New hepatitis C medicines – Frequently Asked Questions

The Minister for Health, the Hon Sussan Ley MP, announced on 20 December 2015, that a number of new medicines would be made available through the Pharmaceutical Benefits Scheme (PBS) from 1 March 2016 for the treatment of chronic hepatitis C.

Which medicines are being listed from 1 March 2016?
The medicines scheduled for listing on the PBS from 1 March 2016 are daclatasvir (Daklinza®); ledipasvir with sofosbuvir (Harvoni®); sofosbuvir (Sovaldi®) and ribavirin (Ibavyr®). The PBS listing for peginterferon alfa-2a (&) ribavirin (Pegasys RBV®) will also be amended to allow its use in combination with sofosbuvir. The listings are subject to final arrangements being formalised with the suppliers of the medicines.

How will the medicines be presented in the PBS Schedule?
The Pharmaceutical Benefits Advisory Committee (PBAC) has advised that in order to ensure the broadest possible access to these medicines, the new hepatitis C medicines will all be available through both the PBS General Schedule (‘Section 85’) and the Section 100 (S100) Highly Specialised Drugs (HSD) Program [but outside the HSD Community Access arrangements introduced on 1 July 2015]. PBS patient and prescriber eligibility will be the same whether the medicines are being prescribed under the PBS General Schedule or the HSD program.

The medicines will be listed in the Schedule using a General Statement for Drugs for the Treatment of Hepatitis C (General Statement) to outline the patient eligibility conditions and prescribing restrictions (Attachment A). Treatment matrices outlining the particular medicines and regimens available through the PBS to individual patients, based on their disease genotype and treatment history, are also included in the General Statement to guide prescribing (Attachment A).

See Attachment B for information on which programme, PBS General Schedule or Section 100 Highly Specialised Drugs (HSD), is appropriate for the prescribing of these medicines.

Will the medicines be subject to restrictions?
Yes, the medicines will be subject to prescribing and patient restrictions (Attachment A).

Are the new treatments being made available for all patients with chronic hepatitis C?
Patients will be eligible for the medicines in accordance with the restrictions outlined in the General Statement. The medicines are being made available through the PBS for all adult patients with chronic hepatitis C infection, across all disease genotypes and disease severities will be eligible to receive the new treatments.

The management of a patient’s medical condition, including direction as to the most appropriate therapy option/s, is essentially a matter for the professional clinical judgement of the medical practitioner concerned.

Can children receive these medicines through the PBS?
No. In line with the Therapeutic Goods Administration approved indications, adult patients (aged 18 years or older) with chronic hepatitis C infection, across all disease genotypes and disease severities will be eligible to receive the new treatments.

What are the likely treatment outcomes of these medicines?
Recent advances in antiviral treatment have led to the development of these new medicines, which have a cure rate of greater than 90 per cent. Treatment with these medicines is also
shorter in duration, less complex and much better tolerated than traditional treatments. A link to the PBAC Public Summary Documents and Product Information documents for these medicines is provided under further information.

Who will be able to prescribe these new medicines?
States and territories may have specific requirements about who is eligible to prescribe the new hepatitis C medicines in their jurisdiction.

For the purposes of the PBS subsidy, where state or territory requirements allow, gastroenterologists, hepatologists, or infectious disease physicians experienced in the treatment of chronic hepatitis C infection will be eligible to prescribe the new medicines. All other medical practitioners, including general practitioners (GPs), will also be eligible to prescribe under the PBS, provided that is done in consultation with a gastroenterologist, hepatologist, or infectious disease physician experienced in the treatment of chronic hepatitis C infection.

This prescribing flexibility has been introduced to support initiatives such as the Fourth National Hepatitis C Strategy 2014-2017 (see link provided under further information), and facilitate a greater role for primary care in the treatment of hepatitis C over time.

What does ‘in consultation with’ mean in this context?
For the purposes of prescribing the new hepatitis C medicines, the term ‘in consultation with’ is intended to mean a GP must consult with one of the specified specialists by phone, mail, email, or videoconference in order to meet the prescriber eligibility requirements.

