14.02 SIMEPREVIR, 150 mg capsule, Olysio®, Janssen-Cilag Pty Ltd.

# Purpose of Application

* 1. To seek a PBAC recommendation to change the current Section 100 Highly Specialised Drug Programme public hospital listings for simeprevir (treatment naïve and treatment experience patients) to Authority required (telephone).

# Background

* 1. At its March 2015 meeting, the PBAC advised the Minister that the current listing of simeprevir in combination with peginterferon alfa and ribavirin was no longer cost-effective at the price it was currently listed on the PBS. The Department informed the sponsor with respect to March 2015 PBAC consideration for the new medicines for the treatment of chronic hepatitis C (CHC) infection and invited them to make a submission in relation to that advice.
	2. At its November 2015 meeting, the PBAC recommended the Authority Required listing of simeprevir in combination with sofosbuvir for the treatment of patients with genotype 1 chronic hepatitis C (CHC) infection. During the consideration of the submission, the PBAC noted that the Department had advised the sponsor of simeprevir of the PBAC’s March 2015 advice in relation to its drug and no response had been received from the sponsor.
	3. At its November 2015 meeting, the PBAC advised the Minister that the current listing of simeprevir should be removed or, if retained, the price should be adjusted so that the General Schedule cost of the simeprevir with peginterferon and ribavirin regimen was no more than ''''''% of the cost of the new treatments for CHC recommended at the March and July 2015 PBAC meetings.

# Other relevant factors

* 1. At the meeting between the Pricing Section of the Department and representatives of Janssen (sponsor of simeprevir), ''''''' ''''''''''''''''' '''''''''''' ''''' '''''''''''''''''''' ''''' ''''''''''''''''''''' ''''''' ''''''''''''''' ''''''' '''''''''''' ''''' '''''''''''''''''''''' ''''' ''''''''' ''''''''' ''''''' '''''''''''''''' '''''''''''''''''''''''''''''''''''''''
	2. After careful consideration of both the PBAC’s advice and '''''''''''''''''''''''' ''''''''''''''''''''''', on the 23 December 2015 the Department informed the sponsor of its intention to recommend the Minister (delegate) to:
1. Consider delisting simeprevir from the PBS; OR
2. Consider making the current Section 100 Highly Specialised Drug Programme public hospital listing for simeprevir Authority Required (telephone), consistent with the current Section 100 Highly Specialised Drug Programme private hospital listing for the same drug. An Authority Required (telephone) listing would also be consistent with the PBAC recommendation in respect of the new chronic hepatitis C drugs.
	1. On 15 January 2016 the sponsor acknowledged the aforementioned options and requested changing the current Section 100 Highly Specialised Drug Programme public hospital listing for simeprevir to an Authority Required (telephone) listing.

# PBAC Outcome

* 1. The PBAC recommended to the Minister (delegate) to change the current Section 100 Highly Specialised Drug Programme public hospital listings for simeprevir (treatment naïve and treatment experience patients) to Authority required (telephone).
	2. The Committee noted that at the November 2015 meeting the PBAC recommended simeprevir for use in combination with sofosbuvir, but that the listing conditions have not yet been agreed between the Department and the sponsor.
	3. The PBAC reiterated its previous advice that at its current list price, simeprevir would not be considered a cost-effective treatment for Hepatitis C, following the recent listing of interferon-free oral treatment.
	4. The PBAC also noted that a telephone Authority would be consistent with other oral treatments that would be listed for interferon-free regimens.

**Outcome:**

Recommended

# Recommended listing

* 1. Amend the restriction method for PBS items 10197Q and 10200W to Authority Required – telephone.

# 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.

# Sponsor’s Comment

The sponsor had no comment.