Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

bulevirtide (Hepcludex)

(Gilead Sciences Canada, Inc.)

Indication: Bulevirtide is anticipated to be indicated for the treatment of chronic hepatitis delta virus (HDV) infection in adults with compensated liver disease.

March 18, 2025

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CDA-AMC in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings. **If your group has submitted input that is not reflected within this document, please contact Formulary-Support@cda-amc.ca.**

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CDA-AMC and do not necessarily represent or reflect the views of CDA-AMC. No endorsement by CDA-AMC is intended or should be inferred.

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CADTH

CADTH Reimbursement Review
Patient Input

Name of Drug: bulevertide
Indication: chronic HDV infection
Name of Patient Group: Liver Canada & BC Hepatitis Network
Author of Submission: Jennifer van Gennip

1. About Your Patient Group

Liver Canada: Liver Canada (LC), formerly known as the Canadian Liver Foundation, was first established in 1969 out of the passion and concern of a group of business leaders and doctors who believed that liver disease needed a champion. Since then, LC has relentlessly driven advancements in research, treatment, and support. We exist to promote liver health, increase public understanding and awareness of liver diseases, and provide support to those affected. Our vision is liver health for all. *https://liver.ca*

BC Hepatitis Network: BC Hepatitis Network is dedicated to viral hepatitis work to ensure people everywhere in BC have full access to equitable, stigma-free information, prevention, testing, care, and treatment. We work with community-based health and social service organizations, Indigenous groups, and peer-led groups to provide the information and tools to support viral hepatitis work with those who are most impacted. *https://www.bchep.org*

2. Information Gathering

The perspectives shared in this submission were gathered through an online survey between February 21 and March 8, 2025. The survey link was shared on social media, with other known patient support networks, and with physicians known to be treating patients living with chronic HDV to share within their clinics as they felt appropriate. Six people living with chronic HDV and/or caring for someone with HDV responded to our survey. Survey respondents were adults from Canada (BC, AB, and ON) in their 30s-60s.

Some data shared here was also gathered from a poster at the Canadian Liver Meeting in February 2025 entitled *Bulevirtide for the Treatment of Hepatitis Delta: Real-World Cohort from the Canadian HBV Network*, submitted by Dr. Sebastien Poulin et al., and in conversation with the physicians involved in treating this cohort.

3. Disease Experience

A diagnosis of HDV is often made after patients already have advanced liver disease. It significantly impacts their quality of life and can also be a significant caregiver burden. Frequent and very frequent symptoms include fatigue, lack of appetite, and throwing up/upset stomach. Occasional/more rare symptoms include joint pain, dark urine, and jaundice.

Living with HDV affected respondents' social life, work life, ability to travel, ability to pursue hobbies, and their emotional and psychological wellbeing. One respondent specifically mentioned worrying about the future.

Another respondent noted that they sometimes feel hopeless without a cure for HDV. They noted, "I do not disclose my HBV/HDV status to friends or others outside a very close family circle for fear of being stigmatized."

This respondent also explained, “I knew that I had chronic Hep B since my childhood (for over 38 years), but since learning that I also have Hep D (for the last 12 years), I feel like I live in 6-month intervals. Every six months I go to see my doctor, get blood tests and ultrasounds. Before my 6-month appointments I get very concerned – what if they find something this time?”

All respondents rated the importance of patients having access to new treatments for HDV as a 5 out of 5.

4. Experiences With Currently Available Treatments

The only current treatment option in Canada for HDV is pegylated interferon, however, this treatment is difficult to access as it has not been submitted to CDA-AMC to be reviewed for this indication and most provincial special access requests are denied. As a generic drug, it is eligible for a non-sponsored review, however FMAC has declined our request for a non-sponsored review as it is not seen as a priority by formulary managers.

