ORIGINAL RESEARCH

Public reimbursement policies in Canada for direct-acting antiviral treatment of hepatitis C virus infection: A descriptive study

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ABSTRACT

BACKGROUND: Direct-acting antiviral (DAA) therapies have simplified HCV treatment, and publicly funded Canadian drug plans have eliminated disease-stage restrictions for reimbursement of DAA therapies. However other policies which complicate, delay, or prevent treatment initiation still persist. We aim to describe these plans' existing reimbursement criteria and appraise whether they hinder treatment access. **METHODS:** We reviewed DAA reimbursement policies of 16 publicly funded drug plans published online and provided by contacts with in-depth knowledge of prescribing criteria. Data were collected from May to July 2022. Primary outcomes were: (1) if plans have arranged to accept point-of-care HCV RNA testing for diagnosis; testing requirements for (2) HCV genotype, (3) fibrosis stage, and (4) chronic infection; (5) time taken and method used to approve reimbursement requests; (6) providers eligible to prescribe DAAs; and (7) restrictions on re-treatment. **RESULTS:** Fifteen (94%) plans have at least one policy in place which limits simplified HCV treatment. Many plans continue to require results of genotype or fibrosis staging, limit eligible prescribers, and take longer than 1 day to approve coverage requests. One plan discourages treatment for re-infection. **CONCLUSION:** Reimbursement criteria set by publicly funded Canadian drug plans continue to limit timely, equitable access to HCV treatment. Eliminating clinically irrelevant pre-authorization testing, expanding eligible prescribers, expediting claims processing, and broadening coverage of treatment for reinfection will improve access to DAAs. The federal government could further enhance efforts by introducing a federal HCV elimination strategy or federal high-cost drug PharmaCare program.

KEYWORDS: direct-acting antivirals; hepatitis C virus; policy analysis; public drug plans; public health

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INTRODUCTION

Canada has committed to eliminating viral hepatitis as a major public health threat by 2030, setting benchmarks to reduce new hepatitis C virus (HCV) cases by 90% and ensure that 80% of eligible people receive treatment (1). Direct-acting antiviral (DAA) therapies cure greater than 90% of cases, and without a vaccine against HCV, are key to achieving elimination targets (2–4). As such, DAA access is essential to deliver on Canada's commitment to HCV elimination.

Under the Constitution Act, 1867, the 10 provinces and three territories in Canada have primary responsibility for the administration and delivery of health services to their residents. As per the *Canada Health Act* of 1984 (CHA), eligible Canadian residents are entitled to access the publicly funded, medically necessary health services provided by hospitals and doctors. The federal government provides funding to the provinces and territories (P/Ts) each year through the Canada Health Transfer (CHT) to support them to provide this. However, the P/Ts individually determine how best to spend the CHT and provide CHA-compliant medical services to their residents. While the CHA mandates public coverage of pharmaceuticals administered in hospitals, out-of-hospital prescription drugs are omitted, therefore public provision of drug coverage outside the hospital setting is the sole responsibility of the P/Ts (5). As a result, there is a "patchwork" drug coverage system in Canada, with all P/Ts having their own pharmaceutical insurance plans to cover out-of-hospital prescription drug costs, such as DAA treatment (6). Special federally administered plans provide out-of-hospital public drug coverage to Indigenous communities, federal prison populations, and certain veterans of the Canadian Armed Forces. More than 60% of people in Canada also receive supplemental private out-of-hospital drug coverage. However, private plans only finance 12% of nationwide DAA costs, perhaps because populations affected by HCV in Canada are less likely to have private drug coverage and private insurers shift affected beneficiaries to public plans to minimize costs (7). Additionally, it was estimated in 2022 that 2.8% of the population in Canada was ineligible for either public or private prescription drug coverage, with the largest number of uninsured persons in Ontario and Newfoundland and Labrador (8).

