

<b>Title:</b>	<b>Hepatitis C (HCV) viral load testing March 2000</b>
<b>Agency:</b>	Medicare Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia <a href="http://www.msac.gov.au">http://www.msac.gov.au</a>
<b>Reference:</b>	<b>MSAC application 1021. Assessment report ISSN 1443-7120</b>

### **Aim**

To assess the safety and effectiveness of the service and under what circumstances public funding should be supported. Specifically, to assess whether certain tests for patients with HCV can inform clinical decisions to institute or continue interferon therapy.

### **Conclusions and results**

*Safety* The test is safe.

*Effectiveness* Genotyping and viral load testing is predictive of the response to interferon therapy. As patients with a high viral load and more resistant genotypes can respond to interferon therapy, the predictive value of genotyping and viral load testing is insufficient to exclude a patient from treatment. Viral testing during interferon therapy has greater predictive value than pretreatment determinations and can guide decisions to continue therapy.

*Cost-effectiveness* Cost savings would occur if 15% of patients tested decided not to proceed with interferon therapy as a result of testing. Although viral load testing and genotyping is expensive, it may be cost effective with careful patient selection.

### **Recommendations**

Public funding should be supported for these tests on patients with confirmed HCV where a consultant physician is managing treatment subject to the following new restrictions:

- Genotype testing be restricted to once only for each patient;
- viral load testing is prior to treatment and used only once in a 12 month period;
- viral detection testing be limited to patients undertaking antiviral therapy, and used once prior to treatment and no more than three times in the following 12 months; and
- a maximum of 4 viral detection tests for any course of treatment.

### **Method**

MSAC conducted a systematic review of the biomedical literature by accessing biomedical electronic databases, the Internet and international health technology agency websites. This review investigated the following in patients with HCV:

- pretreatment genotyping/viral load testing predicts the response to interferon therapy; and
- polymerase chain reaction-based viral detection during antiviral therapy predicts sustained virological response.

Cost effectiveness was modelled by comparing the costs of genotyping and viral load testing with an empirical trial of therapy and a qualitative detection test at 12 weeks. The analysis indicates what proportion of patients need to decide not to proceed with interferon therapy as a result of genotyping and viral load testing for cost savings to result.