Patients who indicated that they have experience with peg interferon reported that the treatment was only slightly to moderately effective at managing their HDV (2 or 3 out of 5, with one 4), and that they took it because it was the only option available to them to slow progression of cirrhosis. However, they also reported intolerable side effects, frequent clinic visits for injections, the need to travel to receive their injections, and the frequent blood monitoring as drawbacks.

One patient noted that peg interferon also made them less focused and more easily agitated. While they pushed through and did not miss days of work from side effects, it was a struggle. “While on peg interferon I was more easily agitated, constantly tired, lost some weight, and did not have much of an appetite.” Their platelet counts also dropped to 11-13 and they were concerned about bleeding.

Those who did not have experience with peg interferon indicated that it was not available/funded in their province, and that they were concerned about low efficacy with significant negative side effects that would lower their quality of life.

5. Improved Outcomes

Respondents value achieving stabilized liver disease without significant negative side effects. The possibility of a potential cure was also exciting to respondents. All patients living with HDV are also living with chronic HBV. While there was no expectation that the symptoms of their liver disease would disappear completely, the prospect of liver disease slowing or not progressing to liver cancer or liver failure was considered a positive and valued outcome.

6. Experience With Drug Under Review

As stated on Dr. Poulin’s poster, patients in the CanHepB Cohort reported that bulevirtide was well tolerated, with only mild injection site reactions. The cohort included 13 patients in AB, ON, and QC. Most showed improvements in their liver health and reduced HDV RNA (4 had undetectable RNA and 9 showed a reduction). One is being monitored for possible HDV cure.

One survey respondent indicated that they have experience with bulevirtide through compassionate access from the manufacturer. They shared that side effects were minimal and very manageable. Quality of life was rated at a 4 out of 5, with improved liver test results and stabilization of liver disease (rather than progression). There was also hope as bulevirtide is a potential cure without the risk of negative health outcomes related with peg interferon use.

7. Companion Diagnostic Test

Bulevirtide is not accompanied by a companion diagnostic.

Chronic HDV is a two-step diagnosis through a blood test that detects antibodies against HDV and then confirms active infection by measuring the presence of HDV RNA. Patients are most likely to be screened in primary, acute, public health care settings or hospitals where there is no direct cost to patients.

Chronic HDV is most common among newcomers and immigrants to Canada, who face multiple barriers to timely diagnosis: they are less likely to be screened for viral hepatitis, face limited access to routine care compared to people born in Canada, and are more likely to have fears and stigma surrounding hepatitis. These barriers combined place them at higher risk for late diagnosis and advanced viral hepatitis-related liver disease.

Due to the increased risk of mortality with HDV, the patient community and clinicians alike are advocating for reflex testing for HDV for all positive HBsAg blood tests (people living with chronic hepatitis B) to improve diagnosis rates and begin treatment earlier to stop the progression of liver disease before onset of liver cancer and/or liver failure. Currently reflex testing is not systematic, physicians must make the request. Provinces will not routinely do HDV screening, so if the physician does request it, the provinces currently can only test for antibodies. The confirmatory RNA test must be done at the National Microbiology Lab.

8. Anything Else?

As one survey respondent put it, “HDV is a deadly liver disease (D=Deadly). Bulevertide is a breakthrough treatment for a condition with essentially no other options.”

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

   This submission is authored by Jennifer van Gennip, Executive Director of Action Hepatitis Canada, a coalition of organizations working toward viral hepatitis elimination, that often provides advocacy support to member organizations. Both Liver Canada and BC Hepatitis Network are members of Action Hepatitis Canada.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

   The survey was hosted by Liver Canada, and representatives from Liver Canada, BC Hepatitis Network, and Action Hepatitis Canada analyzed the data.

