

BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit Ministry of Health - PharmaCare.

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an "indication"). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare's drug coverage review process, see the last page of this information sheet.

Information about the drug				
Generic name (scientific name)	glecaprevir-pibrentasvir			
Brand name	Maviret [®]			
Manufacturer	Pfizer Canada Inc.			
Indication	Chronic hepatitis C virus (HCV) infection in children and adolescents ages 3 to less than 18 years			
Has the drug been reviewed by Canada's Drug and Health Technology Agency (CADTH)? (see the note below this table.)	Yes For more information about the CADTH Reimbursement Review (CRR) of glecaprevir-pibrentasvir (Maviret), you can Search the CADTH Reports.			
Public input start date	Wednesday, February 28, 2024			
Public input closing date	Tuesday, March 26, 2024, AT 11:59 PM			
How is the drug taken?	Glecaprevir-pibrentasvir is taken orally (by the mouth).			

Information about the drug				
How often is the drug taken?	Glecaprevir-pibrentasvir is taken once daily, with food. Treatment lasts from 8 to 16 weeks, depending on the type of HCV, the patient's liver health, and the patient's treatment history.			
General drug and/or drug study information	Glecaprevir-pibrentasvir is being reviewed by PharmaCare for the treatment of chronic hepatitis C virus (HCV) infection in children and adolescents aged 3 to less than 18 years of age. HCV is a viral infection that primarily affects the liver. It can lead to acute and chronic liver disease. If an HCV infection lasts for more than six months, it is considered chronic. The virus is transmitted through contact with the blood of an infected person. In some cases, hepatitis C can cause serious liver damage, including cirrhosis (scarring of the liver) and liver cancer. Pediatric HCV is usually passed on from an infected mother to her baby during pregnancy or childbirth. Children can also contract HCV through blood transfusions, organ transplants, or by coming into contact with infected blood through shared needles, although these routes of transmission are less common in pediatric cases. There are several types of HCV, known as genotypes, which are classified numerically from 1 to 7. Genotypes 1, 2, and 3 are the most common, globally. The genotype of HCV can impact how it is treated and how it responds to treatment. Glecaprevir-pibrentasvir works by interfering with the virus's ability to replicate and spread in the body. It targets parts of the virus's life cycle, blocking it's ability to make copies of itself and infect more liver cells. By disrupting the virus's life cycle, glecaprevir-pibrentasvir helps the body's immune system to clear the virus and eliminate the infection.			
	 Percentage of patients attaining a sustained virologic response (SVR) 12 weeks after treatment (SVR12)^a, On-treatment virologic failure (i.e., breakthrough or failure to suppress virus at end of treatment) Post-treatment relapse (i.e., HCV ribonucleic acid (RNA) was detectable following cessation of therapy) 			

^a Defined as an undetectable HCV ribonucleic acid (RNA) at 12 weeks after the last dose of study drug OR as an HCV RNA of less than the lower limit of quantification (15 IU/mL) 12 weeks after the last actual dose of the study drug. RNA uses the information stored in deoxyribonucleic acid (DNA) to build proteins in the body.

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Information about the drug					
	 HCV reinfection (i.e., reinfection at any time up to the last study visit). Changes from baseline in health-related quality of life (HRQoL), measured using Pediatric Quality of Life Inventory (PedsQL) scores, Growth and development, as measured by changes from baseline in height and BMI z-scores^b 				
	 Bad reactions Serious bad reactions Patients leaving the trial due to bad reactions Bad reactions of special interest: None 				
Other considerations	None				

Note:

Canada's Drug and Health Technology Agency (CADTH) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CADTH Reimbursement Review (CRR) in that process, see <a href="https://doi.org/10.1007/jhc.200

Cost of the drug under review compared to other drugs used to treat the same indication							
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Cost Per Course of Therapy ^c			
Pan-Genotypic Treatment Regimens (Treatment for CHC with Genotype 1, 2, 3, 4, 5 or 6)							
Glecaprevir- pibrentasvir (Maviret)	Limited Coverage for patients 18 years of age and older Under Review for Adolescents 12 Years and Older, or Pediatric	Tablet	Once daily for 8 to 16 weeks	\$40,800 to \$81,600			

^b A z-score tells you how far away a particular value is from the average. A z-score of zero indicates that the value being measured (i.e. height, BMI), is exactly the average, while a positive score shows that the value is above the average and a negative score shows the value is below the average.

^c All prices as per PharmaCare Formulary, unless otherwise specified.

Cost of the drug under review compared to other drugs used to treat the same indication							
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Cost Per Course of Therapy ^c			
	Patients Weighing at Least 45 kg						
Glecaprevir- pibrentasvir (Maviret)	Under review for patients 3 to 11 years old, weighing at least 12 kg to less than 45 kg	Sachet of oral granules	Once daily for 8 to 16 weeks	Greater than or equal to 12 kg to less than 20 kg:d \$20,400 to \$40,800 Greater than or equal to 20 kg to less than 30 kg: \$27,203 to \$54,397 Greater than or equal to 30 kg to less than 45 kg: \$33,997 to \$68,003			
sofosbuvir- velpatasvir (Epclusa®)	Limited Coverage for patients 18 years of age and older	Tablets	For patients 12 years of age and older and weigh at least 30 kg: Once daily for 12 weeks	\$61,200			
Treatment Regimens	for CHC with Genotype						
ledipasvir- sofosbuvir (Harvoni™)	<u>Limited Coverage</u> for patients 18 years of age and older	Tablets	For patients 12 years of age and older: Once daily for 12 weeks	\$68,340			

^d Manufacturer's submitted price plus 2% markup.

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called <u>Canada's Drug and Health Technology Agency</u> (CADTH)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: <u>The Drug Review Process in B.C. - Overview.</u>

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.