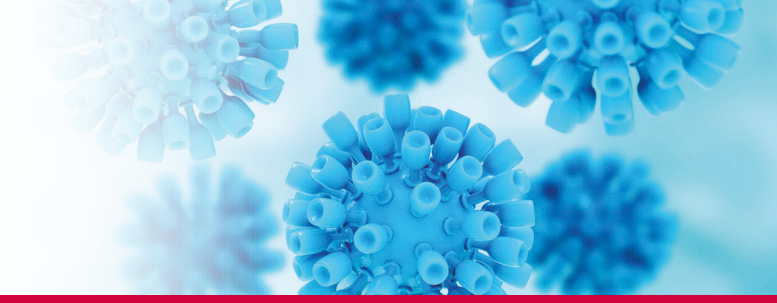
Hepatitis C Virus



Hepatitis C Management Update

INTRODUCTION

Hepatitis C Virus (HCV) continues to be a major public health challenge for Australia, despite the incidence of HCV having declined since the year 2000, it was estimated that there are approximately 227,000 people living with active HCV in Australia.[1] HCV is curable with medical therapy. However, HCV-associated cirrhosis remains a common cause of liver transplantation in Australia.[1]

The Pharmaceutical Benefit Scheme (PBS) listing of direct-acting antiviral (DAA) therapies for HCV treatment in 2016 allowed for patients to be treated by general practitioners under certain criteria. This PBS listing of DAA medicines enables GPs to prescribe HCV medicines in consultation with an experienced gastroenterologist, hepatologist or infectious diseases physician. Additionally, GPs experienced in the treatment of chronic HCV may prescribe independently.

Experience may be gained by providing treatment in consultation with an experienced gastroenterologist, hepatologist or infectious disease physician, for at least 10 people living with HCV infection. These treatments should be completed to sustained virological response before becoming eligible for independent prescribing.[2]

A consultation with one of the above specialists removes the need for GPs to gain formal accreditation when treating HCV and has the increased benefit of improving access to HCV treatment within our communities.[2]

QUALITATIVE AND QUANTITATIVE HCV TESTING

Positive HCV serology confirms a patient has been exposed to the virus at some point in time but does not reveal whether or not the patient has an active infection. To determine this, a molecular test is performed on blood.

The Qualitative HCV RNA test is used to detect the presence of HCV in the blood. Results of HCV RNA are reported as 'positive' or 'detected' if any HCV viral RNA is identified, or 'negative' or 'not detected' if otherwise. A positive HCV RNA result indicates active or current infection. The HCV RNA test may take up to three months to appear positive after viral exposure; however it is usually positive when tested at six weeks.

The HCV Viral Load test is a quantitative test that detects and measures the amount of viral RNA particles in a patient's blood. This test is often performed prior to treatment.

The Qualitative HCV RNA test or the HCV Viral Load may be used during or after treatment to help determine the patient's response to the therapy. Both tests have Medicare restrictions placed on their ordering, and may incur a charge to the patient.

DIRECT-ACTING ANTIVIRAL THERAPIES

Confirming the presence of cirrhosis is an important consideration before starting Direct-Acting Antiviral (DAA) therapy. HCV genotype is the tool to determine the most appropriate DAA therapy for your patient.

The combination of HCV genotype appropriate drugs has been associated with >95% cure rates, and are available through both the PBS General Schedule (Section 85) and the Section 100 (S100) Highly Specialised Drugs (HSD) Program. PBS patient and prescriber eligibility will be the same whether the medicines are being prescribed under the PBS General Schedule or HSD Program.

For current DAA therapy and duration information, please refer to the PBS website[2].

