

Restrictions for reimbursement of direct-acting antiviral treatment for hepatitis C virus infection in Canada: a descriptive study

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Abstract

Background: In Canada, interferon-free, direct-acting antiviral hepatitis C virus (HCV) regimens are costly. This presents challenges for universal drug coverage of the estimated 220 000 people with chronic HCV infection nationwide. The study objective was to appraise criteria for reimbursement of 4 HCV direct-acting antivirals in Canada.

Methods: We reviewed the reimbursement criteria for simeprevir, sofosbuvir, ledipasvir–sofosbuvir and paritaprevir–ritonavir–ombitasvir plus dasabuvir in the 10 provinces and 3 territories. Data were extracted from April 2015 to June 2016. The primary outcomes extracted from health ministerial websites were: 1) minimum fibrosis stage required, 2) drug and alcohol use restrictions, 3) HIV coinfection restrictions and 4) prescriber type restrictions.

Results: Overall, 85%–92% of provinces/territories limited access to patients with moderate fibrosis (Meta-Analysis of Histologic Data in Viral Hepatitis stage F2 or greater, or equivalent). There were no drug and alcohol use restrictions; however, several criteria (e.g., active injection drug use) were left to the discretion of the physician. Quebec did not reimburse simeprevir and sofosbuvir for people coinfecting with HIV; no restrictions were found in the remaining jurisdictions. Prescriber type was restricted to specialists in up to 42% of provinces/territories.

Interpretation: This review of criteria of reimbursement of HCV direct-acting antivirals in Canada showed substantial interjurisdictional heterogeneity. The findings could inform health policy and support the development and adoption of a national HCV strategy.

In Canada, an estimated 220 000 people have chronic hepatitis C virus (HCV) infection.¹ It is estimated that, by 2035, cirrhosis will develop in nearly one-quarter of Canadians with chronic HCV infection, with total associated health care costs per annum rising from about \$161 million in 2013 to about \$258 million by 2032.²

Interferon-free, direct-acting antiviral HCV regimens achieve sustained virologic response rates above 90% even in patients with compensated cirrhosis.^{3–10} Sustained virologic response is associated with lowered risk of liver transplantation, liver-related mortality and all-cause mortality^{11,12} and improved quality-of-life outcomes.^{13,14} Shorter therapy duration and fewer adverse events have further reduced patient-level barriers to care.^{15–18} However, given that the list price for

HCV direct-acting antivirals in Canada is about \$60 000 for a 12-week course, funding all those chronically infected with HCV presents challenges.

A study of sofosbuvir reimbursement criteria in the United States identified considerable variability across state fee-for-service Medicaid plans.¹⁹ Three-quarters of the 42 states with

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data requested evidence of advanced fibrosis (Meta-Analysis of Histologic Data in Viral Hepatitis stage F3) or cirrhosis (stage F4). Furthermore, most states (88%) had restrictions on drug and alcohol use, with half requiring abstinence before the start of treatment. In one-quarter of the states, populations coinfecting with HIV had to be treated with antiretroviral therapy or show suppressed HIV viral loads. Furthermore, one-third of the states limited prescriber type to specialists. These restrictions do not align with published and accepted clinical guidelines.^{20–22} Additional research into Medicaid-managed care programs, federal and state corrections plans, private plans and other payer sources would provide greater context to therapy access in the US.

In contrast to the multitiered, privately financed health care system in the US, Canada has a publicly funded national health insurance program that provides coverage to each resident. Although Canada's 10 provinces and 3 territories are collectively governed by the Canada Health Act, every jurisdiction administers its own health plan. Since 2010, the pan-Canadian Pharmaceutical Alliance, made up of provincial/territorial health minister representatives, has negotiated drug prices with manufacturers.²³ In February 2016, the federal government joined the alliance.^{23,24} For these reasons, it was hypothesized that Canada would have greater reimbursement consistency by jurisdiction than the US.

