Adults with Chronic Hepatitis C

PharmaCare drug coverage for adults with chronic hepatitis C infection

Hepatologists, gastroenterologists, infectious disease specialists and other prescribers experienced with treating chronic hepatitis C (CHC) can apply for coverage of direct-acting antivirals (DAAs) on behalf of adult patients with CHC infection.

PharmaCare covers treatment-naïve or treatment-experienced adults with CHC genotype 1, 2, 3, 4, 5, 6 or mixed genotype who have liver fibrosis stage F0 or greater (Metavir scale or equivalent), including decompensated cirrhosis, with the following regimen coverage:

Pan-genotypic regimens (i.e., for genotype 1 to 6):

- sofosbuvir-velpatasvir (Epclusa™)
- glecaprevir-pibrentasvir (Maviret™)

Genotypic-specific treatment regimens:

- ledipasvir-sofosbuvir (Harvoni®) for genotype 1

Patients who do not achieve sustained virologic response to a DAA regimen (i.e., DAA treatment-experienced) should be considered for retreatment with a salvage regimen. PharmaCare covers DAA treatment-experienced adults with CHC genotype 1, 2, 3, 4, 5 or 6 who have liver fibrosis stage F0 or greater (Metavir scale or equivalent) but not decompensated cirrhosis, with the following salvage regimens:

Pan-genotypic regimen:

- sofosbuvir-velpatasvir-voxilaprevir (Vosevi™)

Genotypic-specific regimen:

- glecaprevir-pribentasvir (Maviret™) for genotype 1

DAAs were approved by Health Canada and reviewed by the CADTH drug reimbursement review, the pan-Canadian Pharmaceutical Alliance, and the B.C. Drug Benefit Council. Drug coverage decisions are based on these reviews and input from specialists, patients, caregivers, and patient groups. For more information on the PharmaCare drug review process, please see the PharmaCare website.

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[1] "Treatment-experienced" is defined as patients who have been previously treated with PegIFN/RBV regimen and have relapsed or have not responded.

[2] "Decompensated cirrhosis" is defined as cirrhosis with a Child-Pugh Score (CPS) of B or C (7 or above).

Testing guidelines for Special Authority requests

To ensure best practices and the optimal treatment regimen is provided, Special Authority requests for coverage for all hepatitis C drug treatment regimens must be accompanied by:

1. A fibrosis score test performed in the last 12 months. Acceptable methods include:
    - liver biopsy, or
    - transient elastography (FibroScan®), or
    - serum biomarker panels–AST-to-platelet ratio index (APRI) score alone or in combination, or
    - other imaging modalities

Supporting documentation must be submitted.

2. A hepatitis C genotype test result. For patients who have relapsed, failed prior therapy, or if reinfection is a consideration, a repeat genotype test is required.

3. An updated hepatitis C virus (HCV) RNA test in the last 12 months and/or post-treatment for DAA-experienced patients.

4. A copy of the most recent bloodwork as outlined on the Special Authority form.

5. Other diagnostic lab tests or clinical evidence as outline on the Special Authority form.

Requests for coverage for patients who meet the criteria for decompensated cirrhosis must be accompanied by supporting lab tests or clinical evidence.

Detailed criteria and Special Authority request forms are available on the PharmaCare website.

Treatment regimen options

Please refer to the PharmaCare criteria or Special Authority request form for the selected medication to determine the appropriate length of therapy or treatment regimen based on a specific patient population.

Genotype 1 treatment-naïve or treatment-experienced, with no cirrhosis or with compensated cirrhosis regimen options

- Epclusa for 12 weeks
- Maviret for 8 or 12 weeks
- Harvoni for 8, 12 or 24 weeks

Genotype 2 or 3 treatment-naïve or treatment-experienced, with no cirrhosis or with compensated cirrhosis regimen options

- Epclusa for 12 weeks for genotype 2 or 3
- Maviret for 8 or 12 weeks for genotype 2
- Maviret for 8 or 16 weeks for genotype 3

Genotype 4, 5, or 6 treatment-naïve or treatment-experienced, with no cirrhosis or with compensated cirrhosis regimen options

- Epclusa for 12 weeks for genotype 4, 5 or 6
- Maviret for 8 or 12 weeks for genotype 4, 5 or 6

Genotype 1 to 6 treatment-naïve or treatment-experienced regimen options for decompensated cirrhosis and post-liver transplantation

Decompensated cirrhosis is defined as cirrhosis with a Child-Pugh Score (CPS) class B or C (a score of 7 or above). Special Authority requests for patients with decompensated cirrhosis must be accompanied by additional documentation and clinical evidence to support the request as outlined in the Special Authority form.

Note: Maviret and Vosevi are contraindicated for patients with decompensated cirrhosis.

Regimen options for treatment-naïve or treatment-experienced patients with decompensated cirrhosis

Pan-genotypic regimen:

- Epclusa with ribavarin (RBV) for 12 weeks
- Epclusa for 24 weeks*

Genotypic-specific regimen:

- Harvoni with RBV for 12 weeks for genotype 1
- Harvoni for 24 weeks* for genotype 1

*Note: The following treatment regimens and duration of 24 weeks are based on American Association for the Study of Liver Diseases (AASLD) guidelines – “Patients with Decompensated Cirrhosis”, which was last updated on October 24, 2022, and were put in place following the discontinuation of RBV.

Regimen options for treatment-naïve or treatment-experienced patients post-liver transplantation, with no cirrhosis or with compensated cirrhosis

- Harvoni with RBV for 12 weeks for genotype 1
- Harvoni for 12 weeks* for genotype 1

*Note: The following treatment regimen and duration of 12 weeks are based on AASLD guidelines – “Patients Who Develop Recurrent HCV Infection Post Liver Transplantation”, which was last updated on October 24, 2022, and was put in place following the discontinuation of RBV.

Note: Other treatment regimen requests for post-liver transplant patients may be considered exceptionally on a case-by-case basis.

Retreatment for DAA-experienced, with no cirrhosis or compensated cirrhosis salvage regimen options

Pan-genotypic salvage regimen:

- sofosbuvir-velpatasvir-voxilaprevir (Vosevi™)

Genotypic-specific salvage regimen:

- glecaprevir-pribentasvir (Maviret™) for genotype 1

Note: additional coverage for ribavirin may be considered on exceptional case-by-case basis. Requests must be accompanied by rationale and additional applicable documents.

Retreatment for HCV re-infected patients, with no cirrhosis or compensated cirrhosis regimen options

- Vosevi is not used for retreatment of HCV reinfected patients
- A first-line DAA treatment regimen should be considered in these cases

Note: Engagement into harm reduction strategies should be reinforced to prevent future reinfection.