BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST

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

HLTH 5478 Rev. 2023/01/24

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 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.

If you have received this fax in error, please write MISDIRECTED across the front of the form and fax toll-free to 1-800-609-4884, then destroy the pages received in error.

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.

Restriced to:

◯ **Gastroenterologist** ◯ **Infectious Disease Specialist** ◯ **Other prescriber experienced with treating chronic Hepatitis C**

SECTION 1 – PRESCRIBER INFORMATION

Name and Mailing Address	
College ID (use ONLY College ID 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

LEDIPASVIR + SOFOSBUVIR: 9901- 0247

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. 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:
  - ☐ Transient elastography (kPa) _____
  - ☐ APRI score _____
  - ☐ Liver biopsy confirmed
- ☐ Copy of most recent bloodwork (i.e. CBC, AST, ALT, bilirubin, albumin) and report confirming fibrosis stage (if applicable) is attached.

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**

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

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].

◯ Liver transplant recipients, treatment-naive or treatment-experienced[2] with no cirrhosis or with compensated cirrhosis[1].
(treatment regimen option provided due to unavailability of ribavirin (RBV) product)

OR

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

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

◯ Treatment-naive or treatment-experienced[2] with decompensated cirrhosis[3].
(treatment regimen option provided due to unavailability of ribavirin (RBV) product)

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

Report all adverse events to the post-market surveillance program, Canadian Vigilance, toll-free 1-866-234-2345 (health professionals only).

Personal information on this form is collected under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* 22(1) and *Freedom of Information and Protection of Privacy Act* 26 (a),(c),(e). The information is being collected for the purposes of (a) administering the PharmaCare program, (b) analyzing, planning and evaluating the Special Authority and other Ministry programs and (c) to manage and plan for the health system generally. If you have any questions about the collection 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.

Hematologist 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.

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