The aim of this study was to appraise reimbursement criteria in Canada for simeprevir, sofosbuvir, ledipasvir–sofosbuvir and paritaprevir–ritonavir–ombitasvir plus dasabuvir. We also reviewed the criteria for Aboriginal people and federal prisoners as these populations are disproportionately affected by HCV infection^{25–28} and receive drug coverage from national plans.

Methods

Data sources

We collected reimbursement criteria for simeprevir (with peginterferon plus ribavirin), sofosbuvir (with peginterferon and/or ribavirin), ledipasvir–sofosbuvir and paritaprevir–ritonavir–ombitasvir plus dasabuvir (with or without ribavirin) for all provinces and territories as well as the national Non-Insured Health Benefits Program and the Correctional Service Canada drug plans ($n = 15$). Because each provincial/territorial health ministry sets its own reimbursement criteria, information was primarily collected from jurisdiction websites, with national plan information collected from federal websites (Table 1).

We extracted data including special authorization request forms, drug formularies, amendments to formularies and drug benefit lists from publicly available online reimbursement information. If desired information was not available online, we contacted the ministry directly. Coauthors who were health care practitioners also facilitated access to documentation. When information could not be retrieved or was not available (e.g., the therapy was not reimbursed), data were labelled “NA” (i.e., not available). If a restriction (e.g., drug

and alcohol use) was not listed with the criteria, data were labelled as “none listed;” this does not necessarily indicate that no restriction exists but, rather, that a written instruction could not be identified.

We obtained restriction information for First Nations people and Inuit from the Non-Insured Health Benefits Program, which reimburses the cost of medications and medical services not covered under provincial/territorial or private plans for these populations. We obtained restriction criteria for prisoners in federal penitentiaries (sentences ≥ 2 yr) from Correctional Service Canada. (Reimbursement for prisoners with sentences of less than 2 years follows criteria set by the province or territory where the sentence is being served, and we did not review this information.)

Data extraction took place from Apr. 22, 2015, to June 21, 2016. Information was collected by 2 of the authors (A.D.M. and S.S.), who cross-checked each other's data; inconsistencies were resolved through consensus. We organized the data using Microsoft Excel.

Primary outcomes

Primary outcomes were based on a previous study of Medicaid reimbursement in the US¹⁹ and included: 1) minimum fibrosis stage required, 2) drug and alcohol use restrictions, 3) HIV coinfection restrictions and 4) prescriber type restrictions. We organized the data into categories so that criteria could be compared across provinces/territories. We categorized fibrosis data as the minimum fibrosis stage required (categories: no restrictions, $\geq F2$, $\geq F3$ or $F4$ of the Meta-Analysis of Histologic Data in Viral Hepatitis scoring system or equivalent). Depending on the jurisdiction, fibrosis stage was assessed by means of transient elastography (e.g., FibroScan), aspartate aminotransferase-to-platelet ratio index score, fibrosis-4 index score or liver biopsy. We categorized drug and alcohol use criteria based on restrictions on current/past drug or alcohol use (categories: yes, no). HIV coinfection data were categorized as to whether people coinfecting with HIV were eligible for treatment (categories: eligible [those with HIV coinfection had the same criteria as those with HCV infection only], ineligible [HIV coinfection was listed in the exclusion criteria]). Prescriber data were categorized as whether a hepatologist, gastroenterologist or infectious disease specialist prescriber was required or nonspecialist options were permitted (categories: specialist, general practitioner). In cases in which a physician with experience treating patients with HCV infection could prescribe treatment once he or she met designated prescriber status as defined by the jurisdiction, this was categorized as “general practitioner.” We also noted treatment eligibility for decompensated cirrhosis (categories: eligible, ineligible, may be considered). We defined decompensated cirrhosis as Child-Pugh score greater than 6 (class B or C).¹⁹

Statistical analysis

We used descriptive statistics to show the proportion of provinces/territories that restrict drug coverage by primary outcome. Map images were created with Tableau Software version 9.0.