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
Liver Canada	Nothing to disclose			
BC Hepatitis Network	Nothing to disclose			
Action Hepatitis Canada: Gilead Sciences			x	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Jennifer Nebesky
Position: CEO
Patient Group: Liver Canada
Date: March 13, 2025

Name: Deb Schmitz
Position: Executive Director
Patient Group: BC Hepatitis Network
Date: March 13, 2025

CADTH

CADTH Reimbursement Review

Clinician Group Input

CADTH Project Number: SR0881-000
Generic Drug Name (Brand Name): Bulevirtide (Hepcludex)
Indication: Chronic Hepatitis Delta Virus (HDV)
Name of Clinician Group: Canadian Hepatitis B Network
Author of Submission: Dr. Carla Coffin

1. About Your Clinician Group

The Canadian Hepatitis B Network (www.canadianhbvnetwork.ca) is a collaborative organization of health care professionals and researchers from across Canada with an interest in advancing excellence in Hepatitis B patient care, research and education. Our members are leaders in Canadian medical care and treatment of patients with Hepatitis B and Hepatitis D. We are specialists in Internal Medicine, Hepatology, Gastroenterology, and Infectious Disease.

Le Réseau canadien de l'hépatite B (www.canadianhbvnetwork.ca) est un organisme collaboratif regroupant des professionnels de la santé et des chercheurs de partout au Canada qui souhaitent promouvoir l'excellence dans les soins, la recherche et l'éducation aux patients atteints d'hépatite B. Nos membres sont des chefs de file en matière de soins médicaux et de traitement des patients atteints d'hépatite B et d'hépatite D au Canada. Nous sommes des spécialistes en médecine interne, hépatologie, gastroentérologie et maladies infectieuses.

2. Information Gathering

Information was gathered during monthly teleconferences, email correspondence, and face to face meeting at the Annual Canadian Liver meeting. We are also collaborating on real world research study of BLV treatment in Canada.

Les informations ont été recueillies lors de téléconférences mensuelles, de correspondances par courriel et de rencontres en personne lors de la Réunion canadienne sur le foie annuelle. Nous collaborons également à une étude de cas réels sur le traitement du BLV au Canada.

3. Current Treatments and Treatment Goals

There are limited treatment options for hepatitis Delta. Interferon (Pegylated Interferon) is recommended therapy but used off-label (i.e., the product monograph only lists it for HBV monoinfection). Further, Interferon (IFN) treatment is poorly tolerated, can have severe side effects and is usually not effective (i.e., 20-30% success rate). Interferon also has non-specific side effects that can cause life threatening hepatic flares. The drug can only be used with extreme caution in patients with cirrhosis and is not recommended in decompensated cirrhosis (Coffin CS, Fung SK et al., Can. Liv. Journal 2019; Management of Hepatitis B). Although oral nucleos(t)ide can suppress the hepatitis B virus DNA (viral load) to undetectable or very low levels, the nucleos(t)ide analogs have no effect on the hepatitis delta virus. Finally, there have been recent issues with procurement of IFN in Canada. Thus, Hepatitis Delta is considered an Orphan Disease.

Les options thérapeutiques pour l'hépatite Delta sont limitées. L'interféron (interféron pégylé) est un traitement recommandé, mais son utilisation est hors indication (c'est-à-dire que la monographie du produit ne le mentionne que pour la mono-infection par le

VHB). De plus, le traitement par interféron (IFN) est mal toléré, peut avoir des effets secondaires graves et n'est généralement pas efficace (c'est-à-dire un taux de succès de 20 à 30 %). L'interféron a également des effets secondaires non spécifiques qui peuvent provoquer des dommages hépatiques potentiellement mortels. Le médicament ne peut être utilisé qu'avec une extrême prudence chez les patients atteints de cirrhose et n'est pas recommandé en cas de cirrhose décompensée (Coffin CS, Fung SK et al., Can. Liv. Journal 2019; Management of Hepatitis B). Bien que les nucléos(t)ides oraux peuvent supprimer l'ADN du virus de l'hépatite B (charge virale) à des niveaux indétectables ou très faibles, ces derniers n'ont aucun effet sur le virus de l'hépatite Delta. Enfin, des problèmes sont récemment survenus dans l'approvisionnement en IFN au Canada. L'hépatite Delta est donc considérée comme une maladie orpheline.