Public drug plans independently establish their reimbursement criteria and approval processes for DAA coverage, creating a maze of rules governing publicly funded DAA access across Canada. Despite the removal of disease stage restrictions on DAA reimbursement in 2018 (9), policies remain that constrain equitable treatment access (10,11). Certain plans require liver fibrosis staging and HCV genotyping before approving coverage claims. Providers may use these results in clinical management, but they do not affect patients' eligibility for DAA treatment or reimbursement. Additionally, some plans limit eligible DAA prescribers to specialist physicians, require providers to submit coverage requests by fax instead of faster and more reliable modalities such as telephone or an online portal, and restrict eligibility in cases of reinfection, further delaying or preventing treatment initiation for many patients.

Simplifying DAA reimbursement criteria and processes could reduce burdens on prescribers, patients, and drug plans, facilitating equitable access to life-saving therapy. Streamlined DAA treatment processes reduce the interval between HCV diagnosis and therapy, thereby augmenting treatment initiation and continuation, particularly for marginalized people (12,13). To support the adoption of simplified DAA reimbursement criteria in

Canada, the *Blueprint to inform hepatitis C elimination efforts in Canada* (henceforth, *"Blueprint"*) recommends eliminating genotype, fibrosis stage, and repeat HCV testing requirements for treatment reimbursement, expanding the pool of eligible prescribers, and expediting pre-authorization processes (14).

We, therefore, aim to assess the degree to which publicly funded Canadian drug plans' DAA reimbursement policies optimize access to DAAs in line with *Blueprint* recommendations. Our objective is to determine whether inequities in DAA access which may impede Canada's ability to meet its 2030 viral hepatitis elimination targets exist across Canada in publicly funded drug plans.

METHODS

Study design

We employed a cross-sectional design and descriptive methods to compare DAA reimbursement policies.

Primary outcomes

We determined the most important domains pertaining to public DAA reimbursement criteria across Canada based on expert input from HCV treatment providers, academic researchers, and representatives from community-based organizations that support people affected by HCV in Canada. These domains were: (1) any criteria patients must meet to be eligible for reimbursement by public drug plans; (2) which providers are eligible to prescribe DAAs; (3) documentation or clinical evidence required to be submitted when requesting DAA drug coverage; (4) the method that providers use to request drug coverage. Under those domains, we developed the seven following primary outcomes from suggested activities in the *Blueprint* (14) which gauged coherence between a drug plan's reimbursement criteria and strategies likely to enhance progress towards HCV elimination: (1) if plans have arranged to accept positive point-of-care HCV RNA tests to demonstrate chronic HCV infection; (2) if laboratory-confirmed HCV genotype is required when prescribing DAAs; (3) if evidence of fibrosis staging is required; (4) if two or more laboratory-confirmed positive HCV RNA tests taken at least 6 months apart are required for DAA approval; (5) the method for submitting and time taken to approve coverage requests; (6) who may submit DAA coverage requests; and (7) whether drug plans limit DAA treatment following reinfection.

Data sources and collection

We identified 16 public drug plans which cover most patients diagnosed with HCV infection in Canada. These include plans from all 13 provinces and territories, the Non-Insured Health Benefits (NIHB) program for Canadians with First Nations status, and programs administered by Correctional Services Canada (CSC) and Veterans Affairs Canada.

First, we reviewed available online formularies, special authorization request forms, and benefit lists for each drug plan to collect information pertaining to our primary outcomes. Second, we consulted a tiered list of contacts to confirm the accuracy of these online data and provide any missing information related to our outcomes. We sorted known contacts into the following order according to their ability to provide high-fidelity information: (1) drug plan representatives, (2) independent experts, and (3) co-authors familiar with a given plan's reimbursement criteria. We then reached out to contacts in this order for each drug plan to request they complete a data entry form mapped to our outcomes. When available, we pre-filled fields with data from online sources. When contacts from one tier were unable to provide the requested information, we consulted contacts from the next tier if available. Sources and validation of analyzed data are summarized in Supplementary Table 1.

