



OMBITASVIR PLUS PARITAPREVIR PLUS RITONAVIR AND DASABUVIR WITH OR WITHOUT RIBAVIRIN FOR CHRONIC HEPATITIS C

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

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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, MSP number, phone number, prescriber's fax number, critical for a timely response

SECTION 2 - PATIENT INFORMATION

Patient (family) name, patient (given) name(s), date of birth, date of application, personal health number (PHN), critical for processing

SECTION 3 - BACKGROUND DIAGNOSTIC INFORMATION

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

- Compensated liver disease (Child Pugh score = A (5-6))
Genotype 1 has been confirmed (dated May 2012 or later)
Detectable levels of hepatitis C virus (HCV RNA) in the last six months.
A fibrosis stage F2 or greater (Metavir scale or equivalent).
Transient Elastography (kPa)
APRI score
FIB-4 score
liver biopsy confirmed

Not eligible for coverage:

- 1. Patients who are at high risk for non-compliance.
2. Patients who are currently being treated with another HCV antiviral agent.
3. Retreatment requests.
4. Patients who have previously been treated with NS3/4A protease inhibitors- or sofosbuvir-based regimens including ledipasvir-sofosbuvir

PHARMACARE USE ONLY

Table with 3 columns: STATUS, EFFECTIVE DATE (YYYY / MM / DD), DURATION OF APPROVAL

PATIENT NAME	PHN	DATE (YYYY / MM / DD)
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SECTION 4

A: GENOTYPE 1A PATIENTS

Ombitasvir plus Paritaprevir plus Ritonavir and Dasabuvir with Ribavirin¹: 12 WEEKS (coverage is for a maximum of 12 weeks – no renewals)

- Treatment-naïve or treatment-experienced³ and non-cirrhosis.
- Treatment-naïve and compensated cirrhosis². Liver biopsy report or transient elastography report must be attached.
- Treatment-experienced (previous PARTIAL reponse or RELAPSE to pegINF/RBV) and compensated cirrhosis². Liver biopsy report or transient elastography report must be attached.

Ombitasvir plus Paritaprevir plus Ritonavir and Dasabuvir with Ribavirin¹: 24 WEEKS (coverage is for a maximum of 24 weeks – no renewals)

- Treatment-experienced (previous NULL response to pegINF/RBV) and compensated cirrhosis². Liver biopsy report or transient elastography report must be attached. Please provide evidence of Null response to previous pegINF/RBV therapy.

B: GENOTYPE 1B PATIENTS

Ombitasvir plus Paritaprevir plus Ritonavir and Dasabuvir: 12 WEEKS (coverage is for a maximum of 12 weeks – no renewals)

- Treatment-naïve or treatment-experienced³ and non-cirrhosis.

Ombitasvir plus Paritaprevir plus Ritonavir and Dasabuvir with Ribavirin¹: 12 WEEKS (coverage is for a maximum of 12 weeks – no renewals)

- Treatment-naïve or treatment-experienced³ and compensated cirrhosis². Liver biopsy report or transient elastography report must be attached.

NOTES:

1. Ribavirin (Moderiba™) is provided through the AbbVie Care support program. Please contact AbbVie for information on how to obtain a supply of this medication. Prescription is required for drug distribution.
2. Compensated cirrhosis is defined as cirrhosis with a Child Pugh score = A (5-6)
3. Treatment-experienced patients are patients who have previously been treated with pegINF/RBV and did not receive an adequate response (i.e. prior relapsers, partial responders or null responders).

SECTION 5: ADDITIONAL COMMENTS

<p>Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the <i>British Columbia Pharmaceutical Services Act</i> and <i>Freedom of Information and Protection of Privacy Act</i>. 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.</p>	<p>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.</p> <p>_____ Prescriber's Signature (Mandatory)</p>
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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.