Do patients need to have attended an appointment with a gastroenterologist, hepatologist, or infectious diseases physician experienced in the treatment of chronic hepatitis C infection prior to being prescribed one of the new medicines by a medical practitioner?
For the purposes of PBS subsidy, patients do not need to have attended an appointment with a gastroenterologist, hepatologist, or infectious diseases physician experienced in the treatment of chronic hepatitis C infection prior to being prescribed one of the new medicines by a medical practitioner. The prescribing medical practitioner, however, must consult with one of these specialists by phone, mail, email, or videoconference prior to prescribing.

The management of a patient’s medical condition, including direction as to the most appropriate therapy option/s, is essentially a matter for the professional clinical judgement of the medical practitioner concerned.

Will these medicines require a PBS Authority approval prior to prescribing?
Yes. Prescribers may use either the written or telephone channels to seek approval from the Department of Human Services [Medicare] before prescribing these medicines under the PBS. The PBS Authority type for these medicines will not be streamlined; the correct PBS Authority type will be Authority required (written or telephone) in all instances.

The Authority Prescription Application Service, administered by DHS-Medicare, can be contacted on 1800 888 333.

If patients are prescribed a course of treatment requiring more than one medicine, a separate authority prescription will need to be authorised for each medicine for PBS subsidy.

What information will eligible prescribers be required to provide when seeking authority to prescribe these treatments under the PBS for a particular patient?
Prescribers will be required to provide the following information at the time of application:
  a. the hepatitis C virus genotype; and
b. the patient’s cirrhotic status (non-cirrhotic or cirrhotic).

Prescribers must also document the following information 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.

These requirements are set out in the PBS Schedule in the General Statement for Drugs for the Treatment of Hepatitis C (Attachment A).

Additional information, such as viral load and liver function test results, is not required as part of an application for PBS subsidy.

Can these medicines be prescribed for prisoners?
It is the responsibility of state and territory governments to support the health care of people in custodial settings.

However, the Australian Government recognises the importance of maintaining prisoner access to treatments for a number of conditions with high prevalence in the prisoner community. This is achieved through prisoner access to medicines supplied through the PBS HSD Program. The Australian Government has therefore agreed to fund the cost of these new hepatitis C medicines for prisoners through the HSD arrangements.

From 1 March 2016, state and territory health and justice departments will ensure that there are processes in place to ensure that prisoners are able to access these medicines, in accordance with the PBS eligibility requirements.

Will there be limits on how many prescriptions can be written at any one time? That is, can prescriptions be written for the full 8, 12 or 24 week course of treatment (whichever applies)?
An eligible prescriber will be able to apply for the appropriate number of repeats to cover the duration of the relevant PBS-subsidised treatment course.

Will patients be able to receive repeat treatment or be prescribed a different course of treatment under these restrictions?
Repeat treatment and use of a subsequent or different course of treatment with the new medicines is not supported by current evidence. Although the current PBS restrictions do not prohibit patients receiving repeat treatment or a different course of treatment, the Department will be reviewing the use of these new medicines in the future to ensure they remain value for money for Australian taxpayers.

Will community pharmacies be able to dispense these new hepatitis C medicines?
The PBS dispensing rules will not change for these new listings.

If a prescription is issued under the S85 General Schedule, approved pharmacists in the community will be able to dispense these new medicines.

However, if a prescription has been written by an eligible prescriber under the S100 HSD arrangements in a public hospital, approved pharmacists in the community will not be able to dispense the new hepatitis C medicines under the PBS. In this scenario, these prescriptions (i.e. written by an eligible prescriber in a public hospital), may only be dispensed by a section 94 approved hospital authority.

Before supplying these new medicines under the PBS, pharmacists should ensure the PBS Authority prescriptions they may be presented have been approved by DHS-Medicare.
How will wholesalers and pharmacies be paid for supplying and dispensing these medicines?
In accordance with existing arrangements, payments to wholesalers and pharmacies for the supply and dispensing of the new medicines under the PBS will be made as per the current scheduled fees and mark-ups for the General Schedule (Section 85) and Section 100 Highly Specialised Drugs Program, whichever applies.