4. Treatment Gaps (unmet needs)

4.1. Considering the treatment goals in Section 3, please describe goals (needs) that are not being met by currently available treatments.

There is an urgent unmet medical need for improved therapies for hepatitis Delta / HBV coinfection. The HDV causes the most severe form of viral hepatitis in humans. HDV requires the HBV surface (or envelope) protein to infect the liver. Thus, HDV can only infect people that also have HBV.

Due to shared routes of transmission (i.e., blood-borne, sexual routes) individuals can acquire HBV and HDV at the same time or HDV can superinfect a patient with underlying chronic hepatitis B infection. Studies have shown that up to 80% of people superinfected with HDV develop end-stage liver disease and cirrhosis within 5-10 years of infection (Rizzetto M et al., J Hepatol 2021 74(5):1200). A recent nationwide study conducted by the Canadian Hepatitis B Network, led by Dr. Carla Osiowy (Chief Viral Hepatitis Testing (retired), National Microbiology Laboratory, Public Health Agency of Canada) found ~5% seroprevalence in a Canadian HBsAg positive referred population (N=7000). This study found that compared to HBV monoinfected patients, those with hepatitis delta coinfection were more likely to develop severe (grade 3) liver fibrosis, cirrhosis, hepatocellular carcinoma and require a liver transplant (Osiowy C et al., Molecular epidemiology and clinical characteristics of hepatitis D virus infection in Canada. Journal or Hepatology reports; V4 (5), May 2022). This large, multi-centre Canadian study highlighted the need for increased HDV surveillance and improved treatment to prevent the development of end-stage liver disease.

Il existe un besoin médical urgent et non satisfait de meilleurs traitements contre la co-infection par le virus de l'hépatite Delta et le VHB. Le VHD est responsable de la forme la plus grave d'hépatite virale chez l'homme. Le VHD a besoin de la protéine de surface (ou enveloppe) du VHB pour infecter le foie. Ainsi, le VHD ne peut infecter que les personnes également atteintes du VHB.

En raison des voies de transmission communes (c.-à-d., voies sanguines et sexuelles), les individus peuvent contracter le VHB et le VHD en même temps, ou le VHD peut surinfecter un patient atteint d'une infection chronique sous-jacente par l'hépatite B. Des études ont montré que jusqu'à 80 % des personnes surinfectées par le VHD développent une maladie hépatique terminale et une cirrhose dans les 5 à 10 ans suivant l'infection (Rizzetto M et al., J Hepatol 2021 74(5) : 1200). Une étude nationale récente réalisée par le Réseau canadien de recherche sur le VHB et menée par la Dre Carla Osiowy (ancienne chef de section des hépatites virales, Laboratoire national de microbiologie, Agence de la santé publique du Canada), a trouvé une séroprévalence d'environ 5 % dans une population canadienne référée positive à l'AgHBs (N = 7 000). Cette étude a révélé que, par rapport aux patients mono-infectés par le VHB, les patients coinfectés par l'hépatite Delta étaient plus susceptibles de développer une fibrose hépatique grave (grade 3), une cirrhose, un carcinome hépatocellulaire et de nécessiter une transplantation hépatique (Osiowy C et al., Molecular epidemiology and clinical characteristics of hepatitis D virus infection in Canada. Journal of Hepatology reports; V4 (5), may 2022). Cette vaste étude canadienne multicentrique a souligné la nécessité d'une surveillance accrue du VHD et de meilleurs traitements pour prévenir le développement d'une maladie hépatique en phase terminale.