Table 1: Provincial/territorial and federal health ministries in Canada

Jurisdiction	Health ministry	Website
Province/territory		
British Columbia	British Columbia Ministry of Health	www.gov.bc.ca/health
Alberta	Alberta Health	www.health.alberta.ca
Saskatchewan	Saskatchewan Ministry of Health	www.saskatchewan.ca/government/government-structure/ministries/health
Manitoba	Manitoba Health	www.gov.mb.ca/health
Ontario	Ontario Ministry of Health and Long-Term Care	www.health.gov.on.ca
Quebec	Quebec Ministry of Health and Social Services	www.msss.gouv.qc.ca
New Brunswick	New Brunswick Department of Health	www2.gnb.ca/content/gnb/en/departments/health.html
Nova Scotia	Nova Scotia Department of Health and Wellness	http://novascotia.ca/DHW
Prince Edward Island	Prince Edward Island Department of Health and Wellness	www.gov.pe.ca/health
Newfoundland and Labrador	Newfoundland and Labrador Department of Health and Community Services	www.health.gov.nl.ca/health
Yukon Territory	Yukon Health and Social Services	www.hss.gov.yk.ca
Northwest Territories	Northwest Territories Health and Social Services	www.hss.gov.nt.ca
Nunavut	Nunavut Department of Health	www.gov.nu.ca/health
National		
Non-Insured Health Benefits Program*	Health Canada	www.hc-sc.gc.ca
Correctional Service Canada formulary†	Correctional Service Canada	www.csc-scc.gc.ca

*Federally funded public drug benefit program for First Nations people and Inuit.
†Federally funded public drug benefit program for federal prisoners (sentences ≥ 2 yr).

Results

Provinces/territories

Simeprevir with peginterferon plus ribavirin

Simeprevir was approved for use in HCV genotype 1 infection in combination with peginterferon plus ribavirin. Patients with genotype 1a infection required resistance testing showing absence of NS3 polymorphism Q80K.

Prince Edward Island did not reimburse simeprevir. Eleven (92%) of the 12 other jurisdictions required a fibrosis stage of F2 or greater (Table 2); Quebec did not provide this information (Appendix 1, available at www.cmajopen.ca/content/4/4/E605/suppl/DC1). No drug and alcohol use criteria were listed. In 2 jurisdictions (17%) (Manitoba and Ontario), people coinfecting with HIV were eligible for treatment with the same criteria as for HCV monoinfection. This population was ineligible for treatment in Quebec; however, coauthors who were health care practitioners in that province specified that exceptions could be granted via the “patient d’exception” (exception patient) measure, whereby a prescriber provides additional justification for treatment. Five provinces/territories (42%) required specialist prescribing, and 3 jurisdictions (25%) allowed general practitioners to prescribe. Seven jurisdictions (58%) prohibited treatment for patients with decompensated cirrhosis.

Sofosbuvir with peginterferon and/or ribavirin

Sofosbuvir was approved for use in genotypes 1–3 infections in combination with peginterferon and/or ribavirin. In Quebec, reimbursement for genotype 4 infection was also permitted.

Sofosbuvir was not reimbursed in Prince Edward Island. Eleven provinces/territories (92%) required fibrosis stage F2 or greater (Table 3). Quebec did not list this information (Appendix 2, available at www.cmajopen.ca/content/4/4/E605/suppl/DC1). Coauthors who were health care practitioners in Quebec indicated that there were no known fibrosis stage restrictions. No jurisdiction listed drug and alcohol use restrictions. There were no stated restrictions for HIV-coinfected people in 9 jurisdictions (75%). Those coinfecting with HIV were not eligible for treatment in Quebec, although exceptions could be granted through the “patient d’exception” measure. Eight jurisdictions (67%) permitted general practitioners to prescribe, and 3 jurisdictions (25%) required specialist prescribers; Quebec did not list this information. Treatment of decompensated cirrhosis was considered on a case-by-case basis in 8 jurisdictions (67%).

