

Reimbursement Recommendation

Glecaprevir-Pibrentasvir (Maviret)

Indication: Hepatitis C

Sponsor: AbbVie Corporation

Final Recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Maviret?

Canada's Drug Agency (CDA-AMC) recommends that Maviret be reimbursed by public drug plans for acute hepatitis C virus (HCV) infection in adults and in pediatric patients aged 3 years and older and weighing 12 kg or more, if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) determined that it is uncertain whether Maviret demonstrates acceptable clinical value in patients with acute HCV infection. Evidence from a clinical trial showed that Maviret given for 8 weeks led to high treatment response and no failure or relapse after treatment in adults with acute HCV infection. However, because the treatment was not compared with anything else, the evidence is very uncertain. There were other uncertainties in the evidence, such as the proportion of patients who would have had a spontaneous resolution if they did not receive Maviret. However, clinical experts considered the results to be strong evidence of drug efficacy because the rate of HCV clearance 12 weeks after the last dose of treatment was much higher than what would be expected without treatment. They also noted that the harms were consistent with the use of Maviret in chronic HCV infection.

CDEC considered that there is a significant unmet clinical need for patients with acute HCV infection and for the broader population at risk of contagion. Currently, there is no reimbursed on-label treatment of acute HCV infection, and people are asked to wait until chronic HCV infection develops before accessing treatment. A patient's health can be affected because progression to a chronic infection can lead to liver disease, which is associated with mortality and can be debilitating. Also, the wait enables transmission of the virus to others at a time when the condition is more contagious. The committee noted that there are ethical and practical challenges with comparative trials that do not treat some patients and thus delay a potential cure, which means that trials are unlikely to be conducted in this fashion.

Based on these considerations, CDEC concluded that Maviret may address the significant unmet need to a degree that justifies a positive recommendation despite the uncertainty in the clinical value.

Summary

Which Patients Are Eligible for Coverage?

Maviret should only be reimbursed for adults with acute HCV infection and for pediatric patients aged 3 years and older and weighing 12 kg or more with acute HCV infection, in line with the Health Canada indication.

Maviret should only be covered for patients with a positive HCV ribonucleic acid (RNA) test and who have not received treatment for the current HCV infection. It should only be initiated for 8 weeks.

What Are the Conditions for Reimbursement?

Maviret should only be reimbursed if it is prescribed by a clinician with experience in the diagnosis and management of HCV infection, it is not used in combination with any other antiviral for the treatment of HCV, and the per-course cost of Maviret does not exceed the per-course cost of the least costly direct-acting antiviral reimbursed for chronic HCV infection. Important budget impact considerations must be addressed for health systems to be able to adopt Maviret.

Review Background

- **Disease background:**

- HCV is transmitted through contact with infected blood, such as with shared needles or sexual contact. During the first 6 months of infection after exposure (“acute HCV infection”), people are often asymptomatic, and some infections (15% to 25%) may clear on their own (“spontaneous clearance”). However, if the infection lasts longer than 6 months (“chronic HCV infection”), there is a risk of liver damage, including fibrosis, cirrhosis, hepatocellular carcinoma, and liver-related mortality.
- It is very difficult to estimate the prevalence of acute HCV infection in Canada because it tends to be asymptomatic and screening is not widespread. It is also difficult to distinguish between acute and chronic HCV infection because the timing of exposure is often not known. In 2021, the estimated incidence of acute and chronic HCV infection ranged from 9.4 to 42.3 per 100,000 across the provinces and territories.

- **Indication and reimbursement request:** Glecaprevir-pibrentasvir (GP) has been approved by Health Canada for the treatment of acute and chronic HCV infection in adults and in pediatric patients 3 years of age and older and weighing 12 kg or more. The sponsor is seeking an extension of reimbursement to include acute HCV infection in addition to chronic HCV infection, which currently has a reimbursement recommendation.
- **Drug under review:** Glecaprevir is an NS3/4 protease inhibitor and pibrentasvir is an NS5A inhibitor. The combination is available as a daily tablet (100 mg glecaprevir and 40 mg pibrentasvir) or granule (50 mg glecaprevir and 20 mg pibrentasvir per sachet) taken orally. The dosage recommended in the product monograph for adults, adolescents aged 12 years or older, and pediatric patients who weigh 45 mg or more is 3 tablets daily (300 mg glecaprevir and 120 mg pibrentasvir). For pediatric patients aged 3 years to younger than 12 years who weigh less than 45 kg, the dosage is weight-based.
- **Treatment costs:** At the submitted price of \$238.10 per tablet, the per-course cost of GP is expected to be \$40,000 per patient, based on the Health Canada–recommended dosage. At the submitted price of \$119.05 per sachet, the per-course cost of GP is expected to be between \$20,000 and \$33,334 per patient, based on the Health Canada–recommended dosage.

