Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Hepatitis C Exception Drug Status (EDS) Listings Effective April 1, 2015 according to the following criteria:

Related Information for Prescribers:

- Only prescribers who have completed the Hepatitis C prescriber agreement and become Designated Prescribers may submit Hepatitis C EDS applications for Hepatitis C medications.
- Prescribers interested in becoming a Designated Prescriber can contact the Drug Plan and Extended Benefits Branch at 306-787-8744 or 1-800-667-7581 or dp.sys.support@health.gov.sk.ca to receive a copy of the prescriber agreement.
- Designated Prescribers are asked to complete the Hepatitis C therapy – EDS Application Form for each patient and return it, along with a copy of the fibroscan report, to the Drug Plan for assessment.
- Designated Prescribers may indicate on the Hepatitis C therapy – EDS Application Form if direct observed therapy or DOT is recommended for their patient.

- **ledipasvir/sofosbuvir, tablet, 90mg/400mg (Harvoni-GSI)**

  For patients that meet the eligibility criteria outlined below clinicians will be encouraged to use Harvoni as the preferred therapeutic option over other covered therapies (e.g., interferon-based regimens with NS3/4A protease inhibitors or polymerase inhibitors). This recommendation is based on Harvoni's advantages in some patient populations, including potentially higher SVR rates, improved tolerability, no need for concomitant interferon or ribavirin therapy, shorter course of therapy, and once daily dosing.

  For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis)[1] according to the following criteria:

  - Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other physician experienced in treating hepatitis C as determined by the Drug Plan
  - Lab-confirmed hepatitis C genotype 1
  - Patient has a quantitative HCV RNA value within the last 6 months
  - Fibrosis stage F2 or greater (Metavir scale or equivalent)

Duration of therapy reimbursed:

Genotype 1 Patient Population	**Duration of therapy**
Treatment naïve, non-cirrhotic, viral load < 6 M IU/mL	8* weeks
Treatment naïve, non-cirrhotic, viral load ≥ 6 M IU/mL OR Treatment naïve, cirrhotic OR Treatment-experienced[1], non-cirrhotic	12 weeks
Treatment-experienced[1], cirrhotic	24 weeks

**For this population cohort, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have borderline or severe fibrosis (F3-4) or if they are co-infected with HIV.*

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of Harvoni (Re-treatment requests will **NOT** be considered)

NOTES:

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6).
2. Treatment experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
3. HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above.
4. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.

- **sofosbuvir, tablet, 400mg (Sovaldi-GSI)**

For the treatment of adult patients with chronic hepatitis C infection with compensated liver disease, (including compensated cirrhosis)[1] as follows:

<u>Genotype 1 [for 12 weeks in combination with Pegylated interferon (PegIFN)/Ribavirin (RBV)]</u>:

- treatment-naive patients

OR

<u>Genotype 2 (for 12 weeks in combination with RBV):</u>

- Treatment-naïve patients in whom interferon (IFN) is medically contraindicated[2]
  OR
- PegIFN/RBV treatment-experienced[3] patients

OR

Genotype 3 (for 24 weeks in combination with RBV):

- Treatment-naïve patients in whom interferon (IFN) is medically contraindicated[2] OR
- PegIFN/RBV treatment-experienced[3] patients

AND

Who meet **ALL** of the following:

A. Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other physician experienced in treating hepatitis C as determined by the Drug Plan.
B. Lab-confirmed hepatitis C genotype 1, 2, or, 3
C. Patient has a quantitative HCV RNA value within the last 6 months
D. Fibrosis stage F2 or greater (Metavir scale or equivalent)

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent
- Patients who have previously received a treatment course of Sovaldi (Re-treatment requests will **NOT** be considered).

NOTES:

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6)
2. Medical contraindication to IFN is defined as hypersensitivity to peginterferon or interferon alfa-2a or 2b, polyethylene glycol or any component of the formulation resulting in discontinuation of therapy; **OR** presence of significant clinical comorbidities which are deemed to have a high risk of worsening with IFN treatment. Details are required regarding patient's contraindications and/or risk of worsening significant comorbidities.

3. Treatment-experienced patients (with Genotype 2 or 3) are defined as patients who have previously been treated with PegIFN/RBV and did NOT receive adequate response.

4. HIV-HCV co-infected Patients may be considered as per criteria listed above.

5. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.

- **ribavirin, tablet, 400mg, 600mg (Ibavyr-PED)**

For use within a listed combination therapy regimen for the treatment of chronic hepatitis C. Patients must meet the EDS criteria, and be approved for, the listed adjunctive Hepatitis C therapy to be used in combination with ribavirin.

Treatment must be prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other physician experienced in treating hepatitis C as determined by the Drug Plan.

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch
2nd Floor, 3475 Albert Street
Regina, Saskatchewan S4S 6X6
(306) 787-3317
1-800-667-7581