Ledipasvir–sofosbuvir

Ledipasvir–sofosbuvir was approved for use in HCV genotype 1 infection.

Prince Edward Island did not reimburse this treatment (Figure 1). Eleven provinces/territories (92%) required fibrosis

Table 2: Key eligibility criteria for reimbursement of simeprevir with peginterferon plus ribavirin for treatment of hepatitis C virus infection, by jurisdiction

Jurisdiction	Restriction				
	Minimum fibrosis stage required	Substance use	HIV coinfection	Prescriber	Decompensated cirrhosis
Province/territory					
British Columbia	F2	None listed	None listed	General practitioner	None listed
Alberta	F2	None listed	None listed	None listed	Ineligible
Saskatchewan	F2	None listed	None listed	General practitioner	None listed
Manitoba	F2	None listed	Eligible	Specialist	Ineligible
Ontario	F2	None listed	Eligible	General practitioner	Ineligible
Quebec	None listed*	None listed	Ineligible†	None listed	None listed
New Brunswick	F2	None listed	None listed	None listed	Ineligible
Nova Scotia	F2	None listed	None listed	Specialist‡	Ineligible
Prince Edward Island	NA	NA	NA	NA	NA
Newfoundland and Labrador	F2	None listed	None listed	None listed	Ineligible
Yukon	F2	None listed	None listed	Specialist	Ineligible
Northwest Territories	F2	None listed	None listed	Specialist‡	None listed
Nunavut	F2	None listed	None listed	Specialist‡	None listed
Federal					
Non-Insured Health Benefits Program	F2	None listed	None listed	Specialist‡	None listed
Correctional Service Canada	F2§	None listed¶	None listed	None listed	None listed

Note: NA = not available.
 *However, coauthors indicated that in practice there were no fibrosis stage restrictions.
 †However, exceptions could be granted via the "patient d'exception" (exception patient) measure.
 ‡None listed in criteria; however, a specialist prescription was required for peginterferon-based treatments.
 §Treatment prioritized to patients with stage F3 or F4 fibrosis; treatment for those with stage F0, F1 or F2 fibrosis was reviewed on a case-by-case basis.
 ¶Directly observed therapy required.

stage F2 of greater (Table 4). In Quebec, fibrosis stage requirements depended on the number of years the treatment had been on the market. In year 1 (July 2015–July 2016), evidence of advanced fibrosis (\geq stage F3) or cirrhosis was required. In years 2–3, patients with moderate (stage F2) or mild (stage F1) fibrosis plus an indicator of poor prognosis such as coinfection with HIV or hepatitis B virus will be required. For years 4–6, all patients will be eligible for treatment regardless of fibrosis stage. There were no drug and alcohol use restrictions. However, in British Columbia, at the prescriber's discretion, "patients who are at high risk for non-compliance" were ineligible, and Saskatchewan provided a directly observed therapy option for prescribers. In all 12 jurisdictions, people coinfecting with HIV were eligible for treatment with HCV monoinfection criteria. Nine provinces/territories (75%) allowed general practitioners to prescribe, and 3 jurisdictions (25%) required specialist prescribers. In 8 jurisdictions (67%), patients with decompensated cirrhosis "may be considered" for treatment. Patients with decompensated cirrhosis were eligible for treatment in Quebec.

Paritaprevir–ritonavir–ombitasvir plus dasabuvir (with or without ribavirin)

Paritaprevir–ritonavir–ombitasvir plus dasabuvir (with or without ribavirin) was approved for use in genotypes 1a or 1b subtype infections. Prince Edward Island permitted treatment of genotype 4 infection.

