Hepatitis C (HCV)

Disclaimer

This pathway is about new curative treatments for hepatitis C that are available in primary care.

Key links

APRI (AST to Platelet Ratio Index) Calculator

University of Liverpool: Hepatitis Drug Interactions

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South Eastern Melbourne PHN Hepatitis C (HCV) pathway
Background

**About Hepatitis C (HCV)**

- Hepatitis C is transmitted by blood-to-blood contact.
- Sexual transmission and perinatal transmission are uncommon.
  - People living with HIV carry a higher chance of transmission through sex.
  - In-utero vertical transmission occurs in approximately 5% of infants. Children born to women living with HCV should be tested when appropriate. Hepatitis C has not been shown to be transmitted through breastfeeding.
- In acute infection, most people are asymptomatic:
  - About 25% of people will spontaneously clear hepatitis C in the 6 to 12 months after acute infection.
  - Those who do not clear the infection are described as having chronic hepatitis C.
- Chronic hepatitis C is slowly progressive over decades but excess alcohol intake, poor nutrition, obesity, diabetes, and co-infection (hepatitis B and HIV) accelerate liver damage.
- Typically after 20 to 30 years, some patients will experience progressive liver fibrosis, and may develop signs and symptoms of cirrhosis, liver failure, or hepatocellular cancer.
- New direct acting antivirals (DAAs) are oral medications, very well tolerated, and cure around 95% of patients even if cirrhosis is present.
- Pangenotypic regimens (treat all HCV genotypes) are available.
- There is no longer a PBS requirement for remote specialist consultation for general practitioners or nurse practitioners if they have training or previous experience with HCV treatment.

**Assessment**

1. Take a careful and respectful history to check if patient has **risk factors** for HCV.

**Risk factors**

- Injecting drug use (may have been only once)
- Blood products or organ donor recipients before 1990 in Australia, or any time overseas
- Tattoos and body piercing
- History of imprisonment or other custodial settings
- Medical or dental treatments in countries where equipment may not have been adequately sterilised
- Needle stick injury or occupational exposure to blood or body substances e.g., healthcare workers
- Sexual partners of people with HCV (higher risk of transmission for men who have sex with men and people with HIV infection)
- People born in countries with high HCV prevalence e.g., Southeast Asia, Middle East, Africa
- Aboriginal and Torres Strait Islander populations
- Children born to HCV-positive mothers (low risk of transmission)
- Evidence of liver disease
- Known HIV or hepatitis B infection
2. Check for signs of liver disease:

### Acute hepatitis

**Signs of acute hepatitis**
- Fever
- Gastrointestinal symptoms – abdominal pain, anorexia, nausea, vomiting
- Icteric features, jaundice, dark urine, pale faeces – may not be present in anicteric hepatitis
- Enlarged tender liver and/or spleen
- Urticaria, and joint pains

### Cirrhosis

**Signs of cirrhosis**
- Jaundice
- Leukonychia
- Spider naevi
- Palmar erythema
- Gynaecomastia
- Muscle wasting
- Liver enlargement
- Shrunken liver
- Hardened liver edge
- Ascites

### Acute liver failure

**Acute liver failure**
Defined as a rapid decline in hepatic function, characterised by:
- jaundice.
- hepatic encephalopathy.
- associated with coagulopathy INR > 1.5

3. If risk factors, screen with **hepatitis C antibody (anti-HCV) test** and also ask for **HCV RNA PCR** to be performed if anti-HCV is positive to avoid delays.

### HCV RNA PCR testing

- Positive HCV RNA PCR (qualitative) confirms current infection. Patient is eligible for 1 test in 12 month period if anti-HCV positive (MBS 69499).
- Approximately 25% of patients will spontaneously resolve their infection in the first 6 to 12 months.
- Positive HCV RNA in a person with no evidence or suspicion of recent infection is indicative of chronic hepatitis C infection.
- If anti-HCV positive and HCV RNA negative (resolved infection) and ongoing risk, annual HCV RNA testing is recommended.
Hepatitis C antibody (anti-HCV) test

A positive anti-HCV test indicates exposure to the virus but does not prove current infection.

