Canadian Cancer Society
Société canadienne du cancer

CANCER DRUG ACCESS FOR CANADIANS

SEPTEMBER 2009

Executive Summary

Access to cancer drugs – defined as the ability to obtain recommended cancer drug treatments in a timely manner and without financial hardship – is expected by all Canadians as part of the health system that we rely upon for such potentially life-saving interventions.

While the publicly funded health system provides cancer drugs administered in hospitals and clinics free of charge to patients, half of newer cancer drugs are taken at home and are the responsibility of the patient. Since their costs are prohibitive to all but the wealthiest Canadians, access to cancer drugs has to a very large extent become dependent on public and private insurance. This system of coverage is now the “gatekeeper” for cancer patients to obtain many needed therapies.

Having inadequate coverage has enormous cost implications for patients and their families. With a price tag of $65,000, the average cost per course of treatment with newer cancer drugs is approaching the average annual income of Canadian households. Three quarters of newer cancer drugs taken at home cost over $20,000 a year. The introduction of these high-priced cancer drugs during the past few years has exposed gaps and disparities in our patchwork system of coverage.

Not all Canadians are insured for these costs. Some have no coverage at all and may not be able to afford to purchase an individual policy. Canadians who do have insurance are usually required to pay co-insurance amounts which can be in the tens of thousands of dollars. In some cases, patients are denied drugs that their oncologist has prescribed because the drug plan has not included them on its formulary, or list of covered drugs.

Some public and private drug plans have responded positively to these new challenges. Several provincial governments have established high-cost drug programs to provide some protection for their residents. Only two jurisdictions remain without a universal program. Private insurers have increased the maximum payouts for claims to reflect the new drug cost realities and many plans cap beneficiaries’ out-of-pocket expenses.

However, major challenges remain. One in twelve Canadian families still face catastrophic drug costs (defined here as greater than three per cent of net household income), even in provinces where universal coverage exists. Many Canadians, especially seasonal or self-employed workers and those with low incomes, do not have access to affordable insurance. Workers who lose their jobs are vulnerable because almost all private insurance is employer sponsored.

There are no agreed standards for the financial burden placed on Canadian families for prescription drugs. Private drug plans typically require 20 per cent co-payment for prescriptions – this amounts to $13,000 for an average course of treatment with a

newer cancer drug, or 17 per cent of an average family's income. More than one in six private plans has an annual or lifetime cap, many of which are below the costs of newer cancer drugs. As public and private drug plans attempt to control their expenditures, cost are shifting increasingly to patients. The health of patients is at risk as many (especially those with low incomes) forgo drug treatments as costs rise.

There are also no agreed standards concerning which drugs should be covered. Because each of Canada's 19 public drug plans and myriad private plans makes its own decisions, there are significant disparities between provinces and between public and private insurers regarding which specific cancer drugs are covered. While the interim Joint Oncology Drug Review made a significant impact over the past two years in reducing interprovincial disparities, it remains unclear whether this body will become a permanent structure. Also, there are instances where clinical guidelines recommending certain drug treatments are published by a province but are not funded by their drug program.

Canadians' confidence in the system of access has eroded – a recent survey showed that almost half the respondents felt that, if diagnosed with cancer today, they would not have access to all the medications needed for treatment. The gaps and disparities in our present system are complex and multifaceted. Accordingly, a concerted program of action is called for that brings together all sectors to focus on these serious issues for the benefit of all Canadians.

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1. Introduction

Access to cancer drugs has become a critical issue for Canadians. The introduction of a new generation of medications with rapidly escalating costs has pressurized health systems, revealing holes in the public and private structures upon which cancer patients and their families depend for their lives and their health.

Importance of the issue

Having access to cancer drugs means that all Canadians should be able to obtain the medications recommended by their oncologist, based on clinical evidence, in a timely manner and without financial hardship. The structures that make this possible include the cancer care system, publicly funded drug plans and private insurance.

There are many gaps in the present system that need to be recognized and addressed. Because half of all newer cancer drugs are taken at home they are not covered by the public health system, patients require coverage either by public or private drug plans. Not all Canadians have insurance.

And while it is indisputable that recent advances in cancer drug treatments have had a positive impact on clinical outcomes, their prices are far beyond a level that we have seen before. This factor, combined with a significant increase in the utilization of drugs as a mode of therapy, have put pressure on insurers to manage cancer drugs much more closely. As a result, costs have shifted from drug plans to patients and access to specific cancer drugs has become more restricted.

The issue of access to cancer drugs is important not just to patients to but to every Canadian. Nearly all of us will be affected by cancer at some point in our lifetimes, either directly or through someone close to us. Most cancer patients are treated by drug therapies, yet the majority of Canadians do not know whether they will be able to access the drugs they need. Most are, understandably, unaware of whether their insurance will cover the drugs they need until they are needed. Confidence in the system of coverage is low, perhaps due to the widespread publicity this issue has received in recent years. Almost half of Canadians (43%) believe that, if diagnosed with cancer today, they would not have access to all the medications needed for treatment.[1]

[1] Myeloma Canada Press Release; *Canadians lack confidence in access to cancer medications;* February 25, 2009.

Dimensions of the issue

Numbers of Canadians at risk

According to Canadian Cancer statistics 171,000 Canadians developed cancer in 2008.[2] Of people who are diagnosed with cancer, the vast majority receive some form of drug therapy — in addition to surgery and radiation — as part of their treatment. Forty per cent of Canadian women and 45 per cent of men are expected to develop cancer in their lifetimes.

Approximately 700,000 Canadians — over one in fifty — are living with cancer that was diagnosed up to ten years earlier. These numbers will become larger in the future as the incidence of cancer increases (largely due to an aging population) and people living with cancer survive longer.