Highlights of Input From Interested Parties

The patient groups (Liver Canada, Centre Associatif Polyvalent d'Aide Hépatite C, and the BC Hepatitis Network) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- Immediate and certain cure, prevention of transmission, and avoiding progression to chronic disease were important goals of treatment.
- The experience of being diagnosed with acute HCV infection but needing to wait for treatment is confusing and creates uncertainty and fear of transmitting the virus to others. This can impact patients' personal relationships. Delayed treatment can undermine patient engagement, which can

result in missed appointments, loss of contact, and disengagement from care; these factors can increase the likelihood of progression to chronic infection and transmission to others.

- Currently, patients are faced with the burden of preventing transmission and experience both difficulty navigating the health system and stigma associated with HCV infection.

A group of 7 independent clinicians and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and place in therapy for the drug under review:

- The lack of a licensed treatment for HCV infection in the acute phase is an important missed opportunity. Treating patients in the acute phase is important for people with HCV who are likely to have poor linkage to care and may be lost to follow-up between diagnosis and treatment for chronic HCV infection. Also, they note that the combination of ongoing behaviours associated with a risk of transmission with the high infectivity of HCV during the acute phase increases the likelihood of HCV transmission.
- Widespread access to GP for acute HCV infection would represent a treatment shift and facilitate a test-and-treat approach to treating HCV infection.

The participating public drug programs raised potential implementation issues related to considerations for initiation, renewal, discontinuation, and prescribing of therapy; care provision issues; and system and economic issues.

Recommendation

With a vote of 14 to 1, CDEC recommends that GP be reimbursed for acute HCV infection in adults and in pediatric patients aged 3 years and older and weighing 12 kg or more.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Patients must: 1.1. have received a positive HCV RNA test result 1.2. not have received treatment for the current HCV infection.	Patients with acute HCV infection treated with GP in the M20-350 single-arm study experienced very high viral clearance rates, which suggests widespread HCV cure. It can be difficult to determine whether an HCV infection is acute or chronic, but this distinction is less relevant if there is a positive reimbursement recommendation for both acute and chronic HCV infection. With consideration of precautions noted in the product monograph, it is imperative that there be few restrictions on who should receive GP, to ensure patients	HCV RNA testing from a blood sample is widely available and typically used for diagnosis, but DBS can also be used. The limit of detection with DBS can be higher, but because the viral load is typically high in acute HCV infection, accuracy remains acceptable. A qualitative test (giving a yes or no result) is valid and unlikely to lead to false positives or false negatives. Antibodies may not appear for 8 to 12 weeks after the infection, so an antibody test may not be useful for detecting HCV in people with an acute infection. HCV RNA is likely positive before antibodies are present.

