BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST

SIMEPREVIR WITH PEGINTERFERON PLUS RIBAVIRIN FOR CHRONIC HEPATITIS C

HLTH 5397 Rev. 2016/10/20

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 Hepatitis C in treatment-naive and treatment-experienced patients with no cirrhosis or with compensated cirrhosis (**Child Pugh score = A(5-6)**) who meet all the following criteria:

☐ Patient has HCV genotype 1 (provide copy of current PCR genotype report dated May 2012 or later).

☐ Detectable levels of hepatitis C virus (HCV RNA) in the last six months.

☐ Physician and patient are responsible for completing all appropriate HCV RNA tests for Response Guided Therapy and Futility Rules. Failure to do so may result in delay or termination of PharmaCare coverage. Compliance will be monitored.

☐ Lab confirmed NS3 Q80K polymorphism negative for genotype 1a subtype.

☐ A fibrosis stage F2 or greater (Metavir scale or equivalent) and values or confirmation provided below (complete ONE):

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

Not eligible for coverage:

1. **Patients who have contraindications to simeprevir with peginterferon alfa plus ribavirin or are at high risk for non-compliance to the treatment.**
2. **Patients who have previously been treated with a HCV NS3 / NS4A protease inhibitor, or are currently being treated with HCV NS5A / NS5B polymerase inhibitor.**

PHARMACARE USE ONLY

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

PRINT RESET

PATIENT NAME	PHN	DATE (YYYY / MM / DD)

SECTION 4A – RESPONSE-GUIDED THERAPY

Treatment Futility Rule - Applies to ALL patients: If the patient has HCV RNA results >/= 25 IU/mL at treatment week 4 **OR** if the patient has confirmed detectable HCV RNA at treatment week 12 or 24, then discontinue the therapy regimen.

☐ **Treatment-naive patients with no cirrhosis or with compensated cirrhosis**

OR

☐ **Treatment-experienced patients with no cirrhosis or with compensated cirrhosis who experienced prior relapse to PegIFN/RBV therapy**

Prior Relapser defined as patients with undetectable HCV RNA at end of previous peginterferon/ribavirin (PegIFN/RBV) therapy with a subsequent detectable HCV RNA.

INITIAL COVERAGE is 12 weeks of simeprevir and 14 weeks of PegIFN/RBV.

ADDITIONAL COVERAGE: If patient responds to therapy as measured by reduction of HCV RNA results to less than 25 IU/mL at **treatment week 4 and undetectable at treatment week12** (to allow for 2 week turnaround for lab results), patient is eligible for additional coverage up to 34 weeks of PegIFN/RBV as per **Response Guided Therapy Guideline** (see below).

HCV RNA at Treatment			Action
Week 4	Week 12	Week 24	
Undetectable	Undetectable	Undetectable	12 weeks of simeprevir with 24 weeks of PegIFN/RBV.
Less than 25 IU/mL	Undetectable	Undetectable	12 weeks of simeprevir with 48 weeks of PegIFN/RBV.
>/= 25 IU/mL detectable OR	Detectable OR	Detectable	Discontinue ALL treatment (Futility Rule)

SECTION 4B – FULL COURSE THERAPY

Treatment Futility Rule - Applies to ALL patients: If the patient has HCV RNA results >/= 25 IU/mL at treatment week 4 **OR** if the patient has confirmed detectable HCV RNA at treatment week 12 or 24, then discontinue the therapy regimen.

☐ **Treatment-experienced patients with no cirrhosis or with compensated cirrhosis**

- **Previous Partial Responders:** Patients with a decrease in HCV RNA ≥ 2-log10 IU/mL by week 12 on previous peginterferon/ribavirin (PegIFN/RBV) therapy and with detectable HCV RNA.
- **Null Responders:** Patients with < 2-log10 IU/mL decline in HCV RNA by week 12 on previous PegIFN/RBV therapy.

INITIAL COVERAGE is 12 weeks of simeprevir and 14 weeks of PegIFN/RBV.

ADDITIONAL COVERAGE: If patient responds to therapy as measured by reduction of HCV RNA results to less than 25 IU/mL at **treatment week 4 and undetectable at treatment week 12** (to allow for 2 week turnaround for lab results), patient is eligible for additional coverage of 34 weeks of Peg IFN/RBV.

HCV RNA at Treatment			Action
Week 4	Week 12	Week 24	
Undetectable or less than 25 IU/mL	Undetectable	Undetectable	12 weeks of simeprevir with 48 weeks of PegIFN/RBV.
>/= 25 IU/mL detectable OR	Detectable OR	Detectable	Discontinue ALL treatment (Futility Rule)

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.