4. If HCV RNA positive (i.e., chronic infection), arrange:

**Further investigations**

*Further investigations*

**Virology:**
- HCV genotype and subtype – patient is eligible for 1 test in 12 month period if being evaluated for treatment (MBS 69491)
- HCV RNA level (quantitative) – patient is eligible for:
  - 1 test in a 12 month period for pretreatment evaluation, or
  - 2 tests in 12 months for efficacy of treatment (MBS 69488).
- HBV (HBsAg, anti-HBs, anti-HBc), HIV, HAV serology

**Other investigations:**
- FBE, LFTs, aspartate aminotransferase (AST), urea and electrolytes, estimate glomerular filtration rate (eGFR), INR
- Pregnancy test for women of child bearing age
- Perform ECG if ribavirin therapy is planned and aged > 50 years, or cardiac risk factors

**Liver fibrosis assessment**

*Liver fibrosis assessment*

- Liver biopsy is no longer a pre-treatment requirement.
- **AST-to-platelet ratio index (APRI) is a useful initial assessment.**
  - If a patient score is less than 1.0 and there is no concern about risk of cirrhosis, further fibrosis assessment is not necessary.
  - If the score is 1.0 or more, request Fibroscan.
  - If the score is less than 1.0, but there is an increased pre-test probability of cirrhosis (e.g. physical signs of chronic liver disease, history of heavy alcohol use), then cirrhosis is not ruled out – request Fibroscan.
- Transient elastography (Fibroscan) measures liver stiffness.
- Several private radiology providers are offering ultrasound-based shear wave elastography (SWE), which is:
  - similar but not exactly the same as Fibroscan.
  - less well validated.

A very low or very high liver stiffness from SWE is likely to be accurate but in between readings are of unclear significance. Fibroscan is preferred, if available.
**Abdominal ultrasound**

*Abdominal ultrasound in liver disease*

This is used to assess:

- structure and integrity of the liver
- portal hypertension
- splenomegaly
- abdominal varices
- hepatocellular carcinoma.

*Repeat every 6 months in patients with cirrhosis for HCC surveillance.*

5. If anti-HCV negative and
   - recent exposure, repeat anti-HCV in 3 months and 6 months.
   - ongoing risk of exposure, repeat anti-HCV every year.

**Management**

**Practice Point - Stress importance of compliance**

Advise the patient that adherence to direct acting antiviral drug (DAA) is critical, as the first course offers the best chance of cure.

1. If any **serious hepatic complications**, refer to [Emergency Department](#).

**Serious hepatic complications**

- *Acute liver failure*
- *Sepsis in a patient with cirrhosis*
- *Severe hepatic encephalopathy*
- *Severe ascites restricting movement and breathing*

2. If previous experience and/or have support from clinician with experience in hepatitis C, **initiate treatment with direct-acting antiviral (DAA) drugs**.

**Initiating treatment with direct-acting antiviral (DAA) drugs**

Once chronic infection has been established and necessary investigations completed, patients can be quickly and easily treated with DAA therapy in the primary care setting.

1. Although newer DAAs are much safer than previous peginterferon-based treatments for HCV, consider reviewing **knowledge and skills** in the diagnosis, treatment, and management of HCV, and requirements for prescribing of DAAs under S85 and S100.

*General practitioner knowledge and skills resources*
- Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) – *What ASHM does in Hepatitis C*
- Gastroenterology Society of Australia (GESA) – *Hepatitis C Treatment*
- Victorian PHN Alliance – *Curing Hepatitis C: Your role as a GP*

2. Before starting treatment with DAAs, review concomitant medicines using the University of Liverpool’s drug interaction checker. Medicines to treat hepatitis C have many **contraindications** and **drug interactions**.

**Drug interactions**  
Especially amiodarone, PPIs, anti-HIV, statins, common antibiotics.  
See [Hepatitis Drug Interactions](#).

**Contraindications**  
For example:  
- Ensure medication selected is appropriate for kidney function, some DAAs are currently contraindicated in patients with eGFR of < 30 mL/min.  
- No DAAs are recommended for use during pregnancy and breastfeeding, and none are currently PBS listed for treatment of children or adolescents aged < 18 years.

Note: Ongoing injecting drug use (people who inject drugs – PWID) or psychiatric co-morbidity are not contraindications to treatment. To encourage completion of treatment, it is essential to engage with the patient’s treatment team, including specialists, community pharmacy, and family.

3. Discuss commencing contraception therapy prior to initiating DAAs in women of childbearing age.

4. Discuss ceasing complementary and alternative medicines with patients during the treatment period to optimise the likelihood of cure.