Of the 13 provinces/territories, 11 (85%) required fibrosis stage F2 or greater (Table 5). Fibrosis stage F3 or F4 was required in Quebec in year 1, with increased eligibility in subsequent years (Appendix 3, available at www.cmajopen.ca/content/4/4/E605/suppl/DC1). Prince Edward Island had no fibrosis stage requirements. There were no drug and alcohol use restrictions. At the discretion of the prescriber, Prince Edward Island listed "methadone or equivalent for at least 6 months" and "stable address" in the inclusion criteria and active injection drug use in the exclusion criteria. Eleven jurisdictions (85%) allowed patients coinfecting with HIV to receive therapy with HCV monoinfection criteria. Prince Edward Island required those coinfecting with HIV to be treated off-island by a specialist. Three jurisdictions (23%) required specialist pre-

Table 3: Key eligibility criteria for reimbursement of sofosbuvir with peginterferon and/or ribavirin for treatment of hepatitis C virus infection, by jurisdiction

Jurisdiction	Restriction				
	Minimum fibrosis stage required	Substance use	HIV coinfection	Prescriber	Decompensated cirrhosis
Province/territory					
British Columbia	F2	None listed*	Eligible	General practitioner	May be considered
Alberta	F2	None listed	Eligible	General practitioner	May be considered
Saskatchewan	F2	None listed†	Eligible	General practitioner	May be considered
Manitoba	F2	None listed	Eligible	Specialist	May be considered
Ontario	F2	None listed	Eligible	General practitioner	May be considered
Quebec	None listed‡	None listed	Ineligible§	None listed	None listed
New Brunswick	F2	None listed	Eligible	Specialist	May be considered
Nova Scotia	≥ F2	None listed	Eligible	General practitioner	May be considered¶
Prince Edward Island	NA	NA	NA	NA	NA
Newfoundland and Labrador	F2	None listed	Eligible	General practitioner	None listed
Yukon	F2	None listed	Eligible	Specialist	May be considered
Northwest Territories	F2	None listed	None listed	General practitioner	None listed
Nunavut	F2	None listed	None listed	General practitioner	None listed
Federal					
Non-Insured Health Benefits Program	F2	None listed	None listed	General practitioner	None listed
Correctional Service Canada	F2**	None listed††	None listed	None listed	None listed
Note: NA = not available. *No specific criteria, but exclusion criteria state: "Patients who are at high risk for non-compliance." †However, prescriber could indicate that directly observed therapy was recommended; also, the patient consented (via signature) to understanding treatment adherence. ‡However, coauthors indicated that in practice there were no fibrosis stage restrictions. §However, exceptions could be granted via the "patient d'exception" (exception patient) measure. ¶Source: coauthor. **Treatment prioritized to patients with stage F3 or F4 fibrosis; treatment for those with stage F0, F1 or F2 fibrosis was reviewed on a case-by-case basis. ††Directly observed therapy required.					

scribing, and 8 jurisdictions (62%) permitted prescribing by general practitioners. In 9 jurisdictions (69%), patients with decompensated cirrhosis were ineligible for treatment.

First Nations people and Inuit and federal prisoners

The Non-Insured Health Benefits Program and Correctional Service Canada criteria required a minimum of stage F2 fibrosis for all treatments (Tables 2–5). Correctional Service Canada criteria stated that directly observed therapy was mandatory, and treatment was prioritized for patients with stage F3 or F4 fibrosis. Non-Insured Health Benefits Program criteria required specialist prescribing for simeprevir.

Both national drug plans permitted populations coinfecting with HIV to be treated with ledipasvir–sofosbuvir.

Interpretation

We found variability in criteria for reimbursement of HCV direct-acting antivirals by jurisdiction in Canada. Depending on the treatment, 85%–92% of provinces/territories limited reimbursement to patients with fibrosis stage F2 or greater. No alcohol or drug use restrictions were found. Quebec listed HIV coinfection restrictions. Overall, 23%–42% of jurisdictions restricted prescriber type to specialists.