Data extraction and analysis

We created a data extraction table comparing DAA reimbursement policies by public drug plan and primary outcome. When we were unable to retrieve the desired information as described above, we labelled the field "NA." We used *Blueprint* benchmarks to develop the following three-level system rating reimbursement policies' performance on each primary outcome: limits, may limit, or facilitates rapid or simplified HCV treatment. Two authors (GS and SB) reviewed each drug plan's policies, populated the extraction table, and agreed on the appropriate performance rating to apply by outcome. We compiled descriptive statistics in Microsoft Excel to summarize outcome performance across plans.

RESULTS

Number of publicly funded drug plans assessed

We obtained partial DAA treatment reimbursement criteria from online resources for nine (56%) of the 16 publicly funded drug plans studied. Contacts provided complete data entry forms for 12 (75%) drug plans which validated and filled any gaps in data we collected from online resources. Co-authors confirmed the accuracy of information collected online and supplied missing data for two (13%) additional plans. We were able to collect Yukon's full reimbursement criteria from online resources and Nunavut's partial reimbursement criteria from data previously collected in 2021. However, relevant authorities within the governments of the Yukon and Nunavut did not respond to our requests for information by January 2023. Data were collected from May 1, 2022 to September 30, 2022. Full results are summarized in Table 1.

Point of care HCV RNA testing of active HCV infection

Given that Health Canada, the principal federal agency regulating medical laboratory testing, has not approved point-of-care HCV RNA testing, 15 plans (94%) do not state that point-of-care results may be used to confirm chronic HCV infection. However, Prince Edward Island explicitly permits the use of point-of-care tests for confirmation of chronic HCV infection through a research-use-only exemption.

HCV genotype testing

Six plans (38%) require providers to submit the results of HCV genotype testing even when prescribing pan-genotypic regimens. British Columbia normally mandates that genotype results be included in coverage requests, but due to the COVID-19 pandemic, suspended and has not yet re-enforced this requirement. While Ontario does state in its formulary criteria that genotype results must be provided, our contact indicated that this requirement is rarely enforced. Similarly, our contact in Nova Scotia reported that coverage may be approved prior to receipt of genotype results in the event of testing delays, but this requires extra follow-up from providers.

Fibrosis staging

Four plans (25%) require evidence of fibrosis staging before reimbursing treatment. Three plans (19%) require providers to report whether their patients have cirrhosis when submitting coverage requests, but do not require supporting evidence. The Northwest Territories and Nunavut continue to request fibrosis staging for patients with previous DAA treatment experience.

Confirmation of chronic infection

Two plans (13%) require more than one positive HCV RNA test result to approve coverage of DAA treatment. Of these, Newfoundland and Labrador will only approve requests which demonstrate laboratory or clinical evidence of chronic HCV infection. Providers may use a second positive HCV RNA test result administered at least 6 months apart from the first result to satisfy this requirement. Likewise, Ontario requires a second positive HCV RNA test result but allows prescribers to instead describe alternative clinical evidence establishing chronic infection.

Time taken and method for approval of DAA treatment

Eight plans (50%) have policies which require providers to submit coverage requests before reimbursement of DAA therapy is initiated. Another five plans (31%) typically approve coverage in 5 days or less, while the remaining three (19%) estimate that approvals may take as long as 2 to 4 weeks. All plans which usually take longer than 1 day to process requests require providers to submit a form by fax.

Eligible DAA prescribers

Three plans (19%) require that prescribers be or have consulted with specialists with expertise in HCV management. Nine plans (56%) permit requests from prescribers experienced in HCV management without documented consultation of a specialist (eg, hepatologist, gastroenterologist, infectious disease specialist). Three plans (19%) do not state any DAA-specific limits on eligible prescribers. We were unable to obtain details on eligible prescribers for Nunavut.

