BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST

LEDIPASVIR PLUS SOFOSBUVIR WITH OR WITHOUT RIBAVIRIN (RBV) FOR CHRONIC HEPATITIS C

HLTH 5478 Rev. 2017/03/17

For up to date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1 800 609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

Restricted to:

☐ **Gastroenterologist** ☐ **Infectious Disease Specialist** ☐ **Other physician experienced with treating chronic Hepatitis C**

SECTION 1 – PRESCRIBER INFORMATION

NAME AND MAILING ADDRESS ☐ MAIL CONFIRMATION

☐ COLLEGE ID **OR** ☐ MSP NUMBER

PHONE NUMBER (INCLUDE AREA CODE)

CRITICAL FOR A TIMELY RESPONSE →

PRESCRIBER'S FAX NUMBER

SECTION 2 – PATIENT INFORMATION

PATIENT (FAMILY) NAME

PATIENT (GIVEN) NAME(S)

DATE OF BIRTH (YYYY / MM / DD)

DATE OF APPLICATION (YYYY / MM / DD)

CRITICAL FOR PROCESSING →

PERSONAL HEALTH NUMBER (PHN)

SECTION 3 – BACKGROUND DIAGNOSTIC INFORMATION

For the treatment of patients with Chronic Hepatitis C genotype 1 who meet all the following criteria:

☐ Genotype 1 has been confirmed and a copy of the genotype report is attached. Genotype 1 report must be dated May 2012 or later. For treatment-experienced patients, genotype must be from post-treatment course.

☐ Detectable levels of hepatitis C virus (HCV RNA) in the last twelve months and a copy of the quantitative HCV RNA report is attached.

☐ Stage of fibrosis has been evaluated within ONE year by one of the following methods, and a copy of the report or most recent labwork (i.e. CBC, AST, ALT, bilirubin, albumin) is attached:

- ☐ Transient Elastography (kPa) _____
- ☐ liver biopsy confirmed
- ☐ FIB-4 score _____
- ☐ APRI score _____

AND confirm one of the following:

☐ A fibrosis stage F2 or greater (Metavir scale or equivalent).

OR

☐ A fibrosis stage less than F2 (Metavir scale or equivalent) AND one or more of these additional conditions:

- ☐ Co-infection with HIV or hepatitis B virus.
- ☐ Post organ transplant (i.e. liver and/or non-liver organ transplant).
- ☐ Extra-hepatic manifestations. Supporting documentation must be submitted.
- ☐ Chronic kidney disease stage 3, 4 or 5 (i.e. eGFR < 60mL/min/1.73m^2 for at least 3 months).
- ☐ Co-existent liver disease with diagnostic evidence for fatty liver disease (eg. non-alcoholic steatohepatitis). A copy of ultrasound report is required.
- ☐ Diabetes and receiving treatment with anti-diabetic medication(s).
- ☐ Woman who is planning to get pregnant within the next 12 months.

Not eligible for coverage:

1. **Patients who are at high risk for non-compliance.**
2. **Patients who are currently being treated with another HCV direct-acting antiviral agent**

PATIENT NAME	PHN	DATE (YYYY / MM / DD)

SECTION 4

Ledipasvir plus Sofosbuvir: 8 weeks. Coverage is only considered for non-cirrhotic patients with the following condition:

☐ Treatment-naive, mono-HCV infected, fibrosis stage < F3 and HCV RNA < 6 million IU/mL

OR

Ledipasvir plus Sofosbuvir: 12 weeks (*Coverage is for a maximum of 12 weeks. No renewals.)*

☐ Treatment-naive with no cirrhosis (including advanced fibrosis stage ≥ F3) or with compensated cirrhosis[1].

☐ Treatment-experienced[2] with no cirrhosis.

☐ HIV/HCV-1 co-infected, treatment-naive or treatment-experienced[2] with no cirrhosis or with compensated cirrhosis[1].

OR

Ledipasvir plus Sofosbuvir: 24 weeks (*Coverage is for a maximum of 24 weeks. No renewals.)*

☐ Treatment-experienced[2] with compensated cirrhosis[1].

OR

Ledipasvir plus Sofosbuvir with Ribavirin: 12 weeks (*Coverage is for a maximum of 12 weeks. No renewals.)*

☐ Treatment-naive or treatment-experienced[2] with decompensated cirrhosis[3].

☐ Liver transplant recipients, treatment-naive or treatment-experienced[2] with no cirrhosis or with compensated cirrhosis[1].

NOTES:

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh score = A (5-6).
2. Treatment-experienced patients are patients who have previously been treated with PegINF/RBV with or without HCV protease inhibitors and did NOT receive an adequate response.
3. Decompensated cirrhosis is defined as cirrhosis with a Child Pugh score = B or C (7 or above). Supporting documentation must be submitted (i.e. clinical history, a copy of ultrasound report, and laboratory test report (i.e. CBC, AST, ALT, bilirubin, albumin, INR))

SECTION 5 – ADDITIONAL COMMENTS

Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* and *Freedom of Information and Protection of Privacy Act*. It will not be disclosed to any persons without the patient's consent.The information you provide will be relevant to and used solely to (a) provide PharmaCare benefits for the medication requested, (b) to implement, monitor and evaluate this and other Ministry programs, and (c) to manage and plan for the health system generally. If you have any questions about the collection or use of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.
Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONLY

STATUS	EFFECTIVE DATE (YYYY / MM / DD)	DURATION OF APPROVAL

PRINT CLEAR FORM