Where can I find the PBAC recommendations for these new treatments?
General information regarding the PBS is available on the PBS website at [www.pbs.gov.au](http://www.pbs.gov.au).


Where can I get further information about hepatitis C and these medicines?

The updated Schedule of Pharmaceutical Benefits takes effect from 1 March 2016.


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:

- the hepatitis C virus genotype; and
- the patient’s cirrhotic status (non-cirrhotic or cirrhotic)

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

- 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
- 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

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Naïve</th>
<th>Treatment Experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>LEDIPASVIR/SOFOSBUVIR [8 or 12 weeks]</td>
<td>LEDIPASVIR/SOFOSBUVIR [12 weeks]</td>
</tr>
<tr>
<td></td>
<td>DACLATASVIR and SOFOSBUVIR [12 weeks]</td>
<td>DACLATASVIR and SOFOSBUVIR [12 or 24 weeks]</td>
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<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
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<td>Genotype 2</td>
<td>SOFOSBUVIR and RBV [12 weeks]</td>
<td>SOFOSBUVIR and RBV [12 weeks]</td>
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<td>Genotype 3</td>
<td>DACLATASVIR and SOFOSBUVIR [12 weeks]</td>
<td>DACLATASVIR and SOFOSBUVIR [12 weeks]</td>
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<td>SOFOSBUVIR and RBV [24 weeks]</td>
<td>SOFOSBUVIR and RBV [24 weeks]</td>
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<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
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<td>Genotype 4, 5, 6</td>
<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
</tr>
</tbody>
</table>

**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

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<td>LEDIPASVIR/SOFOSBUVIR [24 weeks]</td>
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<td>OR</td>
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<tr>
<td>DACLATASVIR and SOFOSBUVIR and RBV [12 weeks]</td>
<td>DACLATASVIR and SOFOSBUVIR [24 weeks] ³</td>
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<td>OR</td>
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<td>DACLATASVIR and SOFOSBUVIR [24 weeks]</td>
<td>DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] ³</td>
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<td>SOFOSBUVIR and PEG-IFN/RBV [12 weeks]</td>
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<tr>
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<thead>
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<th>Genotype 3</th>
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<tr>
<td>SOFOSBUVIR and RBV [24 weeks]</td>
<td>DACLATASVIR and SOFOSBUVIR [24 weeks] ³</td>
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<td>OR</td>
<td>OR</td>
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<tr>
<td>DACLATASVIR and SOFOSBUVIR [24 weeks]</td>
<td>SOFOSBUVIR and RBV [24 weeks]</td>
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<td>OR</td>
<td>OR</td>
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### KEY
- PEG-IFN/RBV – peginterferon alfa-2a (&) ribavirin
- RBV – ribavirin

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¹ 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.

² 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.

³ [DACLATASVIR and SOFOSBUVIR and RBV] for treatment-experienced cirrhotic patients:
- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa/RBV.

⁴ [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.
### DACLATASVIR

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<td>Daklinza [BQ]</td>
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</table>

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required – In Writing**

**Authority required - Telephone**

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

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<td>Daklinza [BQ]</td>
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Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 24 weeks.
## LEDIPASVIR + SOFOSBUVIR

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<tr>
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### LEDIPASVIR + SOFOSBUVIR

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<tr>
<td>28</td>
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<td>Harvoni [GI]</td>
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**Note** Special Pricing Arrangements apply.

### Authority required – In Writing

### Authority required - Telephone

*Chronic hepatitis C infection*

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 8 weeks.

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### LEDIPASVIR + SOFOSBUVIR

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<tr>
<td>28</td>
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<td>Harvoni [GI]</td>
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</table>

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**Note** Special Pricing Arrangements apply.

### Authority required – In Writing

### Authority required - Telephone

*Chronic hepatitis C infection*

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

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### LEDIPASVIR + SOFOSBUVIR

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<td>Harvoni [GI]</td>
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**Note** Special Pricing Arrangements apply.