HOW TO ORDER

Clinical guidance for diagnosing and treating Hepatitis C[1]:

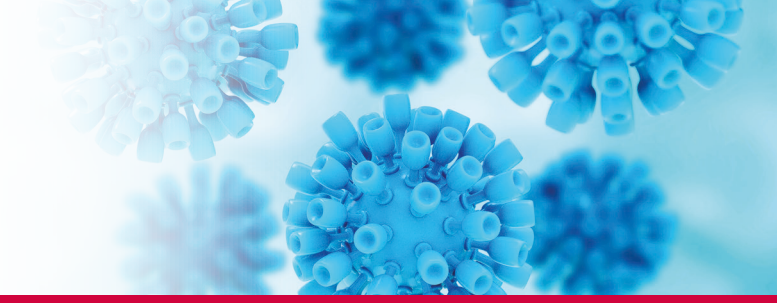
Diagnosis	
Hepatitis C antibody (serology)	Serology indicates previous or current infection
Qualitative HCV RNA test	Presence indicates active infection

Post-Diagnosis (Pre-treatment)	
HCV Viral Load test (Quantitative)	Confirms infection if detected
HCV genotype	Genotype determines treatment regimen

A wallchart summarising clinical guidance for treating HCV infection is available through your local Medical Liaison Officer or from the Gastroenterological Society of Australia (GESA).

>>> CONTINUED OVERLEAF

Hepatitis C Virus



>>> CONTINUED FROM OVERLEAF

FREQUENCY OF TESTING

Test	Frequency of Testing
Anti-HCV (serology)	Monday to Saturday
HCV Viral Load test (Quantitative)	Tuesday and Friday
HCV genotype	Tuesday
Qualitative HCV RNA test	Monday and Thursday

MEDICARE BILLING CRITERIA

Qualitative HCV RNA test

A patient is eligible for a Medicare rebate if at least one of the following criteria is satisfied:

1. The patient is Hepatitis C seropositive;
2. The patient's serological status is uncertain after testing;
3. The test is performed for the purpose of:
   - Determining the Hepatitis C status of an immuno-suppressed or immunocompromised patient; or
   - The detection of acute Hepatitis C prior to sero-conversion where considered necessary for the clinical management of the patient.

The patient may have a maximum of **one test** within a 12 month period.

Qualitative HCV RNA test in patients undergoing therapy

A patient is eligible for a Medicare rebate if:

They are undertaking antiviral therapy for chronic HCV infection and the test is performed for the detection of Hepatitis C viral RNA.

The patient may have a maximum of **four tests** within a 12 month period.

HCV Viral Load test (Quantitative)

A patient is eligible for a Medicare rebate if:

1. The Quantitative HCV RNA is used in their pre-treatment evaluation or;
2. The Quantitative HCV RNA can be used in the assessment of efficacy of a patient's antiviral therapy.

The patient may have a maximum of **two tests** within a 12 month period.

HCV genotype

A patient is eligible for Medicare rebate if:

The patient is HCV RNA positive and is being evaluated for antiviral therapy of chronic HCV.

The patient may have a maximum of **one test** within a 12 month period.

Please be aware if the patient does not fulfil the Medicare Criteria guidelines above a fee may apply.

FURTHER INFORMATION

For further information please contact Dr R Vohra, Dr S Appleton, or Dr P Bartley on **(03) 6711 2000**

References

1. *Hepatitis C Virus Infection Consensus Statement Working Group. Australian recommendations for the management of hepatitis C virus infection: a consensus statement (August 2017). Melbourne: Gastroenterological Society of Australia, 2017. Accessed via http://cart.gesa.org.au/membes/files/Resources/Hepatitis%20C/hepatitis_C_virus_infection_consensus_statement_Aug_2017.pdf*
2. *Pharmaceutical Benefits Scheme. General Statement for Drugs for the Treatment of Hepatitis C (April 2021). Canberra: Australian Government Department of Health. Access via https://www.pbs.gov.au/info/healthpro/explanatory-notes/general-statement-hep-c.*

Healius Pathology Pty Ltd (ABN 84 007 190 043) t/a Tasmanian Medical Laboratories PUB/MR/1364_TML v4 (Jul21)