Treatment for reinfection

Newfoundland and Labrador discourages treatment in cases of HCV reinfection. Eight plans

Table 1: Key reimbursement policies regulating direct-acting antiviral medications for treatment of hepatitis C (HCV) by publicly funded drug plan

Policy limits rapid or simplified HCV treatment | Policy may limit rapid or simplified HCV treatment | Policy facilitates rapid or simplified HCV treatment

Public drug plan	Point of care HCV RNA test can be used for DAA approval	HCV genotype test required*	Fibrosis stage required†	Two HCV RNA+ tests required‡	Time taken & method for DAA approval	Eligible prescribers	Treatment for reinfection
Alberta	No	No	No	No	Faxed form 1-3 days	Specialists or other prescribers with specialist consultation‡‡‡	Considered case-by-case
British Columbia	No	No§	Yes	No	Online Same day	Specialists and other HCV-experienced providers	Yes
Manitoba	No	Yes	No	No	Faxed form 2-14 days	Specialists or other prescribers with specialist consultation	Considered case-by-case
New Brunswick	No	Yes	Yes	No	Faxed form 2-5 business days	Specialists and other HCV-experienced providers	Yes
Newfoundland and Labrador	No	Yes	No	No¶	Faxed form Up to 14 days	Specialists and other HCV-experienced providers	No
Northwest Territories	No	No**	No††	No	Faxed form 1-3 days	No specific restrictions	Considered case-by-case
Nova Scotia	No	Yes‡‡	No§§	No	Approval not required‡‡‡	Specialists and other HCV-experienced providers	Yes
Nunavut	No	No**	No††	No	Faxed form 1-3 days	NA	NA
Ontario	No	Yes¶¶	No	Yes¶¶	Approval not required†††	Specialists and other HCV-experienced providers	Considered case-by-case
Prince Edward Island	Yes	No	No	No	Approval not required†††	No specific restrictions	Yes
Quebec	No	No**	No§§	No	Online 1-3 days	No specific restrictions	Yes
Saskatchewan	No	No**	No§§	No	Faxed form Up to 7 days	Specialists and other HCV-experienced providers	Yes
Yukon	No	Yes	Yes	No	Faxed form Up to 28 days	Specialists or other prescribers with specialist consultation	Considered case-by-case
People with FN status (NIHB)	No	No**	No	No	Faxed form 1 day	Specialists and other HCV-experienced providers	Considered case-by-case
Correctional Service Canada	No	No**	No	No	Approval not required†††	Specialists and other HCV-experienced providers	Considered case-by-case
Veterans Affairs Canada	No	No	No	No	Telephone Same day	Specialists and other HCV-experienced providers	Considered case-by-case

Note: Red = Policy limits rapid or simplified HCV treatment; Orange = Policy may limit rapid or simplified HCV treatment; Green = Policy facilitates rapid or simplified HCV treatment

(*Continued*)

(50%) consider approval on a case-by-case basis, while four plans (25%) do not restrict treatment. We could not obtain treatment criteria for Nunavut.

DISCUSSION

Second-generation DAAs enabled a steady pre-COVID-19 rise in Canadian HCV treatment (15,16), but certain HCV-affected groups continue to access DAAs at lower rates. People living with chronic HCV who have lower incomes and actively inject drugs are less likely to begin treatment (15,17,18). Ensuring these individuals receive equitable access to standard of care, and maintaining HCV treatment initiations at the rates needed to achieve elimination targets requires policies which make DAAs easier to obtain (19). However, 15 (94%) of the Canadian public drug plans we surveyed have at least one policy which limits HCV treatment. Moreover, plans employ very different reimbursement criteria.

Six (37%) and five (31%) plans continue to respectively require HCV genotype and fibrosis staging results before approving DAA coverage. Neither are necessary to establish eligibility for DAA treatment, or to initiate first-line, pan-genotypic DAA regimens used with most HCV patients (2,14). Eliminating these testing requirements could save prescribers, patients, and those adjudicating requests for public drug plans significant time, accelerating treatment initiation (20). Moreover, this would likely create opportunities for cost savings at the provincial and national levels (21).