5. Place in Therapy

5.1. How would the drug under review fit into the current treatment paradigm?

Bulevirtide Offers Substantial Evidence of Clinical Effectiveness in the Treatment of Chronic HDV. Bulevirtide (BLV, Hepcludex®) is a first-in-class novel antiviral drug specifically targeting the binding of HDV (and HBV) to the liver specific cell surface bile acid receptor (i.e., NTCP). In a Phase 3 study (i.e., MYR 301; Wedemeyer et al., NEJM, 2023), after 48 weeks of therapy ~45-48% of BLV treated groups achieved the combined response of undetectable viral load (i.e., HDV RNA below the lower limit of detection) or ≥ 2log10 IU/ml decline from baseline and alanine aminotransferase (ALT) normalization compared to 2% in the delayed treatment group. There was also a statistically significant decrease in liver stiffness measurement (> 3.0 kPA improvement) determined by transient elastography (FibroScan). These clinical endpoints (i.e., ALT normalization, viral suppression and FibroScan) are indicators of significant clinical benefit. Long-term safety and efficacy data is available from a real- world case series of patients treated up to 3 years as a compassionate use program with maintained biochemical and virological response including disappearance of esophageal varices (Loglio A et al., Journal of Hepatol Feb 2022). Moreover, evidence of prolonged clinical benefit is shown in a single-center cohort study of patients with compensated cirrhosis and clinically significant portal hypertension, in which a 48-week course of BLV 2 mg monotherapy was associated with significant virologic and biochemical response, as well as decreased liver stiffness and lack of any observed decompensating events or development of HCC (Degasperi E, JHepatology, 2022 V7(6)). Similarly, a recent Canadian case series of patients receiving BLV through a compassionate use program also showed successful viral suppression and biochemical normalization including those who previously failed Peg-IFN therapy, (Poulin S et al., Poster Presentation, Canadian Liver Journal, February 2025). In summary, based on the pivotal Phase 3 data, available real-world studies, and case series, show positive, clinically meaningful outcomes for BLV treatment of this population have been shown.

Le bulévirtide présente des preuves d'efficacité clinique substantielles dans le traitement d'infection par le VHD chronique. Le bulévirtide (BLV, Hepcludex®) est un nouveau médicament antiviral «premier de sa classe» ciblant spécifiquement la liaison du VHD (et du VHB) au récepteur des acides biliaires (c.-à-d. NTCP) à la surface des cellules du foie. Dans une étude de phase 3 (c.-à-d. MYR 301 ; Wedemeyer et al., NEJM, 2023), après 48 semaines de traitement, environ 45 à 48 % des groupes traités par BLV ont obtenu la réponse combinée d'une charge virale indétectable (c.-à-d. ARN du VHD inférieur à la limite de détection minimale) ou diminution de >/= 2log10 IU/ml du niveau de départ et d'une normalisation de l'alanine aminotransférase (ALT) par rapport à 2 % dans le groupe avec un traitement différé. On a également observé une diminution statistiquement significative de la mesure de la rigidité hépatique (amélioration > 3,0 kPA) déterminée par élastographie transitoire (FibroScan). Ces issues cliniques (c.-à-d. normalisation de l'ALT, suppression virale et FibroScan) sont des indicateurs d'un bénéfice clinique significatif. Des données d'innocuité et d'efficacité au long terme sont disponibles à partir d'une série de cas réels de patients traités jusqu'à 3 ans dans le cadre d'un programme d'utilisation compassionnelle avec une réponse biochimique et virologique maintenue, y compris la disparition des varices œsophagiennes (Loglio A et al., Journal of Hepatol, février 2022).

De plus, des preuves d'un bénéfice clinique prolongé sont démontrées dans une étude de cohorte monocentrique de patients avec cirrhose compensée et hypertension portale cliniquement significative. Dans celle-ci, un traitement de 48 semaines de BLV à 2 mg en monothérapie a été associé à une réponse virologique et biochimique significative, ainsi qu'à une diminution de la rigidité hépatique et à l'absence d'événements de décompensation ou de développement de CHC (Degasperi E, JHepatology, 2022 V7(6)). De même, une récente série de cas avec des patients canadiens recevant du BLV dans le cadre d'un programme d'utilisation compassionnelle a aussi montré une suppression virale et une normalisation biochimique adéquates, y compris chez ceux qui avaient précédemment échoué un traitement par Peg-IFN (Poulin S et al., Présentation par poster, Canadian Liver Journal, février 2025). En résumé, sur la base des données de phase 3 pivots, des études réelles disponibles et des séries de cas, les résultats cliniques sont positifs et pertinents avec le traitement par BLV chez les populations étudiées.

