

# Hepatitis C factsheets

## Emerging treatments



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## Telaprevir and boceprevir

Two agents, telaprevir and boceprevir (protease inhibitors) have finished enrolment into large-scale international trials. The studies were able to single out people who have the harder to treat genotype 1 – with, and without, previous treatment. Results from these trials show considerable benefit and have led to applications for telaprevir being submitted to the US Food and Drug Administration.

Invariably, the drug companies involved will lodge applications for Australian approval and the first protease inhibitors will probably be licensed in Australia by 2012 with potential access through Medicare (if demonstrated to be cost-effective) in late 2012 or 2013.

## Other emerging treatments

Several other protease and polymerase inhibitors are in clinical development, including agents that require single daily dosing (telaprevir and boceprevir are dosed three-times daily).

International phase II studies with MK 7009, TMC435 and BI 201335 (protease inhibitors) are underway and include several Australian hospitals. Other new therapies are in phase II development, including polymerase inhibitors and NS5A inhibitors.

Trials will also shortly commence that are evaluating new therapies including polymerase inhibitors and NS5A inhibitors in people with genotype 2 and 3 (protease inhibitors have poor activity against these genotypes, particularly genotype 3).

## Introduction

Treatment of chronic hepatitis C (also called hep C) has improved in recent years, particularly since the advent of pegylated interferon and ribavirin combination therapy.

Between 50-80% of people achieve a sustained virological response (SVR) following 24 or 48 weeks therapy – the response and duration of treatment depends on someone's hep C virus genotype. However, treatment numbers remain low, in part due to treatment side effects and length of therapy.

The development of new therapeutic agents such as protease and polymerase inhibitors provides hope that treatment responses will be improved over shorter treatment durations. This is particularly important for people with genotype 1 infection. Studies have revealed several important features:

- these individual oral therapy agents will be used with pegylated interferon and ribavirin in combination
- triple therapy may cause additional side effects
- early hep C virus resistance is an important issue, particularly for protease inhibitors
- treatment responses should be improved by at least 20-30% and with the potential to shorten the duration of treatment.

## Treatment regimes

The new triple therapy treatments (Telaprevir and Boceprevir) will only benefit people with genotype 1.

It is likely that people who begin treatment and experience a rapid viral response (RVR) within the first four weeks will need only 24 weeks of treatment. A rapid viral response is when someone responds really well – the level of virus in their blood dropping significantly – in the first four weeks of treatment.

Those people who do not experience a rapid virological response will need the full 48 weeks of treatment.

## Other drugs in development

For a comprehensive listing of hep C treatment drugs that are currently in development, visit <http://www.hcvdrugs.com/>

## Also see

For further information about developments in hep C treatment, please contact the *Hepatitis Helpline* on 9332 1599 (Sydney callers) or 1800 803 990 (NSW regional callers).

- This factsheet was developed by Hepatitis NSW. It was reviewed by the Hepatitis NSW Medical and Research Advisory Panel.