Financial perspective

How much do Canadians spend on cancer drugs?

According to IMS Health,[3] Canadians spent $1.1 billion on cancer drugs in 2008, representing 5.4 per cent of total pharmaceutical purchases in Canada.

Half of cancer drugs are not covered by the publicly funded health system

Just over half of all costs for cancer drugs are paid by hospitals and clinics. Under the terms of the *Canada Health Act,* drugs administered in an institution must be covered by the public health system. Eleven of the 21 cancer drugs introduced since 2000 (including five of the top ten selling oncology medications) are administered at home and are therefore the patient's responsibility.

Cancer drug costs are rising rapidly

Cancer drug costs have risen dramatically during the past five years. Purchases of cancer drugs increased more than twice as fast (16.5 per cent annually) as the pharmaceutical market as a whole (seven per cent annually) and over five times as fast as the growth in cancer incidence (three per cent).

The proportion of cancer control budgets that is allocated to drugs has tripled over the past two decades in some jurisdictions.[4] This is attributed in part to increased demand and in part to higher prices. In the treatment of colorectal cancer, for example, the cost of a drug treatment regimen has risen from $300 in the 1980s, to $10,000 in the 1990s, to between $20,000 and $30,000 in this decade.

For cancer drugs taken at home, the picture is similar. Of the 12 cancer drugs approved by Health Canada since 2000 that are administered outside a hospital or clinic, three-quarters cost $20,000 or more annually.

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[2] Canadian Cancer Statistics 2009.
[3] IMS Health Incorporated. Canadian Drug Store and Hospital Purchases.
[4] Dr. Tony Fields, Alberta Cancer Board; CAMO presentation, Toronto, April 30, 2009.

Table 1 Cost of cancer drugs taken at home (year of approval: 2000-2009)

Cancer Drug	Cancer Site	Drug Cost (per year)
Aromasin	Breast	$1,825 [5]
Eligard	Prostate	$3,800 [6]
Faslodex	Breast	$1,825 [7]
Gleevec	Leukemia, Stomach	$37,350 [8] to $74,490 [9]
Nexavar	Kidney, Liver	$63,875 [10]
Revlimid	Myeloma	$131,765 [11]
Sprycel	Leukemia	$50,000 to $55,000 [12]
Sutent	Kidney, Stomach	$60,200 [13]
Tarceva	Lung	$19,465 [14]
Tasigna	Leukemia	$66,600 [15]
Tykerb	Breast	$35,000 [16]
Velcade	Myeloma	$30,000 to $57,000 [17]

For cancer patients without adequate insurance protection, these costs can be devastating.

What action has been taken?

Calls have been made for many years to include pharmaceuticals within the orbit of the *Canada Health Act*. The founders of medicare originally intended for drugs and dental services to be added to the public health system over time, but this vision has never been followed through. As the role of drugs in medicine has increased in modern times, and as access problems have begun to surface with the introduction of high cost specialty drugs, the situation has become acute.

The issue of access to cancer drugs was brought to public attention in 2005 through the news media. Lisa Priest, a reporter for the Globe and Mail, won the Michener

[5] RAMQ Liste de médicaments June 2009
[6] ESI Canada Health Flash, vol. 6, no. 1, 2004.
[7] ESI Canada Health Flash, vol. 6, no. 4, 2004.
[8] Ontario Public Drug Programs; CED Recommendation, July 2007
[9] Ontario Drug Benefit Formulary January 2006
[10] Ontario Public Drug Programs; CED Recommendation, January 2009
[11] Ontario Public Drug Programs; CED Recommendation, April 2009
[12] Ontario Public Drug Programs; CED Recommendation, November 2008
[13] PPS January 2007 and Ontario Public Drug Programs; CED Recommendation May 2008
[14] RAMQ Liste de médicaments June 2009
[15] ESI Canada Health Flash, vol. 11, no. 1, 2009
[16] Dr. Lorne Brandes: *The hope, the hype, the hard reality of cancer drug development;* CTV News, June 9, 2009
[17] Cancer Advocacy Coalition of Canada; Annual Report Card 2005 and Canadian Press; *Ontario myeloma patients want their drug funded;* Jul. 24 2005

award for public-service journalism for her work covering Herceptin access in that year. Her series of articles on cancer drug access was published in late 2007 and several other newspapers have since covered the issue with regularity.

During the same period, the Cancer Advocacy Coalition of Canada presented articles critical of the system in each of its annual Report Cards. Since 2004, each publication has focused on an aspect of inequity in access to cancer drugs and each release has been accompanied by widespread news media coverage.

Throughout the past few years, two major issues have taken centre stage: catastrophic drug coverage and interprovincial inequities. A third issue that is now emerging is that of insurance coverage.

Catastrophic drug coverage

Public attention has been most acutely focused on catastrophic drug coverage during the past three years. This is the most visible and potentially soluble inequity.

Both the Romanow and Kirby commissions recommended in 2002 that Canadians be covered for catastrophic drug costs.[18,19] However, the National Pharmaceuticals Strategy, announced in 2004 to address drug access and system sustainability, has stalled.

Several organizations have come forward with position papers calling for catastrophic coverage for all Canadians. The Canadian Medical Association, the Canadian Pharmacists Association and other professional organizations have posted position papers on their websites, as have a multitude of patient organizations.

In 2007 and 2008, Newfoundland & Labrador and Nova Scotia introduced expanded pharmacare programs which provide some degree of coverage for their residents, although these fall short of providing universal catastrophic coverage as defined in this report. This leaves only New Brunswick and Prince Edward Island without any system of universal protection. In September 2008, pressured by patient groups, the health ministers committed at their annual meeting to address the issue during the coming year. In 2009, the new health minister in New Brunswick announced that she is committed to presenting a proposal to her colleagues within the year.[20] Although Prince Edward Island added a large number of cancer drugs to its High Cost Drug Program in 2009, this move falls short of a universal program of catastrophic coverage for all families in the province.