Table 4: Key eligibility criteria for reimbursement of ledipasvir–sofosbuvir reimbursement for treatment of hepatitis C virus infection, by jurisdiction

Jurisdiction	Restriction				
	Minimum fibrosis stage required	Substance use	HIV coinfection	Prescriber	Decompensated cirrhosis
Province/territory					
British Columbia	F2	None listed*	Eligible	General practitioner	May be considered
Alberta	F2	None listed	Eligible	General practitioner	May be considered
Saskatchewan	F2	None listed†	Eligible	General practitioner	May be considered
Manitoba	F2	None listed	Eligible	Specialist	May be considered
Ontario	F2	None listed	Eligible	General practitioner	May be considered
Quebec	F3‡	None listed	Eligible§	General practitioner	Eligible
New Brunswick	F2	None listed	Eligible	General practitioner	None listed
Nova Scotia	F2	None listed	Eligible	Specialist	May be considered¶
Prince Edward Island	NA	NA	NA	NA	NA
Newfoundland and Labrador	F2	None listed	Eligible	General practitioner	May be considered
Yukon	F2	None listed	Eligible	Specialist	May be considered
Northwest Territories	F2	None listed	Eligible	General practitioner	None listed
Nunavut	F2	None listed	Eligible	General practitioner	None listed
Federal					
Non-Insured Health Benefits Program	F2	None listed	Eligible	General practitioner	None listed
Correctional Service Canada	F2**	None listed††	Eligible	None listed	None listed
Note: NA = not available. *No specific criteria, but exclusion criteria stated: "Patients who are at high risk for non-compliance." †However, prescriber could indicate that directly observed therapy was recommended; also, the patient consented (via signature) to understanding treatment adherence. ‡In year 1 (2015/16), only those with stage F3 or F4 fibrosis received reimbursement. §Treated in year 1 if stage F3 or F4 fibrosis. ¶Source: coauthor. **Treatment prioritized to patients with stage F3 or F4 fibrosis; treatment for those with stage F0, F1 or F2 fibrosis was reviewed on a case-by-case basis. ††Directly observed therapy required.					

In contrast to Canada, 74% of state fee-for-service Medicaid plans in the US limit reimbursement to patients with evidence of advanced fibrosis or cirrhosis (stage F3 or F4).¹⁹ Clinical guidelines state that *all* patients with chronic HCV infection, irrespective of disease stage, should receive treatment,^{20–22} including prioritization of treatment for populations at risk of transmitting HCV, e.g., people who inject drugs.²² A review by the Canadian Agency for Drugs and Technologies in Health showed that treating patients across all fibrosis stages is cost-effective.²⁹ Quebec implemented tiered fibrosis staging based on cost-effective analyses, a model that could be followed by other jurisdictions. Further-

more, several US states have removed fibrosis stage restrictions following potential lawsuits from patients.³⁰ Fibrosis stage restrictions should be reviewed in Canada.

Although there were no drug and alcohol use restrictions for HCV direct-acting antiviral therapy in Canada, 50% of US states require drug and/or alcohol abstinence before the start of treatment.¹⁹ Considering that treatment of HCV infection for people who inject drugs is safe and effective,³¹ is cost-effective^{32,33} and would prevent HCV transmission,³⁴ removal of these restrictions is warranted. HIV coinfection restrictions were mostly nonexistent in Canada, whereas 25% of US states request evidence of antiretroviral therapy or sup-