Public drug plans differ significantly in how they process requests for coverage. Nine (56%) plans to mandate that providers submit requests by fax. In contrast, we observed that plans which do not require providers to submit coverage requests, or which allow requests to be submitted online or by telephone, estimate shorter delays to treatment coverage approval. For patients with limited financial means or difficulty in accessing health services, eliminating or accelerating pre-treatment coverage approval could significantly improve their chances of initiating therapy (22).

While 94% of drug plans did not accept HCV RNA point-of-care test results for approval of DAA reimbursement, this is difficult for them to remedy since there is no Health Canada–approved diagnostic test in this category. According to the *Blueprint*, HCV RNA point-of-care tests would enable wider access to HCV diagnosis in remote, rural, and other settings where lab facilities are not accessible (14). Additionally, they may improve connection to care for populations who experience a dual burden of poor access to health services and high rates of HCV transmission. Diagnostics companies and all levels of the Canadian government will likely need to collaborate to achieve market entry of HCV RNA point-of-care tests. Rapid resource mobilization and close cooperation between government and industry during the COVID-19 pandemic provide a model for how this could be achieved in Canada.

Our contact for Newfoundland and Labrador noted that treatment for re-infection is discouraged. For example, Newfoundland and Labrador's coverage request form does not provide successful cure and subsequent reinfection as a reason for retreatment (23). As those at low ongoing risk of transmission are treated, re-infections will comprise an increasing share of HCV transmission (24). Ensuring that individuals who experience

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* *Requirement to submit genotype results even when pan-genotypic regimens are being prescribed to treatment-naïve patients*
† *Requirement to submit fibrosis stage when it is not used to determine if patients qualify for HCV treatment*
‡ *Requirement for two consecutive HCV RNA positive tests 6 months apart*
§ *Not during the COVID-19 pandemic for treatment naïve patients requesting pangenotypic regimens, but the requirement may resume in the future*
¶ *Clinical evidence of chronic infection, but not fibrosis stage, required*
** *Genotype results not required for DAA-naïve patients prescribed pan-genotypic regimens*
†† *Fibrosis stage not required for DAA-naïve patients*
‡‡ *Requirement may be waived on an ad hoc basis*
§§ *Proof of fibrosis stage not required, just yes/no for cirrhosis*
¶¶ *Required, but not typically enforced*
*** *Second HCV RNA test may be replaced by other clinical features establishing 6+ month HCV infection*
††† *Approval not required if "limited use code" or "criteria code" stipulations are met. If not eligible for these codes, request must be reviewed and approved, usually within 2-4 weeks*
‡‡‡ *Other providers may independently prescribe on a case-by-case basis in geographic areas where specialists are not available*
DAA = Direct-acting antiviral; FN = First Nations; NIHB = Non-Insured Health Benefits program

re-infection have timely access to repeat courses of DAA therapy not only prevents disease complications and further viral transmission but may also encourage treatment uptake amongst populations most at risk (25,26). Individuals living with HCV who actively inject drugs can feel pressure to opt out of treatment until they no longer use it (27). As such, they may forgo therapy at the time of diagnosis if they believe they will only have one chance to receive treatment (28,29).

Three plans continue to limit eligible prescribers to specialists. In Australia, general practitioners have overtaken specialists as DAA prescribers since the federal government rescinded prescriber-type restrictions in 2016, improving access to HCV treatment (30). Public drug plans could help Canada maintain necessary annual HCV treatment initiations (16) to achieve elimination by 2030 and improve equitable access to HCV treatment by further expanding and supporting eligible DAA prescribers (31).