5.2. Which patients would be best suited for treatment with the drug under review? Which patients would be least suitable for treatment with the drug under review?

Patients with HBV and HDV coinfection and HDV RNA positive are most likely to respond to treatment with the drug under review. Patients most in need of an intervention are those that are HBsAg positive and HDV Antibody positive and HDV RNA positive. This would not differ based on any disease characteristics because HDV coinfected patients are at significant risk of liver disease and cirrhosis within 5 years.

Patients best suited for treatment with the drug under review would be identified by expert specialist clinical judgement – Hepatology or Infectious Disease, as well as utilizing HDV RNA testing. No companion diagnostic test is required.

One potential issue relating to diagnosis is that HDV RNA testing is done at National Reference Lab. While it currently has capacity, we hope this will remain available.

Underdiagnosis due to lack of HDV screening. However, most specialists would have expertise to establish the diagnosis.

Les patients co-infectés par le VHB et le VHD, et positifs à l'ARN du VHD, sont les plus susceptibles de répondre au traitement par le médicament étudié. Les patients nécessitant une intervention sont ceux qui sont positifs à l'AgHBs, aux anticorps anti-VHD et à l'ARN du VHD. Cela ne diffère pas selon les caractéristiques de la maladie, car les patients co-infectés par le VHD présentent un risque significatif de maladie hépatique et de cirrhose dans les 5 ans.

Les patients nécessitant le plus le traitement par le médicament étudié seront identifiés par un expert clinique spécialisé (hépatologie ou maladies infectieuses), ainsi que par un test d'ARN du VHD. Aucun test diagnostique complémentaire n'est requis.

Un problème potentiel lié au diagnostic est que le test d'ARN du VHD est effectué au Laboratoire national de référence. Bien que celui-ci dispose actuellement de capacités suffisantes, nous espérons que cela restera disponible.

Sous-diagnostic dû à l'absence de dépistage du VHD. Cependant, la plupart des spécialistes disposent de l'expertise nécessaire pour établir le diagnostic.

5.3 What outcomes are used to determine whether a patient is responding to treatment in clinical practice? How often should treatment response be assessed?

Outcomes used in clinical practice are aligned with the outcomes typically used in clinical trials, namely HDV RNA suppression and biochemical normalization. A clinically meaningful response to treatment would be HDV RNA suppression, biochemical normalization, improvement in non-invasive fibrosis tests, and/or improvement in symptoms of liver disease decompensation (ascites, variceal bleeding).

Les issus évalués en pratique clinique sont conformes à ceux généralement utilisés dans les essais cliniques, à savoir la suppression de l'ARN du VHD et la normalisation biochimique. Une réponse cliniquement significative au traitement serait la suppression de l'ARN du VHD, la normalisation biochimique, l'amélioration des tests de fibrose non invasifs et/ou l'amélioration des symptômes de décompensation hépatique (ascite, saignements variqueux).

5.4 What factors should be considered when deciding to discontinue treatment with the drug under review?

Failure to respond to therapy (HDV RNA decline and ALT normalization), disease progression and limited lifespan.

Échec de réponse au traitement (baisse de l'ARN du VHD et normalisation de l'ALT), progression de la maladie et durée de vie limitée.

5.5 What settings are appropriate for treatment with Bulevirtide? Is a specialist required to diagnose, treat, and monitor patients who might receive Bulevirtide?

A specialty clinic setting is appropriate with a Hepatology and Infectious Diseases specialist.

