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 medical practitioner or an authorised nurse practitioner[1] 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.

[1] Medicines for the treatment of hepatitis C are listed for prescribing by authorised nurse practitioners under the General Schedule only. Medicines for the treatment of hepatitis C are not listed for prescribing by authorised nurse practitioners under the S100 Highly Specialised Drugs Program.

Hepatitis C - Non-cirrhotic patients

	Treatment naïve	Treatment experienced
Genotype 1	**LEDIPASVIR + SOFOSBUVIR** [8 or 12 weeks] [2] OR **DACLATASVIR** and **SOFOSBUVIR** [12 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR** [12 weeks] [3] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV** [12 weeks] [4] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]	**LEDIPASVIR + SOFOSBUVIR** [12 weeks] OR **DACLATASVIR** and **SOFOSBUVIR** [12 or 24 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR** [12 weeks] [3] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV** [12 weeks] [4] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** and **RBV** [16 weeks] [5] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]
Genotype 2	**SOFOSBUVIR** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]	**SOFOSBUVIR** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]

[2] [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.

[3] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1b HCV.

[4] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1a HCV.

[5] [GRAZOPREVIR + ELBASVIR and RBV] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.

	Treatment naïve	**Treatment experienced**
Genotype 3	**DACLATASVIR** and **SOFOSBUVIR** [12 weeks] OR **SOFOSBUVIR** and **RBV** [24 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]	**DACLATASVIR** and **SOFOSBUVIR** [12 weeks] OR **SOFOSBUVIR** and **RBV** [24 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]
Genotype 4	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** and **RBV** [16 weeks] [5] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]
Genotype 5 & 6	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks]

KEY
PEG-IFN - peginterferon alfa-2a
RBV - ribavirin

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** and **RBV** [12 weeks] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]	**LEDIPASVIR + SOFOSBUVIR** [24 weeks] OR **DACLATASVIR** and **SOFOSBUVIR** [24 weeks] OR **DACLATASVIR** and **SOFOSBUVIR** and **RBV** [12 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV** [12 or 24 weeks] [7] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** and **RBV** [16 weeks] [5] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]
Genotype 2	**SOFOSBUVIR** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]	**SOFOSBUVIR** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]
Genotype 3	**SOFOSBUVIR** and **RBV** [24 weeks]	**DACLATASVIR** and **SOFOSBUVIR** [24 weeks]

[6] [SOFOSBUVIR + VELPATASVIR] for patients with decompensated cirrhosis:
- Use in combination with ribavirin.

[7] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-experienced, cirrhotic patients:
- consider treatment for 12 weeks in patients with genotype 1a HCV (except prior null responders to PEG-IFN and RBV) and genotype 1b HCV; or
- consider treatment for 24 weeks in patients with genotype 1a HCV who have had a previous null response to PEG-IFN and RBV.

	Treatment naïve	**Treatment experienced**
	OR **DACLATASVIR** and **SOFOSBUVIR** [24 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **DACLATASVIR** and **SOFOSBUVIR** and **RBV** [12 or 24 weeks] [8] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6, 9]	OR **SOFOSBUVIR** and **RBV** [24 weeks] OR **SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **DACLATASVIR** and **SOFOSBUVIR** and **RBV** [12 or 24 weeks] [8] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6, 9]
Genotype 4	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** [12 weeks] OR **GRAZOPREVIR + ELBASVIR** and **RBV** [16 weeks] [5] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]
Genotype 5 & 6	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]	**SOFOSBUVIR** and **PEG-IFN** and **RBV** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR** [12 weeks] [6]

KEY
PEG-IFN - peginterferon alfa-2a
RBV – ribavirin

[8] [DACLATASVIR and SOFOSBUVIR and RBV] for cirrhotic patients consider a 24 week regimen of where clinically appropriate.
[9] [SOFOSBUVIR + VELPATASVIR] for patients with genotype 3 infection with compensated cirrhosis:
- Consider addition of ribavirin.