[18] Romanow, R; *Building on Values: The Future of Health Care in Canada*. November 2002.
[19] The Standing Senate Committee on Social Affairs, Science and Technology; *The Health of Canadians – The Federal Role;* October 2002.
[20] *Drug plan is non-negotiable*; Times & Transcript (New Brunswick); July 2nd, 2009.

This matter continues to receive public attention. Most recently, the Canadian Life and Health Insurance Association issued a policy paper calling for a collaborative approach to resolving several issues, including catastrophic coverage.[21]

Interprovincial inequities

A very significant event affecting cancer drug access took place behind the scenes while the issue of catastrophic coverage was escalating in public. One of the most irksome aspects of access for Canadians has always been interprovincial inequities. Why can a cancer patient in British Columbia, for example, receive a particular drug through the public health system when someone living in another province cannot?

In an attempt to help resolve these inequities, and to bring efficiency to the process, the premiers of Saskatchewan and Manitoba in 2006 initiated the interim Joint Oncology Drug Review, which rapidly expanded to include all provinces (except Quebec). To date, the interim Review appears to have had a large impact on aligning funding decisions for cancer drugs across the country and a proposal has been put forward to governments to make this a permanent body.

Prescription drug insurance

The lack of universal coverage of Canadians for the costs of prescription drugs taken at home is emerging as an important issue. This was covered in the Cancer Advocacy Coalition of Canada's 2008 Report Card, released in February 2009, and received widespread press coverage.

Although public and private systems of insurance are in place, not all Canadians are insured and not all insurance is adequate. (Quebec made prescription drug insurance mandatory in 1997 and legislated minimum standards of coverage, but is the only province to do so.) Insurance plans were not designed to cover such high drug costs. As a result, deficiencies are now showing up which leave patients financially burdened, with fewer drugs covered, or experiencing delays and cumbersome paperwork – or all of these – as the insurance system struggles to cope with pressures to control plan costs without sacrificing plan quality.

This report

Each of the concerns described above is discussed in greater detail in this report. The document is designed to provide the facts behind the issues and to identify gaps and disparities.

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[21] Canadian Life and Health Insurance Association. *CLHIA Report on Health Care Policy: Towards a Sustainable, Accessible, Quality Public Health Care System.* June 3, 2009.

The report focuses predominantly on coverage for cancer drugs and takes the perspective of the patient. Access to cancer drugs is a broad topic that includes other aspects that are out of scope for this document, such as:

- Manufacturers' decisions to introduce a new cancer drug in Canada
- Health Canada's approval process: timeliness and restrictions on approvals
- Health Canada's Special Access Program for releasing unapproved drugs for certain patients
- Impact of the Patented Medicines Prices Review Board's policies on controlling cancer drug prices and restricting manufacturers' compassionate drug practices
- The timeliness of funding decisions by payers
- System sustainability
- Comparison of Canada with other industrialized countries

By focusing on a narrow set of issues, it is hoped that a direction for action will be clearer for organizations seeking to improve access to cancer drugs for Canadians.

2. Which Canadians have coverage for cancer drugs?

As noted in the Introduction, cancer drugs administered in hospitals and cancer clinics are paid by the provincial and territorial governments, under the terms of the *Canada Health Act*. Half of newer cancer drugs, however, are taken at home and are the responsibility of the patient.

Fortunately, most Canadians have some form of insurance coverage for these costs. The exception is a large percentage of the populations of two provinces (Prince Edward Island and New Brunswick) who have no coverage. Canadians living east of the Saskatchewan border — where cancer drugs are not automatically covered for all residents through the provincial cancer agency — face varying degrees of financial burden associated with their coverage, even if they have insurance.

Quality of insurance also varies widely with respect to which drugs are covered. Only those medications included on a plan's formulary, of list of covered drugs, will be paid for. The comprehensiveness of drug plan formularies differs between private and public insurance, and among provincial and territorial drug plans, in terms of the number of drugs covered, the timeliness of funding decisions and the bureaucratic complexities involved in applying for access to drugs that are designated as restricted.

What types of insurance coverage do Canadians have?

According to statistics from Applied Management Consultants, 43 per cent of Canadians are covered primarily by a public drug plan for the cost of prescription medications, and 56 per cent primarily by private insurance.[22] The Canadian Life and Health Insurance Association reports that 65 per cent of Canadians have private insurance coverage.[23] (The latter figure is somewhat higher because some individuals, such as retirees, have access to both public and private insurance.)

The proportion of Canadians who are insured by public plans for the cost of cancer drugs specifically is much higher – 68 per cent — because the western provinces (Saskatchewan, Alberta and British Columbia) pay for cancer treatments for all of their residents. Less than one per cent (0.8 per cent) of Canadians have no coverage for cancer drugs — all of whom live in New Brunswick and Prince Edward Island.