Reimbursement condition	Reason	Implementation guidance
	are treated promptly to prevent loss to follow-up and onward transmission.	The AASLD-IDSA <i>HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C</i> can be used to inform management of treatment interruptions, including whether treatment should be extended beyond 8 weeks. As no evidence was presented on the management of treatment failure, relapse, or reinfection, clinicians should follow the applicable AASLD-IDSA guidance should any of these situations arise. International guidelines should be followed for when to offer prophylaxis for HBV reactivation in people with HCV infection.
2. GP should be initiated for an 8-week duration.	Based on the duration of treatment in the M20-350 trial.	HCV RNA assessment 12 weeks after treatment stopped should be performed in the clinic.
Prescribing		
3. GP should be prescribed by a clinician with experience in the diagnosis and management of HCV infection.	It is advisable to provide the treatment in nonspecialist settings where HCV infection is diagnosed. Timely treatment in nonspecialist settings can improve access for individuals who are not well connected to care and are at risk of being lost to follow-up and of further transmitting HCV.	—
4. GP should not be used in combination with any other antiviral for the treatment of HCV.	There is no evidence that combining GP with another antiviral is safe and effective.	CDEC noted that some patients may be taking antiviral treatments for other illnesses.
Pricing		
5. The per-course cost of GP for the treatment of acute HCV infection should be negotiated so that it does not exceed the per-course cost of treatment with the least costly direct-acting antivirals for chronic HCV infection.	Based on the committee's assessment of the evidence, the clinical benefit of GP for the treatment of acute HCV infection is uncertain relative to waiting for the development of chronic HCV infection to treat. Therefore, the per-course cost of GP for acute HCV infection should be no more than the least costly direct-acting antiviral used for the treatment of chronic HCV infection.	The CDA-AMC analysis is based on public list prices for all treatments. Further price reductions may be required if there are price arrangements (discounts) currently in place for any treatment included in the economic analysis.
Feasibility of adoption		
6. The economic feasibility of adoption of GP must be addressed.	At the submitted price, the magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and the CDA-AMC estimates.	—

AASLD-IDSA = American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; CDA-AMC = Canada's Drug Agency; CDEC = Canadian Drug Expert Committee; DBS = dried blood spot; GP = glecaprevir-pibrentasvir; HBV = hepatitis B virus; HCV = hepatitis C virus; RNA = ribonucleic acid.

Rationale for the Recommendation

Clinical Value

Based on the totality of the clinical evidence, CDEC concluded that it is uncertain whether GP demonstrates acceptable clinical value in patients with acute HCV infection. Acceptable clinical value refers to similar or added clinical benefit versus waiting for developing chronic HCV infection.

A single-arm trial (M20-350) provided evidence on the efficacy and safety of 8-week GP treatment in adults with acute HCV infection. Given that there was no comparator, the evidence is very uncertain about the efficacy or harms of GP versus any comparator on virologic response, virological failure, relapse after treatment, and health-related quality of life compared with a relevant comparator. The evidence is also uncertain about the proportion of patients that would have had a spontaneous resolution if they did not have GP.

However, the clinical experts engaged in the review considered there was strong evidence of virological efficacy because the SVR12 rate, a surrogate marker for viral cure, was much higher than what would be expected with spontaneous clearance without treatment. In the trial, 96% of patients had SVR12 and none had on-treatment virological failure. Among the patients who had results available, none had relapse after treatment. Clinical experts also noted that the reported harms were consistent with the use of GP in chronic HCV infection.

In addition to the uncertainty about the effect of the treatment against any comparator, there was also no evidence on the use of GP in people younger than 20 years or in older people. There were also concerns about generalizability to people who inject drugs (who may have lower levels of adherence) because there were fewer of these patients in the trial than what would be expected in clinical practice. There was no evidence on disease transmission, liver-related morbidity, or mortality outcomes.

Given the considerable methodologic limitations in the body of evidence reviewed, comparative clinical benefit of GP versus a relevant comparator is largely unknown. Further information on the committee's discussion around clinical value is provided in the Summary of Deliberation section.

Considering Significant Unmet Clinical Need

CDEC considered that there is significant unmet clinical need for patients with acute HCV infection and for the broader population at risk of contagion. Currently, there is no reimbursed on-label treatment of acute HCV infection, and patients are asked to wait until chronic HCV infection develops before accessing treatment or until spontaneous clearance negates the need for antiviral therapy. This delay often has negative impacts on patient health because progression to chronic infection can lead to liver disease, which is associated with mortality and can be debilitating. Importantly, the delay also enables transmission of the virus to others at a time when the condition is more contagious and transmission-prone behaviour is likely. Consequently, the current approach increases morbidity for others who subsequently become infected with HCV. CDEC considered that there are challenges with evidence generation for antivirals in acute HCV infection. Although a "wait and treat" approach (i.e., delaying treatment until chronic infection is established)

could have been used as a comparator and this reflects aspects of current practice, the committee noted that there are ethical and practical considerations with trials that intentionally delay treatment of a potentially curable infection.

Based on these considerations, CDEC concluded that GP may address the significant unmet need to a degree that justifies a positive recommendation despite the uncertainty in the clinical value.

