Adults with Chronic Hepatitis C

PharmaCare Expanded Coverage for Adults with Chronic Hepatitis C Infection

Effective March 13, 2018, PharmaCare covers treatment-naïve or treatment-experienced adult patients with chronic hepatitis C (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.

PharmaCare coverage includes:

- sofosbuvir-velpatasvir (Epclusa™) with or without ribavirin (RBV) for genotype 1, 2, 3, 4, 5, 6 or mixed genotype
- ledipasvir-sofosbuvir (Harvoni®) with or without RBV for genotype 1
- elbasvir-grazoprevir (Zepatier™) with or without RBV—for genotype 1 or 4
- daclatasvir (Daklinza™) plus sofosbuvir (Sovaldi®) with or without RBV—for genotype 3

In addition, also effective **March 13, 2018**, hepatologists, gastroenterologists, infectious disease specialists, and other physicians experienced with treating CHC can apply for coverage of the new direct-acting antiviral (DAA) on behalf of their adult patients with CHC infection:

- sofosbuvir-velpatasvir-voxilaprevir (Vosevi™) for the treatment of DAA-experienced patients including:
  - NS5A Inhibitor treatment-experienced adult patients with CHC genotype 1, 2, 3, 4, 5 or 6 infection, or
  - Non-NS5A Inhibitor, sofosbuvir-containing regimen treatment-experienced adult patients with CHC genotype 1, 2, 3, or 4 infection.

The new DAAs were approved by Health Canada, and reviewed by the Common Drug Review (CDR), the pan-Canadian Pharmaceutical Alliance, and the B.C. Drug Benefit Council. B.C. PharmaCare drug coverage decisions are based on these reviews and other considerations, including input from specialists, patients, caregivers, and patient groups. For more information on the PharmaCare drug review process, please see the PharmaCare website.

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

1. **Fibrosis staging**—A fibrosis score test performed in the last 12 months. Acceptable methods include liver biopsy, transient elastography (FibroScan®) and serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) score) either alone or in combination, or other imaging modalities. Supporting documentation must be submitted.
2. **Genotype test**—A hepatitis C genotype test result from the BC Center for Disease Control (BCCDC). Patients who received a genotype 1 subtype test result prior to **May 1, 2012** may require a new genotyping test. Repeat genotyping is required for patients who have either relapsed or failed prior therapy, or when reinfection is a consideration.

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3. **HCV RNA test**—An updated HCV RNA test within the last 12 months and/or post-treatment (for DAA-experienced patients) as outlined on the Special Authority form.
4. **A copy of the most recent bloodwork** as outlined on the Special Authority form.
5. **Other diagnostic lab tests or clinical evidence**—as outlined 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.

Genotype 1 Drug Treatment Options

Since March 24, 2015, PharmaCare has covered Harvoni, an all-oral combination DAA therapy for treatment-naïve or treatment-experienced adult patients with CHC genotype 1 infection. Since March 21, 2017, PharmaCare has also covered the following DAA drug options to treat genotype 1 infected patients:

- Epclusa with or without RBV
- Zepatier with or without RBV

Higher cures rates are reported with these DAAs (based upon sustained viral response (SVR)). These drugs are dosed once daily, are generally well-tolerated (compared to interferon-containing regimens) and, in some cases, offer a shorter 8 week duration of therapy for specific populations. See the CDR recommendations for individual DAA drugs.

When selecting therapeutic options for patients with genotype 1 infection, the options are:

- Zepatier without RBV for 8 or 12 weeks or with RBV for 16 weeks
- Epclusa with or without RBV for 12 weeks
- Harvoni with or without RBV for 8, 12 or 24 weeks

Prescribers should consider the Canadian Agency for Drugs and Technologies in Health (CADTH) Therapeutic Review – Drugs for Chronic Hepatitis C Infection and the CDR recommendations regarding Epclusa, Harvoni, and Zepatier.

Genotype 1 to 6 Drug Treatment Options for Special Populations

When considering treatment options for patients with decompensated cirrhosis, defined as Child-Pugh Score (CPS) class B or C (score 7 or above), the Health Canada-indicated options covered by PharmaCare are:

- Harvoni with RBV for 12 weeks for genotype 1
- Epclusa with RBV for 12 weeks for genotype 1 to 6
- Daklinza with Sovaldi plus RBV for 12 weeks for genotype 3

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.

When considering treatment options for patients who are post-liver transplantation, the Health Canada indicated options covered by PharmaCare are:

- Harvoni with RBV for 12 weeks for genotype 1
- Daklinza with Sovaldi plus RBV for 12 weeks for genotype 3

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

Genotype 2 or 3 Drug Treatment Options

As of March 21, 2017, PharmaCare covers the following DAA drug options for genotype 2 or 3 infected patients:

- Epclusa with or without RBV for 12 weeks for genotype 2 or 3
- Daklinza plus Sovaldi with or without RBV for 12 weeks for genotype 3

When selecting therapeutic options for patients with genotype 2 or 3 infection, prescribers should consider the CDR recommendation regarding Epclusa or Daklinza.

Genotype 4, 5 or 6 Drug Treatment Options

As of March 21, 2017, PharmaCare covers all oral combination DAAs for treatment-naïve and treatment-experienced adult patients with CHC genotype 4, 5 or 6 infection. PharmaCare covers the following DAA drug options:

- Zepatier for 12 weeks or with RBV for 16 weeks for genotype 4
- Epclusa with or without RBV for 12 weeks for genotype 4, 5 or 6

Re-treatment for DAA-experienced Drug Treatment Option

As of **March 13, 2018**, PharmaCare covers sofosbuvir-velpatasvir-voxilaprevir (Vosevi™) for the treatment of DAA-experienced including:

- NS5A Inhibitor treatment-experienced adult patients with CHC genotype 1, 2, 3, 4, 5 or 6 infection or
- Non-NS5A Inhibitor, sofosbuvir-containing regimen treatment-experienced adult patients with CHC genotype 1, 2, 3, or 4 infection.

Prescribers should consider the CDR recommendation regarding Vosevi.

- Please note: additional coverage for ribavirin may be considered on exceptional case-by-case basis. Please provide rationale and additional document(s) (if applicable) to support request.
- HCV reinfection: Vosevi is not to be used for retreatment of HCV re-infected patients. A first line DAA treatment regimen should be considered for retreatment of HCV re-infected patients.