

5.22 RIBAVIRIN 200 mg tablet, Ibavyr®, Clinect Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested PBS listing of an additional strength, ribavirin 200 mg, for use in combination therapy with other oral agents for treating chronic hepatitis C infection (CHC). The currently listed strengths are 400 mg and 600 mg.

2 Requested listing

- 2.1 The submission sought to list the 200 mg tablets on the PBS as part of the General Schedule and Highly Specialised Drugs Program (S100 public and private hospitals) as per the current listings for ribavirin.
- 2.2 The current restrictions for ribavirin require that it is used in line with the General Statement for drugs for the treatment of hepatitis C.
- 2.3 No changes to the wording of the current ribavirin restrictions were proposed.
- 2.4 In accordance with subsection 101(3BA) of the National Health Act 1953, the PBAC had previously advised ribavirin should not be treated as interchangeable on an individual patient basis with other recommended treatments of CHC.

3 Background

- 3.1 Ribavirin is TGA registered for use in combination with other oral agents for the treatment of CHC in adults.
- 3.2 Ribavirin 200 mg tablets were registered on the ARTG on 15 March 2016.

Clinical place for the proposed therapy

- 3.3 The submission claimed that the availability of 200 mg tablets would remove the need for the physical splitting of higher strength tablets to achieve lower doses in modified dosing regimens, which may be required in a small percentage (up to 10%) of patients, such as those who require a lower re-initiation dose following treatment emergent adverse events.

Consideration of the evidence

Sponsor hearing

- 3.4 There was no hearing for this item as it was a minor submission.

Consumer comments

3.5 The PBAC noted that no consumer comments were received for this item.

Clinical trials

3.6 As a minor submission, no new clinical trials were presented in the submission.

Economic analysis

3.7 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

3.8 The minor submission proposed the same Approved Ex-Manufacturer Price (AEMP) per 200 mg to apply for listing the 200 mg tablet of ribavirin. The minor submission estimated there to be negligible financial implications to the PBS upon listing of the new strength. The submission estimates a small net saving of less than \$10 million over years 1 to 5 of listing. This is summarised in Table 1.

Table 1: Estimated use and financial implications for 200 mg IBAVYR® (ribavirin)

Use and cost of IBAVYR to the PBS/RPBS	Year 1	Year 2	Year 3	Year 4	Year 5
Total treated population	15000	15000	15000	9900	6600
Patients prescribed IBAVYR					
Genotype 1	■	■	■	■	■
Genotype 2	■	■	■	■	■
Genotype 3	■	■	■	■	■
Genotypes 4,5,6	■	■	■	■	■
Patients requiring dose reduction of IBAVYR					
12 week course	■	■	■	■	■
Patients weighing up to 75 kg	■	■	■	■	■
Patients weighing more than 75 kg	■	■	■	■	■
24 week course	■	■	■	■	■
Patients weighing up to 75 kg	■	■	■	■	■
Patients weighing more than 75 kg	■	■	■	■	■
Incremental (Proposed–Current)					
Cost at DPMQ	-\$■	-\$■	-\$■	-\$■	-\$■
PBS	-\$■	-\$■	-\$■	-\$■	-\$■
RPBS	-\$■	-\$■	-\$■	-\$■	-\$■
Co-payments					
PBS	■	■	■	■	■
PBS	\$■	\$■	\$■	\$■	\$■
RPBS	■	■	■	■	■
RPBS	\$■	\$■	\$■	\$■	\$■
Net Cost to PBS/RPBS	-\$■	-\$■	-\$■	-\$■	-\$■

Public Summary Document – July 2016 PBAC meeting

Use and cost of IBAVYR to the PBS/RPBS	Year 1	Year 2	Year 3	Year 4	Year 5
Net Cost to PBS	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
Net Cost to RPBS	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]

Source: Table 2 from Page 2 of the minor submission

The redacted table shows that at year 5, the estimated number of patients was less than 10,000 and the net cost to the PBS would be less than \$10 million.

- 3.9 The estimates in the submission do not appear to take into account the use of the 200 mg tablets in other scenarios (ie, where the daily dose is 600 mg, first dose is 1 x 200 mg tablet and second dose is 2 x 200 mg tablets). Regardless, the listing of the additional strength is not expected to result in an additional cost to the PBS as the proposed price is at the same AEMP as existing strengths.

4 PBAC Outcome

- 4.1 The PBAC recommended the listing of ribavirin 200 mg, for use in combination therapy with other oral agents for treating chronic hepatitis C infection, on the basis that it should have the same listing conditions as existing strengths of ribavirin on the PBS.
- 4.2 The PBAC noted no changes to the wording of the current ribavirin restrictions were proposed.
- 4.3 The PBAC noted that the availability of 200 mg tablets would remove the need for the physical splitting of higher strength tablets to achieve lower doses in modified dosing regimens.
- 4.4 The PBAC accepted the listing of the additional strength is not expected to result in an additional cost to the PBS as the proposed price is at the same AEMP as the currently listed strengths.

Outcome:

Recommend

5 Recommended listing

Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
RIBAVIRIN ribavirin 200 mg tablet, 28	1	5	Ibavyr®	Clinect Pty Ltd

Category / Program	General Schedule / S100 HSD program
Prescriber type:	Medical Practitioners

Public Summary Document – July 2016 PBAC meeting

Condition:	Chronic hepatitis C infection
PBS Indication	Chronic hepatitis C infection
Restriction Level/ Method	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required - Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	<p>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C</p> <p>AND</p> <p>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</p> <p>AND</p> <p>The treatment must be limited to a maximum duration of 24 weeks</p>
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.
Administrative Advice	<p><u>Note</u></p> <p>No increase in the maximum number of repeats may be authorised.</p>
Caution	<p>Ribavirin is a category X drug and must not be given to pregnant women.</p> <p>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.</p>

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
RIBAVIRIN ribavirin 200 mg tablet, 28	1	2	lbavyr®	Clinect Pty Ltd

Category / Program	General Schedule / S100 HSD program
Prescriber type:	Medical Practitioners
Condition:	Chronic hepatitis C infection
PBS Indication	Chronic hepatitis C infection
Restriction Level/ Method	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required - Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

Public Summary Document – July 2016 PBAC meeting

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.
Administrative Advice	<u>Note</u> No increase in the maximum number of repeats may be authorised.
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.

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

7 Sponsor's Comment

The sponsor had no comment.