Further information on the committee's discussion around unmet clinical need is provided in the Summary of Deliberation section.

Developing the Recommendation

Due to the uncertainty in clinical value, CDEC could not recommend whether to reimburse GP or not based on clinical value alone. Therefore, they also considered whether GP addresses a significant unmet clinical need. CDEC concluded that GP addresses a significant unmet clinical need with an acceptable level of certainty. Based on the preceding considerations, CDEC recommended that GP be reimbursed. As part of the deliberation on whether to recommend reimbursement or not, the committee also considered unmet nonclinical need and health inequity. Information on this discussion is provided in the Distinct Social and Ethical Considerations domain in the Summary of Deliberation section.

Because CDEC recommended that GP be reimbursed, the committee also deliberated on whether reimbursement conditions should be added to address important economic considerations, health system impacts, or social and ethical considerations, or to ensure clinical value is realized. The resulting reimbursement conditions, with accompanying reasons and implementation guidance, are stated in [Table 1](#).

Summary of Deliberation

CDEC considered all domains of value of the deliberative framework before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, refer to [Expert Committee Deliberation at Canada's Drug Agency](#).

The committee considered the following key discussion points, organized by the 5 domains of value.



Clinical Value

- **Appropriate comparators:** CDEC noted that the current treatment paradigm for acute HCV infection is to wait until the condition is considered chronic (6 months after exposure) and then treat with direct-acting antivirals (DAAs). They noted that some DAAs approved for chronic HCV infection are currently being used in some jurisdictions for acute infections, but this use is off-label and not consistently applied across the population.
- **Efficacy versus waiting for chronicity:** There was no evidence presented to inform the comparative efficacy of GP in acute HCV compared with waiting for chronicity to treat with DAAs. Instead,

evidence from a phase IIIb single-arm trial (M20-350; N = 286) provided evidence on the efficacy and safety of GP in adults with acute HCV infection. Sustained virologic response 12 weeks after the last dose of treatment (SVR12) was 96% (275/286; 95% confidence interval [CI], 93 to 98) among all study participants who had at least 1 dose of treatment. At the same time point, no patients had on-treatment virologic failure or relapse after treatment.

- **Clinical importance of treatment effects:** Despite the fact that the available evidence was not comparative, CDEC noted that the clinical experts considered the high cure rates in the trial (SVR12) — an important goal of treatment to patients — to be clinically meaningful and provide strong evidence of the efficacy of the treatment in acute HCV infection. They considered that the very high SVR12 rates would be very unlikely to be due to spontaneous clearance, which ranges from as low as 15% to as high as 50%, depending on the population. Avoiding progression to chronic disease and preventing transmission were also important goals of treatment to patients. Consequently, using GP in acute HCV infection may address unmet needs (refer to the next section). However, there is residual uncertainty given that it is not possible to ascertain the spontaneous clearance rate in the trial and no additional evidence, direct or indirect, was submitted.
- **Certainty of the evidence:** Using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework, the evidence is very uncertain for all outcomes because it is based on a single-arm trial. However, as noted previously, the results were considered clinically meaningful by clinical experts.
- **Safety of GP:** Harms reported in the M20-350 trial were consistent with those associated with GP in chronic HCV infection. However, the certainty of the evidence without a comparator is very low, and it was not possible to draw firm conclusions on the safety of GP in acute HCV infection. CDEC also noted that introducing a treatment during the acute stage means that people may experience treatment-associated harms that they would not have experienced if their infection resolved on its own while they were waiting to have treatment for a chronic infection.
- **Children, adolescents, and older adults:** The available evidence did not include children (or the granule form of GP used for children), adolescents, or older adults despite all of these groups being included in the Health Canada indication. Although CDEC heard that clinical experts considered the sponsor's extrapolation from evidence in children with chronic HCV infection to be sufficient and justified, they noted that the lack of evidence results in residual uncertainty about efficacy and safety in these populations and with the granule form of GP.
- **Generalizability to people who inject drugs:** The trial included a smaller proportion of people who inject drugs than would be expected to be treated for acute HCV infection in clinical practice. As a result, adherence in the trial was higher than is expected in a population that includes people who are less likely to be linked to care and more likely to be lost to follow-up. However, the clinical experts noted that in chronic HCV, high cure rates have been observed in people with lower levels of adherence to DAAs, and they would expect the same in acute HCV infection. The trial also included more patients with HIV (50%) than would be expected in clinical practice. The use of opioid agonist

therapy and prior HCV infection were lower in the trial than is expected in clinical practice in a population that consists of a large proportion of people who inject drugs.

