

Hepatitis C Virus

Hepatitis C Management Update

INTRODUCTION

2016 estimates show chronic Hepatitis C virus (HCV) affects approximately 230,000 Australians with the projected number of Australians living with HCV set to triple by 2030.^{1,2}

There are multiple clinical benefits to curing HCV infection, notably as HCV-associated disease is the most common cause of liver transplantation in Australia.²

Recent changes in the Pharmaceutical Benefit Scheme (PBS) listing of direct-acting antiviral (DAA) therapies for HCV treatment allows 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.

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

A positive HCV antibody test 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

HCV genotype is the tool to determine the most appropriate Direct-Acting Antiviral therapy (DAA) for your patient.

The medicines listed on the PBS for treatment of HCV¹

- Daklinza® (daclatasvir)
- Harvoni® (sofosbuvir + ledipasvir)
- Ibavyr® (ribavirin)
- Sovaldi® (sofosbuvir)
- Viekira Pak® (paritaprevir + ritonavir + ombitasvir + dasabuvir)
- Viekira Pak RBV® (paritaprevir + ritonavir + ombitasvir + dasabuvir + ribavirin)

These HCV medicines may be used in various combinations depending on the clinical circumstances and will be 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.

FURTHER INFORMATION

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

References

1. Hepatitis Australia. About Hep C. Updated 27/07/2015. <http://www.hepatitisaustralia.com/hepatitis-c-facts/about-hep-c>
2. Hepatitis C Virus Infection Consensus Statement Working Group. Australian recommendations for the management of hepatitis C virus infection: a consensus statement 2016. Melbourne: Gastroenterological Society of Australia, 2016. Accessed via http://www.gesa.org.au/files/editor_upload/File/PBS%20and%20MBS/Hepatitis%20C%20virus%20infection%20a%20consensus%20statement%202016.pdf

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HOW TO ORDER

Clinical guidance for diagnosing and treating Hepatitis C²

Diagnosis	
Hepatitis C antibody (serology)	Serology indicates exposure
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

At each on-treatment visit assess for medication adherence, treatment adverse effects and drug-drug interactions.

Undergoing Therapy	
Week 0	FBE, U&E, LFTs, INR, HCV RNA level
Week 4	FBE, LFTs
Week 12 +/- 24	FBE, LFTs, Qualitative HCV RNA test
Week 12 after EOT (SVR)	FBE, LFTs, HCV PCR (qualitative)

FREQUENCY OF TESTING

Test	Frequency of Testing
Anti-HCV (serology)	Monday to Saturday
HCV Viral Load test (quantitative)	Tuesday and Friday
HCV genotype	Tuesdays
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 immunosuppressed or immunocompromised patient; or
 - The detection of acute Hepatitis C prior to seroconversion 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:

1. 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 is used in the assessment of efficacy of a patient's antiviral therapy

The test must be made by or on the advice of the specialist or consultant physician who manages the treatment of the patient with chronic HCV Hepatitis.

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

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