Un cadre clinique spécialisé est approprié avec un spécialiste en hépatologie et en maladies infectieuses.

6. Additional Information

Patients afflicted with HDV are often young. They who are at immense risk of severe liver disease, liver failure and liver cancer. There are currently no approved Health Canada treatments indicated for HDV. BLV can achieve an HDV cure and protect patients from the horrible outcomes caused by HDV. BLV is a significant advance in the treatment of this devastating liver disease. We strongly endorse approval for this life-saving breakthrough therapy.

Les patients atteints du VHD sont souvent jeunes et présentent un risque élevé de maladie hépatique grave, d'insuffisance hépatique et de cancer du foie. Il n'existe actuellement aucun traitement approuvé par Santé Canada pour le VHD. De nombreux nouveaux médicaments contre le VHD sont en cours de développement et sont nécessaires pour parvenir à une guérison, mais le BLV représente une avancée significative dans le traitement de cette maladie hépatique dévastatrice. Nous appuyons fortement l'approbation de cette thérapie révolutionnaire qui sauve des vies.

7. Conflict of Interest Declarations: Research funding and fees, paid to Institution from Gilead, GSK, Janssen

To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the clinician group input. CADTH may contact your group with further questions, as needed. Please see the *Procedures for CADTH Drug Reimbursement Reviews* (section 6.3) for further details.

1. Did you receive help from outside your clinician group to complete this submission? If yes, please detail the help and who provided it.

   No outside help was received.

2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission? If yes, please detail the help and who provided it.

   No outside help was received.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review. **Please note that this is required for each clinician who contributed to the input — please add more tables as needed (copy and paste). It is preferred for all declarations to be included in a single document.**

Declaration for Clinician 1

Name: Carla Coffin
Position: Professor of Medicine, University of Calgary
Date: 06-03-2025

☒ **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for Clinician 1

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 2

Name: Sébastien Poulin
Position: Medical Microbiologist & Infectious Disease, CISSS des Laurentides
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 2: Conflict of Interest Declaration for Clinician 2

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Mayur Brahmania
Position: Clinical Associate Professor, University of Calgary
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 3: Conflict of Interest Declaration for Clinician 3

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Add company name				

Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: Kelly Kaita
Position: Section Head, Section of Hepatology, Rady Faculty of Health Sciences, University of Manitoba
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 4: Conflict of Interest Declaration for Clinician 4

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
N/A				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: Alexander Wong
Position: Associate Professor, University of Saskatchewan
Date: 06-03-2025

☐ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 5: Conflict of Interest Declaration for Clinician 5

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Carla Osiowy

Position: Retired - Chief, Viral Hepatitis and Bloodborne Pathogens, National Microbiology Laboratory, Public Health Agency of Canada & Retired - Adjunct Professor, University of Manitoba
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 6: Conflict of Interest Declaration for Clinician 6

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 7

Name: Sergio Borgia
Position: Assistant Clinical Professor, William Osler Health System
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 7: Conflict of Interest Declaration for Clinician 7

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 8

Name: Karen Doucette
Position: Professor of Medicine, University of Alberta
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 8: Conflict of Interest Declaration for Clinician 8

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
N/A				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 9

Name: Craig Jenne
Position: Professor of Microbiology, Immunology and Infectious Disease, University of Calgary
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 9: Conflict of Interest Declaration for Clinician 9

	Check appropriate dollar range*			
Company	**$0 to $5,000**	**$5,001 to $10,000**	**$10,001 to $50,000**	**In excess of $50,000**
Add company name				
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 10

Name: Curtis Cooper
Position: Professor of Medicine, University of Ottawa
Date: 06-03-2025

☒ I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 10: Conflict of Interest Declaration for Clinician 10

Company	Check appropriate dollar range*			
	$0 to $5,000	$5,001 to $10,000	$10,001 to $50,000	In excess of $50,000
Gilead		x		
GSK	x			

* Place an X in the appropriate dollar range cells for each company.