- **Clinical value:** Based on the previously mentioned considerations, CDEC determined that there was uncertainty about whether GP demonstrates acceptable clinical value in patients with acute HCV infection.



Unmet Clinical Need

- **Input on unmet clinical need:** There are no treatment options approved for people with acute HCV infection. Patients noted that waiting until a condition is considered chronic has negative impacts on people's health, and that acute HCV often affects populations experiencing systemic marginalization and equity-deserving groups, both of which have poor links to care and may be lost to follow-up. Progression to chronic infection is associated with liver disease. Increased risk of transmission of the virus to others during an untreated acute phase constitutes an important risk to public health. Off-label treatment for chronic HCV infection is not consistently used and is less likely to be used in people experiencing systemic marginalization and equity-deserving populations.
- **Severity of the disease:** Although acute HCV infection itself may resolve on its own, a large proportion of patients progress to chronic HCV infection, which can lead to liver disease as noted previously. Chronic HCV infection can be life-threatening and seriously debilitating.
- **Availability of treatment options:** Although DAAs are sometimes used off-label, clinical experts note that this use is not widespread. Prescribers are hesitant to prescribe off-label treatments to their patients. DAA reimbursement policies may also mandate proof of chronicity, although this varies across jurisdictions.
- **Difficulty in evidence generation:** CDEC noted that there are challenges with generating evidence in acute HCV infection. The clinical experts considered it unethical to have a control arm, which delayed a potential cure for the disease given that there is a risk of people being lost to follow-up and never being treated, and a risk of transmission to others while waiting for chronicity. CDEC also acknowledged the difficulty in including and retaining people from more transient populations in a clinical trial.
- **Difficulty in identifying acute HCV infection:** CDEC also acknowledged the challenges with diagnosing HCV infection in the acute stage and distinguishing it from chronic infection. There are often no symptoms or symptoms that may not lead to people being tested, and it is challenging to pinpoint the time of infection. Screening, particularly in people who inject drugs, is also not routine, but should be expanded to maximize the benefit of the therapy on population health.
- **Significant unmet clinical need:** Lack of availability of an on-label and accessible treatment in acute HCV infection results in the disease progressing to a chronic infection and risk of transmitting HCV to others during a highly infectious stage. Consequently, CDEC considered there to be significant unmet need in terms of the absence of acceptable alternatives as described in the recommendation framework in [Procedures for Reimbursement Reviews](#).



Distinct Social and Ethical Considerations

- **Equity considerations:** CDEC acknowledged that acute HCV infection disproportionately affects people experiencing systemic marginalization and equity-deserving populations. The committee notes that people from these populations can experience barriers to diagnosis and treatment (including access to off-label treatments), links to care, geographic isolation, systemic inequities, and stigma and discrimination. For example, care settings are often not designed for the needs of people who inject drugs, resulting in poor linkage to care. Because of inadequate links to care, people with acute HCV who are not treated when they are diagnosed are at a high risk of being lost to follow-up and not receiving treatment at all. Because there are potential longer-term impacts of chronic HCV infection, this could have adverse impacts on the health of individuals. Moreover, the risk of spreading HCV to others is high, particularly if there are ongoing behaviours associated with a risk of transmission during the acute phase when the risk of transmission is higher. People experiencing systemic marginalization and equity-deserving populations are unlikely to have off-label treatment for acute HCV infection. They are also more likely to have problems adhering to treatment.
- **Unmet nonclinical need and support:** As mentioned previously, access and linkage to care are problematic for populations experiencing transience and marginalization. CDEC agreed that social support programs are needed in every jurisdiction to help identify, screen, treat, and monitor populations exposed to HCV.
- **Addressing health inequity:** There is limited evidence that GP can address the health inequities in people experiencing marginalization and equity-deserving groups, both of which are more likely to be lost to follow-up while waiting for treatment and may continue to participate in behaviours associated with a risk of transmission to others. Nevertheless, CDEC determined based on clinician input that improved access to treatment during the acute stage could particularly benefit these populations and help address loss to follow-up associated with delaying consideration for antivirals.