5. Discuss potential side-effects associated with DAA treatment (relatively minor side-effects have been noted by some patients).

6. If not trained or no previous experience of HCV complete **remote consultation form for initiation of HCV treatment** and fax to selected specialist to obtain **specialist consultation**. Referral details are on the form, or see [Urgent or Routine Liver Referral](#).

**Specialist consultation**  
General practitioners who are not trained or experienced in HCV treatment are recommended to consult with an **appropriate specialist** by phone, mail, email, or videoconference in order to meet the prescriber eligibility requirements for DAAs under S85. This
requirement is also met by faxing the request to initiate DAA form to available clinics.

**Appropriate specialist**
Appropriate specialists are gastroenterologists, hepatologists, or infectious disease physicians experienced in the treatment of chronic hepatitis C infection.

**Remote consultation form for initiation of HCV treatment**

➢ Word
➢ PDF

7. For treatment durations, see Gastroenterological Society of Australia (GESA) – *Hepatitis C Treatment*.

8. Contact the Authority Prescription Application Service on 1800-888-333 with **required information** for approval to prescribe DAAs.

**Required information**
- The hepatitis C virus genotype, and
- the patient’s cirrhosis status (non-cirrhotic or cirrhotic).

Prescribers must also document the following information in the patient’s medical records:
- Evidence of chronic hepatitis C infection (HCV antibody positive and HCV RNA positive), and
- evidence of the hepatitis C virus genotype.

**Note:** A separate authority prescription will need to be authorised for each medicine for PBS subsidy if prescribing a DAA regimen with > 1 medication component.

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**Arrange referral for hepatitis C (HCV) RNA positive**

3. **Arrange urgent or routine liver referral** for patients who are hepatitis C (HCV) RNA positive and unable to be managed and treated in community-based services.

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**Arrange follow-up to monitor success DAA treatment**

4. Arrange follow-up to monitor success of DAA treatment:
   - Review at one month to:
     - assess compliance, and discuss relevant health promotion e.g. ongoing risk, alcohol consumption.
     - check ALT but only if patient would benefit from seeing this start to normalise.
   - Arrange HCV PCR and LFT for 12 weeks after treatment completed:
     - Treatment outcome is measured by a HCV PCR test. If not detected at this time, the patient is cured (sustained virological response (SVR12)).
 Test of cure is only reliable if performed at least 12 weeks after DAA treatment is completed.

If early-stage or low-level fibrosis and HCV RNA is not detected at 12 weeks post DAA treatment (SVR 12), additional long-term follow-up is not required. SVR12 represents cure of HCV infection.

5. Arrange follow-up for cured patients:
   - Advise HCV antibodies are not protective and reinfection with HCV can occur. Advise regular screening for those who continue to engage in risk-taking behaviour.
   - Patients with cirrhosis need screening for complications such as portal hypertension and 6 monthly liver ultrasound for hepatocellular carcinoma surveillance.
   - Patients with abnormal LFTs post cure, require further assessment and investigations.

**Referral**

- If any serious hepatic complications, refer to Emergency Department.
- Arrange urgent or routine liver referral for patients who are hepatitis C (HCV) RNA positive and unable to be managed and treated in community-based services.

**Information**

**For health professionals**

**Further Information**

- Cancer Council Australia:
  - [Optimal Cancer Care Pathway for People with Hepatocellular Carcinoma: Quick Reference Guide](#)
  - [Optimal Cancer Care Pathway for People with Hepatocellular Carcinoma](#)
- Gastroenterological Society of Australia (GESA) – [Clinical Guidance of Treating Hepatitis C Virus Infection: A Summary](#)
- Hepatitis C Online – [AST to Platelet Ratio Index (APRI) Calculator](#)
- HepC Help – [Home Page](#)
- University of Liverpool – [Hepatitis Drug Interactions](#)

**For patients**

- Better Health Channel – [Hepatitis C](#)
- Hepatitis Victoria – [Hepatitis C Treatment](#)
- LiverWell
- Pharmaceutical Benefits Scheme (PBS) – [New Hepatitis C Medicines: Fact Sheet for Patients and Consumers](#)
Select bibliography

- Australian recommendations for the management of hepatitis C virus infection: a consensus statement 2018. [place unknown]: Gastroenterological Society of Australia (GESA); 2018.

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