### Authority required – In Writing

### Authority required - Telephone

*Chronic hepatitis C infection*

**Clinical criteria:**
Attachment A

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the
Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.
## SOFOSBUVIR

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<th>Max. Qty</th>
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<tbody>
<tr>
<td>SOFOSBUVIR</td>
<td>sofosbuvir 400 mg tablet, 28</td>
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</table>

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### Authority required – In Writing

### Authority required - Telephone

**Chronic hepatitis C infection**

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

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<tr>
<td>SOFOSBUVIR</td>
<td>sofosbuvir 400 mg tablet, 28</td>
<td>1 5</td>
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</table>

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**Chronic hepatitis C infection**

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.
**RIBAVIRIN**

<table>
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<th>Max. Qty</th>
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<tbody>
<tr>
<td>ribavirin 400 mg tablet, 28</td>
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</tr>
<tr>
<td>ribavirin 600 mg tablet, 28</td>
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<td>2</td>
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</table>

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required – In Writing**

**Authority required - Telephone**

Chronic hepatitis C infection

Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

<table>
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<th>Max. Qty</th>
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<tr>
<td>ribavirin 400 mg tablet, 28</td>
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<td>5</td>
</tr>
</tbody>
</table>

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required – In Writing**

**Authority required - Telephone**

Chronic hepatitis C infection

Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
PEGINTERFERON ALFA-2A (&) RIBAVIRIN

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max. Qty Paks</th>
<th>Nr.of Rpts</th>
</tr>
</thead>
<tbody>
<tr>
<td>peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&amp;) ribavirin 200 mg tablet [140 tablets], 1 pack</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&amp;) ribavirin 200 mg tablet [168 tablets], 1 pack</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

**Caution**
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required – In Writing**

**Authority required - Telephone**

Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.
Population criteria:
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
### Appropriate listings, prescription type and dispensing location per patient type and treatment setting, effective 1 March 2016

<table>
<thead>
<tr>
<th>Patient type</th>
<th>Prescriber setting</th>
<th>PBS Authority Prescription type</th>
<th>HSD Prefix on prescription</th>
<th>Dispensing limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private patient</td>
<td>Community</td>
<td>Section 85 (General Schedule)</td>
<td>N/A</td>
<td>PBS approved community pharmacy (‘Section 90’) only</td>
</tr>
<tr>
<td></td>
<td>Private Hospital</td>
<td>Section 85 (General Schedule)</td>
<td>N/A</td>
<td>PBS approved community pharmacy (‘Section 90’) or PBS approved private hospital Authorities (‘Section 94’)</td>
</tr>
<tr>
<td></td>
<td>Public Hospital non-admitted</td>
<td>Section 85 (General Schedule)</td>
<td>N/A</td>
<td>PBS approved community pharmacy (‘Section 90’)</td>
</tr>
<tr>
<td></td>
<td>Public Hospital non-admitted – State or Territory participant in the Pharmaceutical Reforms</td>
<td>Section 85 (General Schedule)</td>
<td>N/A</td>
<td>PBS approved community pharmacy (‘Section 90’) or PBS approved public hospital Authorities (‘Section 94’)</td>
</tr>
<tr>
<td></td>
<td>Public Hospital non-admitted – State or Territory not a participant in the Pharmaceutical Reforms</td>
<td>Section 100 (Highly Specialised Drugs Program)</td>
<td>HSD PUB</td>
<td>PBS approved public hospital Authorities only (‘Section 94’)</td>
</tr>
<tr>
<td>Public patient</td>
<td>Public Hospital / prison outpatients service irrespective of State or Territory participation in the Pharmaceutical Reforms</td>
<td>Section 100 (Highly Specialised Drugs Program)</td>
<td>HSD PUB</td>
<td>PBS approved public hospital Authorities only (‘Section 94’)</td>
</tr>
<tr>
<td>Patient in a custodial setting</td>
<td>Public Hospital / prison outpatients service irrespective of State or Territory participation in the Pharmaceutical Reforms</td>
<td>Section 100 (Highly Specialised Drugs Program)</td>
<td>HSD PUB</td>
<td>Public hospital / May be subject to community pharmacy dispensing under agency arrangements with the respective state or territory government</td>
</tr>
</tbody>
</table>