Policies For Reimbursement Of Direct-Acting Antiviral Treatment For Hepatitis C Virus Infection In Canada: *'A Patchwork Of Obstruction'*

Abstract: #P080

ACTION HEPATITIS CANADA / ACTION HÉPATITES CANADA

CanHepC — Canadian Network on Hepatitis C / Réseau Canadien sur l'Hépatite C

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Introduction

- The first interferon-free direct-acting antiviral (DAA) hepatitis C virus (HCV) treatment regimens were approved for use by Health Canada in 2013.
- At that time, there were disease-stage restrictions on eligibility for reimbursement of DAAs through publicly-funded drug plans.
- Consistent with clinical guidelines, these reimbursement restrictions were all lifted by 2018.
- However, several other non-disease stage related restrictions persist, including; the requirement to submit genotype results even when pan-genotypic regimens are being prescribed to treatment-naïve patients, needing two consecutive HCV RNA positive tests 6 months apart, or needing fibrosis stage to be submitted even when fibrosis stage is not used to determine if patients qualify for HCV treatment.
- These policies prevent being able to implement 'test and treat strategies' which have been shown to accelerate HCV elimination efforts.

Purpose

- The objective of this study was to describe criteria for reimbursement of DAAs for HCV treatment in publicly-funded drug plans across Canada, and appraise them with respect to enabling or obstructing aspects of simplified or rapid HCV treatment initiation which are part of 'test and treat strategies'.

Methods

- We reviewed the reimbursement criteria for DAAs in the 10 provincial, three territorial and three federal publicly funded drug plans including one in federal correctional facilities.
- Data were extracted from October to December 2020.
- The outcomes extracted were selected based on suggested activities put forward in the "Blueprint to Inform Hepatitis C Elimination Efforts in Canada," released in 2019.
- The primary outcomes extracted were the requirement for, or availability of:
  1) rapid or point-of-care HCV RNA test results,
  2) HCV genotype test,
  3) fibrosis staging,
  4) a minimum of six months between the first two positive HCV RNA test results for DAA approval;
  5) the time taken for DAA approval to be given.

Results

- Overall, 94% (15/16) of Canadian publicly funded drug plans have at least one policy in place for DAA reimbursement approval that obstructs simplified or rapid HCV treatment initiation (Figure 1).
- Two plans (13%) restrict the treatment of HCV with DAAs to people with confirmed chronic infection, excluding people with unknown or acute infections until they have had two HCV RNA positive tests six months apart.
- Nine plans (56%) require faxed requests for treatment reimbursement approval, and five (31%) require fibrosis stage to be submitted with all requests (APRI/FIB-4 or FibroScan).
- Six plans (38%) require genotype test results, despite the use of pan-genotypic HCV regimens for treatment-naïve patients.
- Only one plan (Prince Edward Island) accepts results from a finger stick HCV RNA test (e.g. Cepheid GeneXpert assay) as proof of infection only among key populations for reimbursement requests, which is through a Research Use Only exemption as the test is not Health Canada Approved.

Policy obstructs rapid or simplified HCV treatment | Policy may obstruct 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
Alberta	No	No	No	No	Faxed form 1-3 days
British Columbia	No	No#	Yes	No	Online Same day∞
Manitoba	No	Yes	Yes	No	Faxed form 2-14 days
New Brunswick	No	Yes	Yes	No	Faxed form 2-28 days
Newfoundland & Labrador	No	Yes	No	No	Faxed form Up to 28 days
Northwest Territories	No	No%	No^	No	Faxed form 1-3 days
Nova Scotia	No	Yes	No&	No	Approval not required*
Nunavut	No	No%	No^	No	Faxed form 1-3 days
Ontario	No	Yes$	No	Yes	Approval not required*
Prince Edward Island	Yes	No	No	No	Approval not required*
Quebec	No	No%	No&	No	Online Same day
Saskatchewan	No	No%	Yes	No	Telephone Same day
Yukon	No	Yes	Yes	No	Faxed form Up to 28 days
People with FN Status (NIHB)	No	No%	No^	No	Faxed form 1 day
Correctional Service Canada (CSC)	No	No%	No	No	Approval not required*
Veterans Affairs Canada (VAC)	No	No%	No	No	Approval not required*

Abbreviations: First Nations (FN), Non-Insured Health Benefits (NIHB), Direct Acting Antiviral (DAA), hepatitis C virus (HCV).
Temporary during COVID, may continue in future
∞ Province wide online platform for special authority request approval launched, but not yet available for HCV medications
% Genotype not required for DAA-naïve patients being prescribed pan-genotypic regimen
$ Not enforced but technically is actually required
^ Fibrosis stage not required for DAA-naïve patients
& Proof of fibrosis stage not required, just yes/no for cirrhosis
* Uses a 'Limited Use Code' or 'Criteria Code' – no requirement for approval if listed criteria are met. If not eligible for Limited Use criteria, then must be reviewed and that typically takes 2-4 weeks (example is retreatment or treatment of decompensated cirrhosis)

Figure 1. Matrix of hepatitis C treatment reimbursement approval policies for Canadian publicly funded drug plans

Conclusions

- This review of criteria for reimbursement of HCV DAAs in Canada shows substantial interjurisdictional heterogeneity in publicly-funded drug plans.
- These findings could inform health policy at the provincial, territorial and federal levels, allowing identification of specific policy changes that could facilitate HCV treatment uptake, particularly among people who experience marginalisation.
- Removal of requirement for HCV genotyping for DAA reimbursement approval may lead to cost savings
- These findings further support the development and adoption of a national HCV strategy to reduce disparities in treatment access, as well as further support the rationale for a national Pharmacare program in Canada.
- Without the removal of these restrictions on treatment reimbursement eligibility, Canada's progress towards elimination of HCV as a public health threat by 2030 may be jeopardized.

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