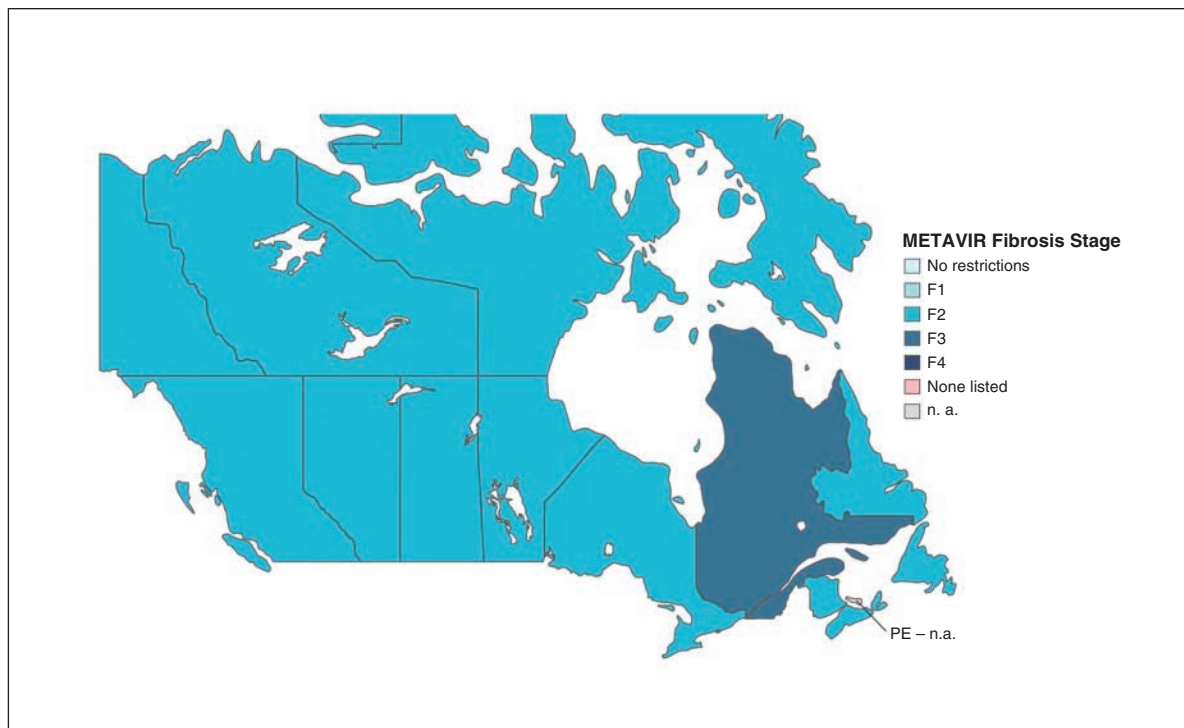


Figure 1: Minimum fibrosis stage required for reimbursement of ledipasvir–sofosbuvir for treatment of hepatitis C virus infection in Canadian provinces/territories. METAVIR = Meta-Analysis of Histologic Data in Viral Hepatitis, n. a. = not available.

pressed HIV RNA levels.¹⁹ Canada's broader access is more aligned with clinical guidelines.^{20–22} Up to half of jurisdictions in Canada restricted prescriber type to specialist. Although specialists are better trained to oversee direct-acting antiviral-based therapy in selected circumstances (e.g., decompensated cirrhosis), providing general practitioners with education, training and linkage to HCV specialists could broaden therapy access to regions where specialists are limited (e.g., Prince Edward Island). In Australia, all general practitioners can prescribe HCV therapies in consultation with a specialist (e.g., via email), a practice that could be emulated in Canada.³⁵

Since March 2016, the Australian government has provided universal access to HCV treatments — committing A\$1 billion over the next 5 years — with no restrictions based on liver disease stage, recent drug use, HIV coinfection or specialist prescribing.^{36,37} Although there is a cap on expenditure, there is none on the number of patients treated per year, with 26 000 treated in the first 5 months of listing (12% of 230 000 people with chronic HCV infection).³⁸ The development of a national drug formulary in Canada could allow for greater standardization of treatment reimbursement and perhaps result in greater “buying power” in negotiating prices for new therapies.³⁹

Limitations

There were several study limitations. Retrieving complete online criteria was challenging. Although ministries provided criteria when contacted, greater information transparency is needed. In addition, online criteria may not be up to date; for example, the Non-Insured Health Benefits Program criteria

updates lagged behind those of other jurisdictions, which could possibly impede treatment access. Also, criteria may have been updated after the data were extracted. Furthermore, this study cannot address implementation of criteria. Additional research might also highlight greater interjurisdictional heterogeneity, e.g., fibrosis stage cut-off values and methodologies differed by jurisdiction. We were unable to retrieve online private health insurance criteria for comparison. Two US studies investigating fewer than 7 state plans showed that insurance type was associated with initiation of HCV infection treatment and approval of reimbursement claims.^{40–42} Similar research in Canada would be beneficial.

