General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

Population criteria: Patient must be aged 18 years or older.
Treatment criteria: Must be treated by a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.
The following information must be provided at the time of application: a) the hepatitis C virus genotype; and b) the patient's cirrhotic status (non-cirrhotic or cirrhotic) The following information must be documented in the patient's medical records: a) evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and b) evidence of the hepatitis C virus genotype

The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

Hepatitis C - Non-cirrhotic patients

	Treatment naïve	Treatment experienced
Genotype 1	LEDIPASVIR/SOFOSBUVIR [8 or 12 weeks] [1] OR DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	LEDIPASVIR/SOFOSBUVIR [12 weeks] [2] OR DACLATASVIR and SOFOSBUVIR [12 or 24 weeks] [3] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [12 weeks] [4] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]

KEY
PEG-IFN/RBV- peginterferon alfa-2a (&) ribavirin
RBV - ribavirin

[1] [LEDIPASVIR/SOFOSBUVIR] for treatment-naïve, non-cirrhotic patients:
- consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
- otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.

[2] A 12 weeks treatment regimen for [LEDIPASVIR/SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor + PEG-IFN alfa/RBV.

[3] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients:
- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa/RBV; or
- consider treatment for 24 weeks in patients who have failed a protease inhibitor + PEG-IFN/RBV.

[4] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients, treatment for 12 weeks in patients:
- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa/RBV.

Hepatitis C – Cirrhotic patients

	Treatment naïve	Treatment experienced
Genotype 1	LEDIPASVIR/SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	LEDIPASVIR/SOFOSBUVIR [24 weeks] [5] OR DACLATASVIR and SOFOSBUVIR [24 weeks] [6] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] [7] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	SOFOSBUVIR and RBV [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [24 weeks] [8] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN/RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]	SOFOSBUVIR and PEG-IFN/RBV [12 weeks]

KEY
PEG-IFN/RBV- peginterferon alfa-2a (&) ribavirin
RBV – ribavirin

[5] A 24 weeks treatment regimen for [LEDIPASVIR/SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor + PEG-IFN alfa/RBV.

[6] A 24 weeks treatment regimen for [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa/RBV; or
- a HCV protease inhibitor and PEG-IFN/RBV.

[7] [DACLATASVIR and SOFOSBUVIR and RBV] for treatment-experienced cirrhotic patients:
- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa/RBV.

[8] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced cirrhotic patients, treatment for 24 weeks in patients :
- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa/RBV.