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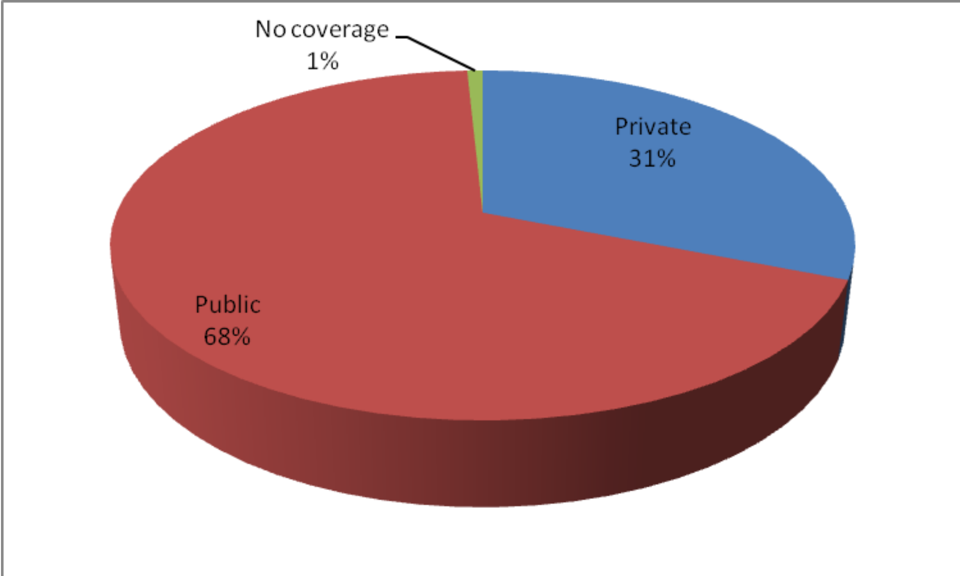
[22] Applied Management Consultants. Population Prescription Drug Insurance Status Model (PRxISM). Coverage of Canadians aged 15+.

[23] Canadian Life and Health Association. *Facts 2008.*

Chart 1 Coverage for cancer drugs in Canada (persons aged 15+)



Source: Applied Management Consultants, 2009

Private insurers play an important role, even in provinces with universal public coverage, as shown in the table below.

Table 2 Public and private payer roles in cancer drug coverage

Province	Public Payer Role	Private Payer Role
BC, AB & SK	Coverage of cancer drugs for all residents	Coverage of cancer drugs not approved for public funding for plan members
MB	Coverage of cancer drugs for all residents after the family prescription costs exceed the income based deductible.	Coverage of cancer drugs until the family prescription costs exceed the income based deductible and coverage of cancer drugs not approved for public funding for plan members.
ON	Coverage of cancer drugs for residents eligible for the public drug plans.	Coverage of cancer drugs for plan members
QC	Coverage of cancer drugs for all residents without private coverage.	Coverage of cancer drugs for plan members
Atlantic	Coverage of cancer drugs for residents eligible for the public drug plans.	Coverage of cancer drugs for plan members
Territories	Coverage of cancer drugs for all residents.	Coverage of cancer drugs for plan members

Source: Applied Management Consultants

Canadians with private insurance have some advantages over those covered solely under a public plan. As will be discussed later, the financial burden may be less, the number of drugs covered is generally higher and funding decisions are usually faster for those with private insurance.

Who is eligible for coverage?

Almost all private insurance coverage in Canada is provided by employers and/or unions to employees and, in some cases, to retirees. Only 2.4 per cent of private insurance is purchased by individuals.[24]

Other Canadians are eligible for coverage of cancer drugs under a provincial, territorial or federal drug plan. Table 3 shows which groups of Canadians are eligible for public coverage, through either the jurisdiction's drug plan or through a specific program designed to protect residents against drug costs that are high relative to the family's income.

These gaps in coverage leave some Canadians vulnerable to drug costs. Low income workers who do not have insurance coverage through their employers are not eligible for public coverage in New Brunswick and Prince Edward Island. In Ontario, they are eligible for coverage of high drug costs only. Higher income workers without private insurance are not eligible for coverage, or must pay prohibitively high deductibles, under the public plans in Nova Scotia and in Newfoundland & Labrador.

Cancer patients living in New Brunswick or Prince Edward Island who are covered by private insurance may not be able to retire since, if they have moderate or high incomes, they will not be eligible for coverage under the public drug plan.

[24] Canadian Life and Health Insurance Association; *Facts 2008*.

Table 3 Eligibility for public coverage of cancer drugs taken at home

	Eligibility for Public Drug Plan	Specific High Drug Cost Program	Gaps in Eligibility
BC	All	N/A	
AB	All	N/A	
SK	All	N/A	
MB	All	N/A	
ON	Seniors Social assistance	All others	
QC	All	N/A	
NB	Low income seniors Social assistance	Limited*	Working families without private coverage. Moderate and high income seniors**
PE	Seniors Social assistance	Specific cancer drugs***	Working families without private coverage. High income families
NS	Seniors, social assistance and low income families	Cancer drugs for low-income residents	Average and high income families without private insurance
NL	Seniors, social assistance and low income families	All others	
YT	All	N/A	
NT	All	N/A	
NU	All	N/A	
Federal	Registered First Nations and Inuit, military, RCMP, inmates, refugees	N/A	

* NB residents may apply to the Department of Social Development for "Health Card Only" benefits which provide 100% coverage for drugs listed on the public formulary. Eligibility for this benefit requires that applicants have high medical expenses relative to income and that they exhaust their personal assets first.
** NB seniors who do not qualify for the public drug plan may purchase drug insurance through the Medavie Blue Cross Seniors' Prescription Drug Program.
*** All PEI residents with net household incomes less than $150,000 per year are eligible to receive some assistance with payments for a selected list of oral cancer drugs.

Which Canadians have no coverage?

Complete lack of insurance coverage is now a problem in two provinces – New Brunswick and Prince Edward Island.