Implications for practice

This review of criteria for reimbursement of HCV direct-acting antivirals in Canada showed greater reimbursement homogeneity than in the US.¹⁹ The purchasing power of the pan-Canadian Pharmaceutical Alliance may partly explain this result, as US states lack an equivalent committee. The alliance process may, however, inadvertently benefit jurisdictions with larger HCV-affected populations (i.e., that purchase more drugs). Prince Edward Island negotiated with a drug manufacturer directly and, as a result, did not offer sofosbuvir and ledipasvir–sofosbuvir.⁴³ The impact of the alliance, especially with the addition of federal plans, will become clearer following further negotiations.⁴⁴

To achieve World Health Organization HCV elimination targets by 2030,⁴⁵ increased uptake of HCV therapy, especially by people who inject drugs, is essential to reduce HCV incidence and contribute to viral elimination in Canada.

Table 5: Key eligibility criteria for reimbursement of paritaprevir–ritonavir–ombitasvir plus dasabuvir (with or without ribavirin) for treatment of hepatitis C virus infection, by jurisdiction

Jurisdiction	Restriction				
	Minimum fibrosis stage required	Substance use	HIV coinfection	Prescriber	Decompensated cirrhosis
Province/territory					
British Columbia	F2	None listed*	Eligible	General practitioner	None listed
Alberta	F2	None listed	Eligible	General practitioner	Ineligible
Saskatchewan	F2	None listed†	Eligible	General practitioner	Ineligible
Manitoba	F2	None listed	Eligible	Specialist	Ineligible
Ontario	F2	None listed	Eligible	General practitioner	Ineligible
Quebec	F3‡	None listed	Eligible§	General practitioner	Ineligible
New Brunswick	F2	None listed	Eligible	General practitioner	Ineligible
Nova Scotia	F2	None listed	Eligible	Specialist	Ineligible
Prince Edward Island	No restrictions	None listed¶	Eligible**	General practitioner	None listed
Newfoundland and Labrador	F2	None listed	Eligible	General practitioner	Ineligible
Yukon	F2	None listed	Eligible	Specialist	Ineligible
Northwest Territories	F2	None listed	None listed	None listed	None listed
Nunavut	F2	None listed	None listed	None listed	None listed
Federal					
Non-Insured Health Benefits Program	F2	None listed	None listed	None listed	None listed
Correctional Service Canada	F2††	None listed	None listed	None listed	None listed

*No specific criteria, but exclusion criteria stated: "Patients who are at high risk for non-compliance."
†However, prescriber could indicate that directly observed therapy was recommended; also, the patient consented (via signature) to understanding treatment adherence.
‡In year 1 (2015/16), only those with stage F3 or F4 fibrosis received reimbursement.
§Treated in year 1 if stage F3 or F4 fibrosis.
¶There were restrictions (e.g., active injection drug use) left to physician's discretion.
**Must be treated by a specialist off-island.
††Treatment prioritized to patients with stage F3 or F4 fibrosis; treatment for those with stage F0, F1 or F2 fibrosis was reviewed on a case-by-case basis.

Restrictions such as fibrosis stage are neither cost-effective nor evidence-based. Although a "one-size-fits-all" strategy has drawbacks (e.g., the ability of provinces/territories to respond to HCV burdens will vary), the development and adoption of a national HCV strategy in Canada akin to those in Australia⁴⁶ and Scotland^{47,48} could facilitate volume-based discounting, reduce provincial/territorial heterogeneity, direct treatment to at-risk populations and broaden equitable access to enable the elimination of HCV infection in Canada.

Conclusion

This review of criteria for reimbursement of HCV direct-acting antivirals in Canada showed substantial interjurisdictional heterogeneity, with most provinces/territories having restrictions based on liver disease stage, few restrictions based

on drug and alcohol use, and allowing prescribing by general practitioners.

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