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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Exception Drug Status (EDS) Benefit According to the Following Criteria:

- **anifrolumab, solution for infusion, 150mg/mL (2mL vial) (mg) (Saphnelo)**

  For use in addition to standard therapy for the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) only if certain conditions are met:

  Initiation:
  Treatment with anifrolumab should be reimbursed when initiated in adult patients with moderate-severe SLE (defined as SLEDAI-2K [systemic lupus erythematosus disease activity index 2000] score of at least 6) and who are unable to control their disease while using oral corticosteroids (OCS) dose of at least 10 mg/day of prednisone or its equivalent in addition to standard of care.

  Treatment with anifrolumab must not be reimbursed when initiated in patients with any of the following:
  - severe or unstable neuropsychiatric SLE
  - active severe SLE nephritis

  The maximum duration of initial reimbursement is for 12 months.

  Renewal:
  Treatment with anifrolumab can be renewed as long as all of the following are met:
  - OCS dose decreased to ≤ 7.5 mg/day of prednisone or its equivalent
  - Reduction in disease activity measured by:
    - Reducing the SLEDAI-2K score to 5 or less, **OR**
    - BILAG (British Isles Lupus Activity Group) improvement in organ systems and no new worsening

  For subsequent renewal, the physician must provide proof that the initial response achieved after the first 12 months of therapy with anifrolumab has been maintained. Subsequent renewals should be assessed annually.

  Anifrolumab should not be reimbursed when used in combination with other biologic treatments.

  Prescribing conditions:
  - Patient should be under the care of a physician with expertise in the diagnosis and management of SLE.
  - Anifrolumab should not be reimbursed when used in combination with other biologic treatments.

- **belimumab, lyophilized powder for intravenous infusion, 24mg/mL (5m vial) (mg), 20mg/mL (20mL vial) (mg); solution for subcutaneous injection, 200mg/mL (mg) (Benlysta)**

  For the treatment of active lupus nephritis (LN) in adult patients who meet all of the following:
  - Have International Society of Nephrology/Renal Pathology Society class III (with or without class V), class IV (with or without class V), or class V (i.e., pure class V),
  - Started standard induction therapy within the previous 60 days,
  - Have not previously failed both cyclophosphamide and mycophenolate mofetil induction therapies,
  - Have not had an eGFR that is less than 30mL/min/1.73m^2, and
  - Are under the care of a rheumatologist or nephrologist experienced in the management of LN.

  Initial approval is for 12 months.

  Renewal criteria:
  Renewal requests that provide proof of beneficial clinical effect, including ALL of the following, may be considered:
  - Reduction in glucocorticoids to less than or equal to 7.5mg/day after 12 months of therapy (consideration may also be given to those whose oral corticosteroid dose remains over 7.5mg/day of prednisone or its equivalent IF there has been a 50% or more decrease from baseline),
  - Estimated eGFR that is no more than 20% less than the value before the renal flare (i.e., the preflare value) or greater than or equal to 60mL/min/1.73m^2,
  - Improved proteinuria defined as:
    - No greater than 0.7g/24 hours after 12 months of therapy if baseline proteinuria is less than 3.5g/24 hours, OR
    - No greater than 0.7 g/24 hours after 18 to 24 months of therapy if baseline proteinuria is in the nephrotic range (i.e., > 3.5 g/24 hours)
  - Have not had an eGFR that is less than 30mL/min/1.73m^2,
  - Have not had the addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti-tumour necrosis factor therapy (such as, adalimumab, etanercept, infliximab), or other biologics (such as rituximab, abatacept), and
  - Are under the care of a rheumatologist or nephrologist experienced in the management of LN.

  In addition, requests for subsequent years will be considered if the initial response in the first 12 months is maintained.

  Renewal approval is for 12 months.

<u>Additional Formulations of Existing Exception Drug Status (EDS) Benefits with Same Criteria:</u>

- **adalimumab, 20mg/0.2mL PFS; 40mg/0.4mL auto-injector; 40mg/0.4mL PFS; 80mg/0.8mL auto-injector; 80mg/0.8mL PFS (Hyrimoz)**

Revised Exception Drug Status (EDS) Criteria

- **glecaprevir/pibrentasvir, tablet, 100mg/40mg (Maviret)**
  For treatment naïve and treatment experienced[1] patients with chronic hepatitis C infection (regardless of fibrosis stage) according to the following criteria:
  - Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6; AND
  - Laboratory confirmed quantitative HCV RNA value within the last 12 months; AND
  - Treatment is prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other prescriber experienced in the treatment of hepatitis C as determined by the Drug Plan.

  Treatment regimens reimbursed:
  Treatment Naïve

Genotype	Treatment Regimen and Duration
1, 2, 3, 4, 5 or 6	8 weeks with or without cirrhosis

Treatment Experienced[1] and previously treated with regimens containing:

Genotype	Previous Treatment Received	Treatment Regimen and Duration	
Genotype 1, 2, 4, 5 or 6	PRS (peg)interferon, ribavirin, and/or sofosbuvir: - (peg)interferon/ribavirin, - sofosbuvir + (peg)interferon/ribavirin, - sofosbuvir + ribavirin	8 weeks without cirrhosis	12 weeks with cirrhosis[2]
Genotype 1	NS3/4A PI (NS5A inhibitor-naïve) - simeprevir + sofosbuvir, or - simeprevir + (peg)interferon/ribavirin, or - boceprevir + (peg)interferon/ribavirin, or - telaprevir + (peg)interferon/ribavirin	12 weeks	
Genotype 1	NS5A (NS3/4A inhibitor naïve) - daclatasvir + sofosbuvir, or - daclatasvir + (peg)interferon/ribavirin, or - ledipasvir + sofosbuvir	16 weeks	
Genotype 3	PRS (peg)interferon, ribavirin, and/or sofosbuvir: - (peg)interferon/ribavirin, - sofosbuvir + (peg)interferon/ribavirin, - sofosbuvir + ribavirin	16 weeks[2]	

Exceptional case-by-case consideration:

- Retreatment for direct acting antiviral failures will be considered on a case-by-case basis. Funding considerations will be based on recommendations from approved clinical practice guidelines. The specific drug regimen may include combination therapy involving a different company's products.

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.
- Genotype is not required to be submitted with the EDS application

[1]Treatment experienced is defined by the Health Canada Product Monograph based on the genotype treated and the scenario in which the previous drug(s) have been used.
[2]See product monograph for dosing recommendations in patients with a liver or kidney transplant.

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

For use as monotherapy 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 12 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]	24 weeks Harvoni
	Treatment-naïve or treatment-experienced[1] liver transplant recipients without cirrhosis, or with compensated cirrhosis[2]	12 weeks Harvoni
	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.
- Genotype is not required to be submitted with the EDS application

[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)**
  For use as monotherapy 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 12 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 of Epclusa
	Treatment-naïve or treatment-experienced[1] with decompensated cirrhosis[2]	24 weeks of Epclusa

  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.
  - Genotype is not required to be submitted with the EDS application.

[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/voxilaprevir, tablet, 400mg/100mg/100mg (Vosevi)**
  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 12 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.
- Genotype is not required to be submitted with the EDS application.

[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).

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