A coordinated national HCV strategy could also play an important role in facilitating health equity and Canada's progress towards elimination of viral hepatitis (32). Variable HCV DAA reimbursement policies across Canada mean patients enrolled in some plans have better access to treatment, or have greater out-of-pocket expenses, than those in others. A federal strategy could help public drug plans align their DAA reimbursement policies with efforts to stem transmission and prevent complications of HCV infection. Alternatively, a federal PharmaCare plan which centralizes public drug plan purchasing and insurance could rectify current gaps in coverage across Canada (33). Implementation of national PharmaCare requires significant amendments to the current legal and institutional framework which constitutes the Canadian health care system, but receives widespread public support (34–36) and is strongly endorsed by the federally convened Advisory Council on the Implementation of National Pharmacare (37).

Our work had several limitations. First, plans did not provide equal information online regarding their DAA reimbursement criteria. To mitigate this issue, we asked representatives, subject matter experts, and co-authors to verify and supplement data we collected from online resources. Using this approach, we were able to obtain complete and validated primary outcome data for all jurisdictions besides the Yukon and Nunavut. These two territories combined represent approximately 2% of the Canadian population, and Indigenous peoples covered by NIHB make up 86% of the population in Nunavut and 23% in the Yukon (38,39). Therefore, a very small number of patients could be impacted by not having complete and validated data for these two territories. Second, our work cannot speak to how providers negotiate reimbursement criteria. However, it does suggest providers may struggle to obtain accurate information regarding reimbursement criteria and coverage requests for DAAs. As a result, clinicians capable of prescribing but new to seeking reimbursement for DAAs may be discouraged from offering HCV therapies, reducing potential access to treatment. Additionally, several contacts who were consulted to confirm the validity of the data we collected proffered additional unrequested data in the form of observations of their experience as DAA prescribers. They stated that while the data we collected were accurate, the application of the criteria by the drug plans is frequently inconsistent. Success in obtaining approval for reimbursement of medications varied widely in their experience, with very little explanation as to why. Almost half the co-authors of this article are active DAA prescribers in Canada, and they validated this observation from their own experience. However, our study did not seek to elucidate this issue. Therefore, these data are of questionable quality and should be considered anecdotal only. Moving to automated online systems to submit and process requests for coverage of DAAs could reduce inconsistency in application of criteria. However, further studies may be needed to fully quantify the extent and scope of this issue.

Third, the public drug plans profiled in this analysis insure neither all DAA treatment costs nor all people living with HCV in Canada. Certain plans impose deductible or co-insurance fees which low-income patients can find unaffordable. Additionally, an unknown number of people living with HCV in Canada are uninsured. Recent immigrants are sometimes unaware of the need or are ineligible to enroll in a drug plan. Others may choose not to enroll if the application process is onerous or regular premiums are required. Efforts to quantify this population are needed. Pharmaceutical companies that manufacture and sell DAA medications in Canada sponsor patient medication assistance programs (PMAP) that provide medications at no cost or cover co-pays for eligible patients, in order to cover individuals without adequate insurance

and expand access to HCV treatment. Studies of PMAPs in the United States have found they are inequitably used, particularly by more vulnerable and marginalized groups, and may contribute to disparities in medication access (40,41). Additionally, PMAPs create duplication of administrative processes, which have been found to create additional costs for physicians offices (42,43). Further research on the impact of PMAPs in Canada may be needed, in order to understand their role in ensuring DAAs are equitably accessible to all Canadian residents.

Public drug plans across Canada impose highly heterogeneous criteria for reimbursement of HCV DAA therapy. Policy and procedural modifications which limit pre-approval testing requirements, accelerate review of coverage requests, and expand the pool of eligible prescribers would likely improve treatment equity and initiation. Individuals must be able to obtain therapy in the event of reinfection to minimize personal impacts, transmission, and health system costs. The federal government could support drug plans in harmonizing their DAA reimbursement policies by developing a national strategy for HCV elimination, in addition to considering inclusion of DAAs in federal PharmaCare. In so doing, Canada will be better positioned to eliminate viral hepatitis as a public health threat by 2030, as well as to progress towards equity in access to health services and positive health outcomes across the country.

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