Since 2007, Newfoundland & Labrador and Nova Scotia have implemented programs that cover low-income residents for a portion of high drug costs. Higher income families continue to face a significant financial burden under these programs. However, one-quarter of the population of Prince Edward Island[25] and 29 per cent of residents of New Brunswick aged 15 and over – over 200,000 persons in total - have no coverage at all and must pay cash for prescription drug expenses. One in five New Brunswick seniors has no coverage, nor do three out of ten working-aged adults in both provinces.[26]

Table 4 No coverage in Prince Edward Island and New Brunswick, by age cohort

	Prince Edward Island			New Brunswick	
Age cohort	Number	Percentage		Number	Percentage
15-29	8,600	29%		41,900	29%
30-64	20,800	31%		119,600	31%
65+				24,300	21%
All age groups	29,400	25%		185,800	29%

Source: Applied Management Consultants

As was shown in the 2009 report of Canadian Cancer Statistics,[27] cancer is a disease that affects all age groups, including adolescents and young adults who bear a higher burden of years lost due to their disease. Many of the medications used to treat the types cancers prevalent in younger persons (including leukemias, lymphomas and brain cancer) are among the list of high-cost drugs noted in the Introduction. Therefore, vulnerability extends across all age groups.

Continuity and flexibility of insurance

Canadians whose circumstances change may be at risk because of interruptions in their insurance status or because they temporarily cannot meet the financial requirements of their insurance plan.

Workers who are insured privately may lose a job which included health benefits. Insurers have in recent years improved offerings to continue coverage for early retirement or job loss. Such “follow me” plans offer the advantage of lower group rates and no restrictions on medical status, provided the employee signs onto the plan when they leave their employer. However, many employees are unaware of these options and of the extent of their exposure to crippling costs without coverage. Even

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[25] PEI’s High Cost Drug Program covers the cost of certain cancer drugs for families with net annual household incomes of less than $150,000.

[26] Applied Management Consultants. Population Prescription Drug Insurance Status Model (PRxISM). Coverage of Canadians aged 15+.

[27] Canadian Cancer Statistics 2009. Available at: www.cancer.ca

if they are aware, a laid-off worker's reduced income may discourage him or her from seeking continued insurance.

Persons who do not have access to an employer-sponsored plan may find the costs of individual insurance prohibitive. In addition, while group plans provide coverage without restrictions, pre-existing medical conditions (such as a history of cancer) may disqualify an applicant from coverage under an individual plan.

For Canadians who change insurers, disparities may cause gaps in coverage. A person who moves from British Columbia to Manitoba, for example, may find that a drug covered under her former plan is not on the formulary in the new province. A retired worker in Ontario may have to pay for a cancer drug that was covered under his former employer's health plan but is not funded by the province.

3. Financial burden of cancer drugs for Canadians

Despite what most Canadians reasonably believe, having coverage for cancer drugs does not equate to a lack of financial burden. Cost-sharing requirements vary significantly among public and private drug plans and can create unexpected hardship for families.

Which costs do insured Canadians pay?

Costs associated with insurance coverage for cancer drugs vary widely across the country and according to whether coverage is provided by a private or public plan.

Cancer drug expenses are 100 per cent covered by the government in Saskatchewan, Alberta, British Columbia, Northwest Territories, Nunavut and by the federal plans (provided the drug is listed on the formulary). Nineteen per cent of private drug plans also do not require payments from planholders.[28]

Other Canadians must pay a portion of cancer drug costs out-of-pocket.

For privately insured Canadians, these costs include co-insurance amounts and premiums. Two-thirds of plans require beneficiaries to pay co-insurance amounts (usually a percentage of the prescription cost) and a further 18 per cent of plans require a fixed co-payment amount.[29]

Public drug plans sponsored by provincial governments generally require a co-insurance payment for prescription drugs. Newfoundland & Labrador, Nova Scotia, Quebec, Manitoba and Ontario's Trillium Drug Program (for high drug costs relative to income) charge an income-based premium or deductible (or sometimes both). Yukon charges a flat premium and no co-insurance amount. Prince Edward Island, New Brunswick and the Ontario Drug Benefit program charge a small co-payment for each prescription.

How much do insured Canadians pay?

Canada ranks second only to the U.S. among industrialized countries in the amount of out-of-pocket costs paid for prescription drugs. Six per cent of Canadians pay over

[28] Applied Management Consultants, June 2009.
[29] Applied Management Consultants, June 2009.

$1,000 per year for drug costs[30] and one in twelve Canadian families spends over three per cent of its net household income on prescription drugs.[31]

Private insurance

For an individual who purchases extended health benefits on their own, premiums range between $1,500 and $3,000 a year and co-insurance is an additional 25 to 30 per cent of the prescription cost.

Group policies are much more common, accounting for 98 per cent of all lives covered by private health insurance in Canada. As the plan sponsor, it is the employer's role to make decisions about cost-sharing and plan quality. The insurance company provides a plan to meet the sponsor's requirements.

Most employers who sponsor a plan share the costs of premiums with employees through payroll deductions. Three-quarters of private plans charge a co-insurance amount which is, most commonly, 20 per cent of the total prescription cost. In those plans where the co-payment amounts are fixed, these are usually from $5 to $25.[32] Some plans set a maximum out-of-pocket expense that the beneficiary has to pay.

Of particular concern to cancer patients, a significant minority of insurance plans have annual or lifetime caps on claim amounts. Beneficiaries of these plans are responsible for all drug costs above this limit. Approximately 18 per cent of beneficiaries are covered by plans with lifetime or annual caps. This proportion has increased by 20 per cent during the past three years. Retirees are especially subject to lifetime maxima.[33]

The amount of the annual maximum that beneficiaries are required to pay has generally shifted upwards in recent years, reflecting increasing costs of prescriptions, however for most plans it remains lower than the cost of most newer cancer drugs. In 2008, the annual maximum (for all extended health benefits claims) was only $10,000 for nearly 70 per cent of beneficiaries who are covered under these types of plans.

