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.

Treatment criteria:
Must be treated by a medical practitioner or an authorised nurse practitioner 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:

- the patient's cirrhotic status (non-cirrhotic or cirrhotic)
- details of the previous treatment regimen (**only** for requests for sofosbuvir + velpatasvir + voxilaprevir (Vosevi®) or glecaprevir + pibrentasvir (Maviret®) for treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

The following information must be documented in the patient's medical records:

a) evidence of chronic hepatitis C infection:
    - antibody to hepatitis C virus (anti-HCV) positive; and
    - repeated hepatitis C virus ribonucleic acid (HCV RNA) positive; and

b) evidence of the hepatitis C virus genotype (where possible)

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
All genotypes (Pan-genotypic regimens)	**SOFOSBUVIR + VELPATASVIR** [12 weeks] OR **GLECAPREVIR + PIBRENTASVIR** [8 weeks]	**SOFOSBUVIR + VELPATASVIR** [12 weeks] OR **SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR** [12 weeks] [1] OR **GLECAPREVIR + PIBRENTASVIR** [8 or 12 or 16 weeks] [2]
Genotype 1	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 2	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 3	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 4	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 5 & 6	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.

KEY

RBV - ribavirin

Hepatitis C – Cirrhotic patients

	Treatment naïve	Treatment experienced
All genotypes (Pan-genotypic regimens)	**SOFOSBUVIR + VELPATASVIR** [12 weeks] [3, 4] OR **GLECAPREVIR + PIBRENTASVIR** [8 weeks] [5]	**SOFOSBUVIR + VELPATASVIR** [12 weeks] [3, 4] OR **SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR** [12 weeks] [1] OR **GLECAPREVIR + PIBRENTASVIR** [12 or 16 weeks] [6]
Genotype 1	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 2	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 3	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 4	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 5 & 6	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.

KEY

RBV – ribavirin

[1] SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.

[2] GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:

- treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

[3] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.

[4] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.

[5] GLECAPREVIR + PIBRENTASVIR – A treatment duration of 12 weeks may be considered for patients with compensated cirrhosis, at the discretion of the prescriber.

[6] GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:

- treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.