Government of Saskatchewan

April 1, 2018
Bulletin #170
ISSN 1923-0761

SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Related Information for Prescribers:

- The April 1, 2018 updates to existing hepatitis C drug EDS criteria will allow patients with a diagnosis of chronic hepatitis C infection, regardless of disease severity or prognosis factors, to qualify for EDS for the following medications.
- Sunvepra (asunaprevir), initially listed April 1, 2017, has been discontinued by the manufacturer and will no longer be an eligible Drug Plan benefit.
- 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 1-800-667-2549 or DPEB@health.gov.sk.ca to receive a copy of the prescriber agreement.

New hepatitis C Exception Drug Status (EDS) listing effective April 1, 2018 according to the following criteria:

- **sofosbuvir/velpatasvir/voxilaprevir, tablet, 400mg/100mg/1000mg (Vosevi-GSI)**

For use as monotherapy for treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6, or mixed genotypes; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

Treatment regimens reimbursed:

Patient Population		Treatment Regimen and Duration
All HCV genotypes	Treatment-experienced(1), non-cirrhotic or compensated cirrhosis(2)	12 weeks

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with a HCV regimen containing:

- NS5A inhibitor (daclatasvir (Daklinza), elbasvir (part of Zepatier), ledipasvir (part of Harvoni), ombitasvir (part of Holkira Pak), velpatasvir (part of Epclusa)) for genotype 1, 2, 3, 4, 5, or 6; OR
- Sofosbuvir (Sovaldi) without an NS5A inhibitor for genotype 1, 2, 3, or 4

(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

Updated hepatitis C Exception Drug Status (EDS) Listings Effective April 1, 2018 according to the following criteria:

- **daclatasvir, tablet, 30mg, 60mg (Daklinza-BMY)**

For use as combination therapy with sofosbuvir, alone or with sofosbuvir and ribavirin, for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 3; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

Treatment regimens reimbursed:

Patient Population		**Treatment Regimen and Duration**
Genotype 3	Treatment-naïve or treatment-experienced(1) without cirrhosis	12 weeks in combination with sofosbuvir
	Treatment-naïve or treatment-experienced(1) with compensated cirrhosis(2) or decompensated cirrhosis(2), or post-liver transplant	12 weeks in combination with sofosbuvir and ribavirin

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

- **elbasvir/grazoprevir, tablet, 50mg/100mg (Zepatier-MRK)**

For use as monotherapy or combination therapy with ribavirin for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1 or 4; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

Treatment regimens reimbursed*:

Patient Population		**Treatment Regimen and Duration**
Genotype 1	Treatment-naïve without cirrhosis, or with compensated cirrhosis(2)	12 weeks**
	Treatment-experienced(1) relapsers without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) genotype 1b with null response, partial response, or virologic breakthrough or rebound, or intolerance to prior treatment	12 weeks
	Treatment-experienced(1) genotype 1a with null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment	16 weeks in combination with ribavirin
Genotype 4	Treatment-naïve without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) relapsers without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-experienced(1) with null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment	16 weeks in combination with ribavirin

**Combination therapy with sofosbuvir (Sovaldi) will not be considered for funding.*
*** As approved by Health Canada, 8 weeks may be considered in treatment-naïve genotype 1b patients without significant fibrosis or cirrhosis.*

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

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

For use as monotherapy or as combination with ribavirin for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

Treatment regimens reimbursed*:

Patient Population		**Treatment Regimen and Duration**
Genotype 1	Treatment-naïve, non-cirrhotic, viral load < 6M IU/mL	8 weeks OR 12 weeks*
	Treatment-naïve, non-cirrhotic, viral load ≥ 6M IU/mL OR Treatment-naïve, cirrhotic(2) OR Treatment-experienced(1), non-cirrhotic	12 weeks
	Treatment-naïve or treatment-experienced(1) with decompensated cirrhosis(2)	12 weeks in combination with ribavirin
	Treatment-naïve or treatment-experienced(1) liver transplant recipients without cirrhosis, or with compensated cirrhosis(2)	12 weeks in combination with ribavirin
	Treatment-experienced(1), cirrhotic(2)	24 weeks

**For this population cohort, evidence has shown that the SVR rates for 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 or if they are co-infected with HIV.*

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

- **ribavirin, tablet, 200mg, 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, an infectious disease specialist or other **prescriber** experienced in treating hepatitis C as determined by the Drug Plan.

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

For use as combination therapy with ribavirin or daclatasvir or both for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 2 or 3; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) or sofosbuvir in combination with daclatasvir (Daklinza) as one of the preferred therapeutic options over sofosbuvir with ribavirin regimens for treatment of genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa or Daklinza in combination with sofosbuvir offers advantages in some patient populations, including potentially higher SVR rates and a shorter course of therapy for genotype 3 infections.

Treatment regimens reimbursed*:

Patient Population		**Treatment Regimen and Duration**
Genotype 2	Treatment-naïve or treatment-experienced(1)	12 weeks in combination with ribavirin
Genotype 3	Treatment-naïve or treatment-experienced(1) without cirrhosis	12 weeks in combination with daclatasvir OR 24 weeks in combination with ribavirin
	Treatment-naïve or treatment-	12 weeks in

	experienced(1) with compensated or decompensated cirrhosis(2)	combination with daclatasvir and ribavirin OR 24 weeks in combination with ribavirin
	Treatment-naïve or treatment-experienced(1) post liver transplant	12 weeks in combination with daclatasvir and ribavirin

**Combination therapy with elbasvir/grazoprevir (Zepatier) will not be considered for funding.*

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

- **sofosbuvir/velpatasvir, tablet, 400mg/100mg (Epclusa-GSI)**

For use as monotherapy or as combination therapy with ribavirin for treatment-naïve or treatment-experienced(1) adult patients with chronic hepatitis C infection according to the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, an infectious disease specialist or other prescriber experienced in treating hepatitis C as determined by the Drug Plan; AND
(ii) Laboratory-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6, or mixed genotypes; AND
(iii) Laboratory-confirmed quantitative HCV RNA value within the last six months.

Treatment regimens reimbursed:

Patient Population		**Treatment Regimen and Duration**
All HCV genotypes	Treatment-naïve or treatment-experienced(1) without cirrhosis, or with compensated cirrhosis(2)	12 weeks
	Treatment-naïve or treatment-experienced(1) with decompensated cirrhosis(2)	12 weeks in combination with ribavirin

Exceptional case-by-case consideration: Retreatment may be considered on a case-by-case basis and may include combination therapy with products from different manufacturers.

NOTES:
Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(1) Treatment-experienced is defined as those who have failed prior therapy with an interferon-based regimen, including regimens containing a HCV protease inhibitor.
(2) Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (score 5-6), and decompensated cirrhosis is defined as cirrhosis with a Child Pugh Score = B or C (score 7 or above).

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