The maxima for plans having a lifetime cap has also risen in recent years, however many beneficiaries remain vulnerable to high cancer drug costs. In 2008, nearly one

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[30] Morgan S, et al.; *Toward High-Performing "Pharmacare" Systems: A Review of Experiences in Seven Countries*. Working paper presented at the 2008 Annual Conference of the Canadian Association for Health Services and Policy Research, Gatineau QC, May 2008.
[31] Statistics Canada. *Table 109-5012 - Household spending on prescription drugs as a percentage of after-tax income, Canada and provinces, annual*, CANSIM (database). http://cansim2.statcan.gc.ca/cgi-win/cnsmcgi.exe?Lang=E&CNSM-Fi=CII/CII_1-eng.htm (accessed: June 29, 2009)
[32] Applied Management Consultants, June 2009.
[33] Applied Management Consultants, June 2009.

in three beneficiaries covered under a plan with a lifetime cap was insured for less than $50,000.[34]

Public insurance

The amount that Canadians covered by a provincial or territorial plan are required to pay varies by jurisdiction and by the individual's demographic status.

Public plans generally do not place upper limits on coverage, with the exception of Alberta's Non-Group Benefits plan which has a $25,000 annual maximum (although this can be waived in certain circumstances). In Quebec, the maximum out-of-pocket cost to any individual with public or private coverage is set by legislation.

To illustrate the variations among types of insurance and among jurisdictions, the following table shows how much residents in ordinary demographic groups would pay for a moderate cancer drug cost of $2,000 per year. (This is the cost of common hormonal therapies for breast and prostate cancers, for example.)

This amount is expressed as a percentage of net household income[35] for three groups:

- Average income senior couple (net income $54,200)
- Average income non-senior family[36] (net income $75,000)
- Low-income non-senior family (net income $30,000) not on social assistance.

For the private insurance examples, only the typical 20 per cent co-insurance amount is shown. Premiums, deductibles and other co-payments are not included.

Table 5 Out-of-pocket costs for $2,000 cancer drug expenses

Type of insurance	Type of family	Public Plan Eligibility	Out-of-pocket cost	Percentage of net family income
Private insurance:				
	Non-senior avg. income	N/A	$400 +	0.5%
	Non-senior low income	N/A	$400 +	1.7%
Public insurance:				
BC	Senior	Yes	$0	0%
	Non-senior avg. income	Yes	$0	0%
	Non-senior low income	Yes	$0	0%
AB	Senior	Yes	$0	0%

[34] Applied Management Consultants; *Trends and Issues in Plan Design*; Insights, Spring 2009
[35] Statistics Canada; *Average income after tax by economic family types.* 2007. The Nova Scotia Family Pharmacare deductible is calculated on gross income; an overall tax rate of 30 per cent was used here to calculate gross income.
[36] "Family" is defined for the purposes of calculation as two adults with two children (i.e., three dependants)

	Non-senior avg. income	Yes	$0	0%
	Non-senior low income	Yes	$0	0%
SK	Senior	Yes	$0	0%
	Non-senior avg. income	Yes	$0	0%
	Non-senior low income	Yes	$0	0%
MB	Senior	Yes	$2,000	3.7%
	Non-senior avg. income	Yes	$2,000	2.7%
	Non-senior low income	Yes	$802	2.7%
ON	Senior	Yes	$124	0.2%
	Non-senior avg. income	No	$2,000	2.7%
	Non-senior low income	Yes	$739	2.5%*
QC	Senior	Yes	$954	1.8%
	Non-senior avg. income	Yes	$954	1.3%
	Non-senior low income	Yes	$954 or less**	3.2% or less
NB	Senior	No	$2,000	3.7%
	Senior with MBC coverage	Yes***	$1,260	2.3%
	Non-senior avg. income	No	$2,000	2.7%
	Non-senior low income	No	$2,000	6.7%
PE	Senior	Yes	$25	0%
	Non-senior avg. income	No	$2,000	2.7%
	Non-senior low income	No	$2,000	6.7%
NS	Senior	Yes	$806	1.5%
	Non-senior avg. income	Yes	$2,000	2.7%
	Non-senior low income	Yes	$1,481	4.9%
NL	Senior	Yes	$2,000	3.7%
	Non-senior avg. income	Yes	$2,000	2.7%
	Non-senior low income	Yes	$1,400 or less**	4.7% or less
YT	Senior	Yes	$500	0.9%
	Non-senior avg. income	Yes	$500	0.7%
	Non-senior low income	Yes	$500	1.7%
NT	Senior	Yes	$0	0%
	Non-senior avg. income	Yes	$0	0%
	Non-senior low income	Yes	$0	0%
NU	Senior	Yes	$0	0%
	Non-senior avg. income	Yes	$0	0%
	Non-senior low income	Yes	$0	0%
Federal	Registered First Nations and Inuit, military, RCMP, inmates, refugees	Yes	$0	0%

* Ontario's Trillium Drug Program covers residents whose drug costs exceed a certain percentage of net household income. The Trillium deductible amount is determined by an income-dependent percentage scale.
** The amount payable may be reduced based on this lower income, however the amount cannot be calculated from the available information. The QC premium covers the cost of all drugs for the patient.

*** NB seniors who are not eligible for the public drug plan may purchase drug insurance through the Medavie Blue Cross Seniors' Prescription Drug Program for a premium of $105 per month.

The table shows the financial disparities that Canadian cancer patients experience depending on whether they have public or private insurance and, among the public plans, disparities based on age, income and on where they live.

In general, Canadians pay less for routine drug costs if they have private insurance compared with those relying on the public system (with the exception of those jurisdictions that cover all the costs of cancer drugs on their formularies). However, this calculation does not take into account any premiums, deductibles or other co-insurance amounts that various plans may require. The highest financial burden is, not surprisingly, felt by lower income New Brunswickers and Prince Edward Islanders who are not eligible for any type of public drug insurance.

