommendation is made, the Federal Cabinet will need to approve the funds to subsidise the medicines before they can be added to the Pharmaceutical Benefits Scheme and made available at an affordable cost.

This process can be complex and subject to delays. What’s more, the criteria to access the new government-subsidised hepatitis C treatments are unknown at this stage.

As a general rule, you need to be eligible for Medicare to access medicines subsidised by the government on the PBS; however, there are some exceptions.

Consequently, no one can tell with any certainty when you might have access to the next wave of hepatitis C medicines.

Also, if you’re researching online, make sure the information you’re reading relates to Australia, and be aware that new hepatitis C medicines become available in different countries at different times.

Don’t put your health at risk by waiting too long

It’s easy to understand why you might prefer to wait for interferon-free treatments to become available. However, by waiting, you could be putting your health at risk.

If you’re 40 years of age or over, you’re likely to experience an accelerated rate of liver damage which increases your risk of developing cirrhosis, liver cancer or liver failure. This is called the ‘Liver Danger Zone’.

You should also bear in mind that symptoms of liver disease may not be felt until the liver is significantly scarred.

Don’t put your health at risk by waiting too long for treatment. Make an appointment with your doctor to have a liver health assessment at least once a year.

What does a liver health assessment involve?

Your doctor will give you a clinical examination and blood tests. They may also use a Fibroscan® – a quick, non-invasive test (similar to an ultrasound) that measures the level of liver scarring to determine the severity of liver disease.

For further information on the liver health assessments see our:

Liver Assessment Factsheet  
http://www.hepatitisaustralia.com/community-resources/

Video of a liver health assessment  
http://www.hepatitisaustralia.com/videos/

If you have chronic hepatitis C and particularly if you are in the ‘Liver Danger Zone’, ask your doctor about having a regular liver health check-up today. A liver check-up is nothing to worry about, it is simple, easy and it could save your life.

www.hepatitisaustralia.com
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