Information sheet for ledipasvir with sofosbuvir (Harvoni)

Applications will be considered by the Hepatitis C Treatments Panel (HepCTP) at its regular meetings and approved subject to eligibility according to the Access Criteria are detailed below.

Harvoni may be used in hepatitis C patients of all genotypes. Harvoni is an oral fixed dose combination tablet which contains 400mg sofosbuvir and 90mg ledipasvir. We understand that Harvoni should always be combined with ribavirin in patients with decompensated cirrhosis, where a lower starting dose (200mg mane 400mg nocte) should be used. Supply of both Harvoni and ribavirin will be via direct distribution for patients with approval from the HepCTP Panel.

The Panel may assess urgent applications in between regular meetings.

Please refer to our website http://www.pharmac.govt.nz/hepatitis-c-treatments/ for links to additional information.

Delivery:

Delivery of Harvoni and ribavirin cannot occur unless the **original scripts** for both treatments have been received by PHARMAC.

Both Harvoni and ribavirin will be delivered from a central distributor to an appropriate address. An appropriate address constitutes: a general practice, clinic, or another suitable address where someone is available to sign for the delivery **at all times** during normal work hours and where the medicines can be appropriately looked after until required.

If approved, the delivery of Harvoni should take between 7-10 days for the treatment to arrive at the nominated address. Please ensure you have discussed this application with the nominated delivery address.

Repeat deliveries will be sent to the nominated address in time to ensure that patients will have continuity of supply noting a patient will require 3 deliveries total (or 6 deliveries total, in the unusual situation where ribavirin is contraindicated).

Access criteria:

Chronic hepatitis C – Advanced disease– ribavirin is not contraindicated

Applications from any relevant practitioner. Approvals valid for 12 weeks for applications meeting the following criteria:

All of the following:

1. Patient has chronic hepatitis C (any genotype); and
2. Ribavirin treatment is not contraindicated; and
3. Any of the following:
   - 3.1 Patient has decompensated cirrhosis (Child-Pugh B or C); or
   - 3.2 Patient has been accepted onto a list for a liver transplant or has received a liver transplant; or
   - 3.3 Patient has essential mixed cryoglobulinaemia with associated purpuric skin rash and; either
     - 3.3.1 Glomerulonephritis; or
     - 3.3.2 Systemic vasculitis.

Chronic hepatitis C – Advanced disease - ribavirin is contraindicated

Applications from any relevant practitioner. Approvals valid for 24 weeks for applications meeting the following criteria:

All of the following:

1. Patient has chronic hepatitis C (any genotype); and
2. Ribavirin treatment is contraindicated; and
3. Any of the following:
   - 3.1 Patient has decompensated cirrhosis (Child-Pugh B or C); or
   - 3.2 Patient has been accepted onto a list for a liver transplant or has received a liver transplant; or
   - 3.3 Patient has essential mixed cryoglobulinaemia with associated purpuric skin rash and; either
     - 3.3.1 Glomerulonephritis; or
     - 3.3.2 Systemic vasculitis.

Application for ledipasvir with sofosbuvir (Harvoni) for Chronic hepatitis C – Advanced disease

Contact details:
HepCTP Coordinator
PO Box 10 254
Wellington
Phone: 0800 023 588 (option 4)
Fax: 04 974 4826
Email: hepcpanel@pharmac.govt.nz

Checklist: before you send your application in please ensure you have:	
Included an original prescription for Harvoni (two three month scripts (with different dates) for Harvoni will be needed, if ribavirin is contraindicated)	☐
Included an original prescription for ribavirin when applicable	☐
I have notified and nominated an appropriate physical delivery address for delivery	☐
I have notified the patient's GP that I have submitted application	☐
I have attached an accompanying clinic letter (including recent liver function test, renal function and full blood count).	☐

Patient			
*NHI			
*Gender		*Date of birth	
*Last name			
*First name		Middle name	
*Address			
*DHB of domicile			

Applicant			
*NZMC number		*Title	
*Full name			
*Department or Practice address			
*DHB			
*Email address			
*Phone		Extension	
*Facsimile			

Are there any others who need to be informed about this application? E.g. Hep C Nurse			
Contact name			
Contact email		Contact Facsimile	
Contact address			

If you are not the patient's GP, please provide the GP's details and PHARMAC staff will notify them of the outcome of this application

Please note, as the applicant we expect that you will notify the GP that you submitted this application to PHARMAC

GP Name	
GP Practice address	
GP Phone	

Nominated delivery address (clinic, general practice or other appropriate address)

Please note the delivery address needs to be where someone is available to accept delivery as the courier will require a signature e.g. a clinic address or GP address.

Deliveries cannot be sent to a Rural Delivery address or a PO Box.

Please notify the delivery address of this application.

Clinic or General Practice Name	
Address	
Phone Number	
Additional comments	

Access Criteria
Complete questions below and provide evidence of support

1.					
	Patient has chronic hepatitis C	☐	Specify genotype		
2.					
	Is ribavirin treatment contraindicated?				
	Yes	☐	If ribavirin is contraindicated the patient will need 24 weeks of treatment with Harvoni. You will need to send PHARMAC two 3 month prescriptions (with different dates) for Harvoni.		
	Estimated glomerular filtration rate (eGFR):		Date:		
	Please include the reasons why ribavirin is contraindicated for your patient (for example, severe vascular disease, haemoglobinopathy, documented RBV allergy or intolerance):				
	No	☐			
3. Please tick one of the following					
	3a.	Patient has decompensated cirrhosis (Child-Pugh B or C); or			☐
	3b.	Patient has been accepted onto a list for a liver transplant; or			☐
			Date accepted onto list if still waiting:		
		Patient has received a liver transplant			☐
			Date of transplant:		
	3c.	Patient has essential mixed cryoglobulinaemia with associated purpuric skin rash; and			☐
		Either	Glomerulonephritis		☐
		Or	Systemic vasculitis		☐

Supporting evidence

Please include any relevant additional information, including attaching relevant clinic letters

Declaration

By submitting this form

- I confirm that all information provided is correct to the best of my knowledge.
- I agree to provide all additional information reasonably requested to PHARMAC, or its agent.
- I will ensure I keep the patients relevant healthcare professionals informed about treatment with Harvoni.
- I will notify the patient's GP that I have submitted this application.
- I will notify the nominated delivery address that I have submitted this application.

Applicant's signature & date:

	Date:	