Among the groups covered under one of the public plans, some pay no out-of-pocket for cancer drugs while others pay more than four per cent of their net family income. Some provinces, such as Ontario and Prince Edward Island, require tiny payments from relatively well-off seniors while providing no coverage for lower income working families. Higher percentages of income are paid by Manitoba seniors and by low-income Newfoundlanders & Labradorians.

Implications of increasing out-of-pocket expenses

Over time, insurers have increasingly shifted costs onto beneficiaries.[37] This has enabled some groups of Canadians to continue receiving coverage that would otherwise have been too expensive for the plan sponsor. In some cases, efficiencies have been gained as unnecessary treatments have been curtailed.

However, certain vulnerable populations have been placed at increased risk because of increasing out-of-pocket expenses. Several Canadian studies have shown that when these expenses rise, patients tend to reduce their use of needed medications.

Following Quebec's introduction of cost-sharing user fees, researchers from McGill University documented a 9.1 per cent decrease in the use of essential drugs among seniors and 14.4 per cent among welfare recipients.[38] Similar results were found in more recent studies among rheumatoid arthritis patients in British Columbia[39,40] and

[37] Applied Management Consultants, 2009.
[38] Tamblyn, R et al. *Adverse events associated with prescription drug cost-sharing among poor and elderly persons*. JAMA, vol.285, no. 4, p. 421, 2001.
[39] Liac, X et al.; *The impact of cost sharing of prescription drug expenditures on health care utilization by the elderly: Own- and cross-price elasticities*; Health Policy, vol. 82, Issue 3, p. 340-347, 2007.
[40] Anis, AH et al. *When patients have to pay a share of drug costs: effects on frequency of physician visits, hospital admissions and filling of prescriptions*; Canadian Medical Association Journal, vol. 173 no. 11, p. 1335, November 2005.

among asthma sufferers in Ontario.[41] Reports from the U.S. show comparable findings.[42,43]

Certain socioeconomic groups are more vulnerable to these costs. A recent study reported that, overall, eight per cent of Canadians did not fill their prescriptions because of cost.[44] In a health survey of 13,587 Canadians, nine per cent said they did not take their medications as prescribed because of cost concerns. These individuals were more likely to be: low income earners, in a poorer state of health, experiencing debilitating pain and seeing a doctor more frequently.[45] A recent study from Newfoundland found that rural cancer patients were more likely to make treatment decisions based on the cost of drugs than those living in urban areas. This was thought to be most likely due to the former group's self-employed or seasonal working status and consequent lack of employer-sponsored insurance.[46]

Patients who cannot afford to take their prescription drugs employ a variety of coping strategies. A study from the U.S. Veterans Administration system which surveyed 4,055 adults taking prescription medications for a chronic disease concluded:

> *"Overall, 31% of respondents reported pursuing at least one of the strategies over the prior 12 months. Twenty-two percent had cut back on necessities, 16% had increased their debt burden, and 18% had underused prescription drugs. Among patients who underused their medication, 67% also had cut necessities or increased debt. ... [The] use of all these strategies was especially common among patients who were low-income, in poor health, and taking multiple medications."*[47]

Cancer patients who experience temporary or permanent reductions in their income due to their disease may be especially at risk. A recent study from Laval University showed that breast cancer patients suffer an average drop in income of 27 per cent while under treatment.[48] This situation has implications for patients who must pay all or part of the costs of their drug treatments.

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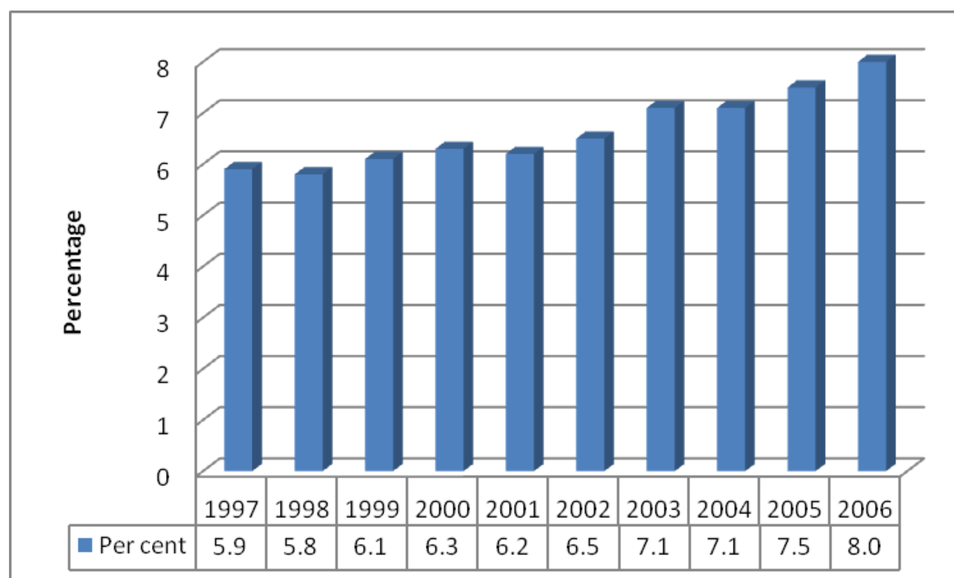
[41] Ungar, WJ et al.; *Effect of Cost-Sharing on Use of Asthma Medication in Children*; Arch Pediatr Adolesc Med. vol.162, no. 2, p.104, 2008.
[42] Doshi, JA; *Impact of a Prescription Copayment Increase on Lipid-Lowering Medication Adherence in Veterans*; Circulation, vol. 119, no. 3, p.390, 2009.
[43] Goldman, DP et al.; *Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health*; JAMA, vol. 298, p. 61, 2007.
[44] Schoen C et al.; *Toward higher-performance health systems: adults' health care experiences in seven countries*; Health Affairs, vol. 26, no. 6, p. w717, 2007.
[45] Kennedy and Morgan; *A Cross-National Study of Prescription Non-Adherence Due to Cost: Data from the Joint Canada-United States Survey of Health*; Clin. Ther., vol. 28 #8 p. 1217, Aug. 2006.
[46] Mathews, M, et al. *How important are out-of-pocket costs to rural patients' cancer care decisions?* Can J Rural Med, vol. 14, no. 2, p. 54, 2009.
[47] Heisler, M et al.; *Patient strategies to cope with high prescription medication costs: who is cutting back on necessities, increasing debt, or underusing medications?*; J Behav Med. Vol. 28 no. 1 p. 43, Feb 2005.
[48] Lauzier, S et al.; *Wage Losses in the Year After Breast Cancer: Extent and Determinants Among Canadian Women*. J Natl Cancer Inst, vol.100, p.321, 2008.