Economic Considerations

- **Health impacts of GP versus relevant comparators:** Treating patients with acute HCV with GP is predicted to be associated with a gain of 0.08 life-years compared to treating patients upon the development of chronic HCV and may result in a gain of 0.12 quality-adjusted life-years compared to treating patients upon the development of chronic HCV over a lifetime (56-year) horizon. Delaying treatment until the development of chronic HCV results in additional cases of HCV infection, resulting in additional disease management and treatment costs for these newly infected people.
- **Cost of GP versus relevant comparators:** Treating patients with acute HCV with GP is predicted to be associated with lower costs to the health care system than treating patients upon the development of chronic HCV infection (incremental costs = −\$32,967) over a lifetime (56-year) time horizon, primarily driven by reduced costs associated with disease management.
- **Key findings of the economic evaluation:** Based on the submitted evidence using the sponsor's cost-utility analysis, the CDA-AMC base-case analysis found that treating patients with acute HCV

with GP was more effective and less costly than treating patients upon the development of chronic HCV infection.

- **Certainty of the evidence:** There is a lack of direct clinical evidence comparing treatment of acute HCV with GP with waiting until chronic HCV develops to treat using a DAA to inform the cost-utility analysis. However, the key findings of the economic evaluation are robust to assumptions about HCV transmission, acute HCV treatment efficacy, and rates of spontaneous HCV infection clearance. In a scenario analysis in which the impact of treating patients with acute HCV on the transmission of HCV is excluded, the incremental cost-effectiveness ratio for GP is \$6,318 per quality-adjusted life-year gained.



Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that reimbursing GP for the treatment of acute HCV will result in approximately \$6.4 million of cost savings over the first 3 years of reimbursement compared to the amount currently spent on comparators, with an estimated expenditure of \$62.8 million on GP over this period. The actual budget impact of reimbursing GP will depend on the proportion of otherwise untreated patients (as a result of spontaneous remission and loss to follow-up) that will access treatment in the acute setting, the impact of transmission of HCV on drug costs, and trends in the increasing screening and diagnosis of HCV.
- **Organizational implications:** CDEC discussed the fact that jurisdictions should consider developing a multifaceted approach to HCV control at the population level. CDEC remarked that optimal patient care, with a goal of HCV cure and broader disease eradication, may be achieved by treatment with GP only if patients are detected early and can be properly initiated on therapy and followed up to ensure treatment adherence and success. Patient and prescriber education is key to this goal. CDEC noted that HCV screening is not widespread and improved screening is needed. The use of an approved finger prick test could augment screening, particularly in high-prevalence settings like drug consumption sites. Therapy could be physically available in clinics that are likely to see and diagnose HCV in individuals who may be lost to follow-up, who do not have a primary provider, or who do not have a permanent address. Jurisdictions should consider implementing incentives or other mechanisms to promote return to clinic for care of individuals at an increased risk of being lost to follow-up. For example, transportation to the clinic may be considered in the therapy plan.
- **Equity considerations:** CDEC considered that few barriers should be in place in the health care system to access GP for HCV infection. This is to ensure that patients at risk are treated promptly and do not progress to severe disease while being at risk of spreading the infection.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information (links to the full documents for the review can be found on the [project webpage](#)):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor, as well as relevant ethical issues related to GP (refer to the Main Report and Supplemental Material document)
- the sponsor's comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 3 patient groups, Liver Canada, Centre Associatif Polyvalent d'Aide Hépatite C, and the BC Hepatitis Network (refer to the Patient and Clinician Group Input document)
- input from 1 clinician group and a group of 7 independent clinicians (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Supplemental Material document)
- input from 2 clinical experts with expertise in the management of acute HCV infection consulted by CDA-AMC.

CDEC Information

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Sally Bean, Daryl Bell, Dan Dunskey, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Dr. Dennis Ko, Dr. Christine Leong, Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Carla Velastegui, Dr. Edward Xie, and Dr. Peter Zed.

Meeting date: June 25, 2026

Regrets: None

Conflicts of interest: One expert committee member did not participate due to considerations of conflict of interest.



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