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Programmes provinciaux de medicaments
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PEI Pharmacare Bulletin

Issue (2025-01) **January 14, 2025**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: DECEMBER 31, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR

Sofosbuvir	**Sovaldi**	**400mg**	**Tablet**	**02418355**	**GIL**
Criteria	For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:				

	Approval Period
Genotype 2 • Without cirrhosis • With compensated cirrhosis	12 weeks in combination with ribavirin (RBV)
Genotype 3 • Without cirrhosis • With compensated cirrhosis	24 weeks in combination with RBV

Clinical Notes:
1. Genotype must be provided.
2. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Note:
• Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection)

Program Eligibility	Hepatitis Drug Program

Sofosbuvir/Ledipasvir	**Harvoni**	**400mg/90mg**	**Tablet**	**02432226**	**GIL**
Criteria	For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:				

	<table><tr><th></th><th>Approval Period</th></tr><tr><td>Genotype 1 - Treatment naïve without cirrhosis, who have pre-treatment HCV RNA level < 6 million IU/mL and mono-HCV infected only </td><td>8 or 12 weeks</td></tr><tr><td>Genotype 1 - Treatment-naïve without cirrhosis, who have pretreatment HCV RNA level ≥ 6 million IU/mL - Treatment-naïve with compensated cirrhosis - Treatment-naïve with advanced liver fibrosis (Fibrosis stage F3-F4) - Treatment-experienced without cirrhosis - HCV/HIV co-infected without cirrhosis or with compensated cirrhosis - Liver transplant recipients without cirrhosis or with compensated cirrhosis. </td><td>12 weeks</td></tr><tr><td>Genotype 1 - Treatment-experienced with compensated cirrhosis - Decompensated cirrhosis </td><td>24 weeks</td></tr></table> Clinical Notes: 1. Genotype must be provided 2. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C). Claim Note: • Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).
Program Eligibility	Hepatitis Drug Program

Sofosbuvir/Velpatasvir	**Epclusa**	**400mg/100mg**	**Tablet**	**02456370**	**GIL**
Criteria	For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria: <table><tr><th></th><th>Approval Period</th></tr><tr><td>Genotypes 1,2,3,4,5,6 or mixed genotypes - Patients with compensated cirrhosis - Patients without cirrhosis </td><td>12 weeks</td></tr><tr><td>Genotypes 1,2,3,4,5,6 or mixed genotypes - Patients with decompensated cirrhosis </td><td>24 weeks</td></tr></table> Clinical Note: • Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C). Claim Note: • Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).				
Program Eligibility	Hepatitis Drug Program				

<table>
<tr><th>Sofosbuvir/Velpatasvir/ Voxilaprevir</th><th>Vosevi</th><th>400mg/100mg/100mg</th><th>Tablet</th><th>02467542</th><th>GIL</th></tr>
<tr><td>Criteria</td><td colspan="5">For treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

<table><tr><th></th><th>Approval Period</th></tr><tr><td>Genotypes 1,2,3,4,5,6 or mixed genotypes
• Patients with compensated cirrhosis
• Patients without cirrhosis</td><td>12 weeks</td></tr></table>
Clinical Note:
• Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Note:
• Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescriber experienced in treating a patient with hepatitis C infection).</td></tr>
<tr><td>Program Eligibility</td><td colspan="5">Hepatitis Drug Program</td></tr>
</table>

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JANUARY 28, 2025)

<table>
<tr><th>Product (Generic name)</th><th>Product (Brand name)</th><th>Strength</th><th>Dosage Form</th><th>DIN</th><th>MFR</th></tr>
<tr><td>Mirikizumab</td><td>Omvoh</td><td>300mg/15mL
100mg/mL
100mg/mL</td><td>Vial
Prefilled Syringe
Prefilled Pen</td><td>02539861
02539853
02539845</td><td>LIL</td></tr>
<tr><td>Criteria</td><td colspan="5"><u>Ulcerative Colitis</u>
For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

• Refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks AND prednisone ≥ 40mg daily for two weeks or IV equivalent for one week) OR
• Corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.

Clinical Notes:
• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
• Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
• Patients with severe disease (partial Mayo > 6) do not require a trial of 5-ASA

Claim Notes:
• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
• Combined therapy with biologic therapies or JAK inhibitors for UC will not be reimbursed.
• Initial Approval: 6 months</td></tr>
</table>

	• Initial reimbursement will be for 300mg intravenous dose at Week 0, Week 4, and Week 8. If patients do not have adequate therapeutic response at Week 12, 300mg will be reimbursed at Weeks 12, 16 and 20. Subsequent reimbursement for maintenance dosing will be for a maximum dose of 200mg every 4 weeks. • Renewal Approval: 1 year. • Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically: o a decrease in the partial Mayo score ≥ 2 from baseline, and o a decrease in the rectal bleeding subscore ≥ 1.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program