The future

Canadians can expect to continue to pay an increasing portion of their incomes on drug costs in the future. A steady trend is shown in the following chart which depicts the proportion of households which pay more than three per cent of their net incomes on prescription drugs. (Three per cent is a commonly accepted cut-off that defines drug costs as catastrophic — a topic discussed in the next section.)

Chart 2 Percentage of Canadian households spending more than three per cent of net income on prescription drugs[49]



This trend is expected to continue for several reasons.

Increased offloading to beneficiaries

Private insurance figures show an increasing proportion of beneficiaries with co-payment requirements and overall reductions in plan maxima as plan sponsors grapple with accelerating drug costs.[50] Another factor is that, as with pensions, defined-contribution plans — including Health Care Savings Accounts — are becoming increasingly popular for extended health benefits plans. This plan design allows the sponsor much greater financial certainty by placing the risk on the beneficiary to select the degree of coverage they need. Out-of-pocket expenses can be expected to

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[49] Statistics Canada. *Table 109-5012 - Household spending on prescription drugs as a percentage of after-tax income, Canada and provinces, annual*, CANSIM (database).
http://cansim2.statcan.gc.ca/cgi-win/cnsmcgi.exe?Lang=E&CNSM-Fi=CII/CII_1-eng.htm
(accessed: June 29, 2009)
[50] Applied Management Consultants, June 2009.

rise in the short-term also due to workers losing coverage as they become unemployed in greater numbers during the present recession.[51]

U.S. trends are similar to those in Canada.[52] Employers are reluctant to reduce the quality of coverage and so they have offloaded expenses onto employees. Out-of-pocket spending there grew by one-third from 2004 to 2007[53] and the percentage of underinsured Americans grew by two-thirds in the same period.[54]

Private insurance for high-cost drugs

Wealthier Canadians are recognizing the gaps in insurance coverage and are purchasing separate insurance to cover serious illnesses. At the end of 2007, almost 775,700 Canadians were covered under critical illness plans on either a group or an individual basis – a ten per cent increase over the previous year.[55] However, there is a growing population of low income workers who cannot afford this option.

Movement towards income-based public drug plans

On the public side, there is a trend for provincial drug plans to move away from entitlement-based systems (which automatically cover groups such as seniors) and toward income-based plans. All provinces except Ontario, New Brunswick and Prince Edward Island now have some eligibility criteria and/or co-insurance scales based on income. In addition, provinces such as Alberta are reducing subsidies on their universal drug plans and are moving towards market-value premiums.

Tiered drug plans

This aspect of the American experience may be a harbinger for the future of Canadian prescription drug insurance. Tiered health plans – a feature of six out of seven U.S. drug plans – are designed so that plan members pay a range of premiums depending on the type of drugs covered. Some health insurance companies have begun charging patients who have serious or chronic conditions such as cancer and rheumatoid arthritis much more for specialized drugs – up to 33 per cent of the prescription cost, compared with the usual 20 per cent.[56] Approximately one in five Canadians who

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[51] Doug Cooper; *The Impact of the Recession on Group Insurance & Drug Benefits*; Insights, vol. 4. issue 4, p. 22, 2009.

[52] Thomas Gryta; *Drug Costs Lead To Tight Reimbursement, Pressure On Patients*; Dow Jones Newswires; August 21, 2008.

[53] Gabel, JR et al. *Trends In Underinsurance And The Affordability Of Employer Coverage, 2004–2007*. Health Affairs, vol. 28, no. 4 (2009): w595–w606

[54] Schoen, C et al. *How Many Are Underinsured? Trends among U.S. Adults, 2003 and 2007*; Health Affairs, vol. 27, no. 4 (2008): w298–w309

[55] Canadian Life and Health Insurance Association Facts 2008.

[56] *The sick support the well. Tier 4 drug pricing punishes seriously ill patients*; The Register-Guard (Oregon); 21 April 2008.

have private insurance are estimated to have multi-tiered health benefits plans and this trend is increasing.[57]

Quality of insurance coverage

Surprisingly to most Canadians, being insured does not guarantee that a cancer drug recommended by their oncologist will be covered. There is marked variability in the quality of insurance, as measured by the number of newer drugs on the formulary, the timeliness of funding decisions, and the insurer's flexibility in dealing with unusual clinical circumstances.

Delays

A widespread practice that can seriously undermine the quality of insurance coverage for cancer patients is Special Authorization. A public or private drug plan with a managed formulary requires that certain criteria are met before it will authorize payment for certain drugs. This process can be lengthy. For example, 20 per cent of reviews by the Ontario Drug Benefit Program in 2005 took longer than three weeks.[58] Most cancer patients cannot wait this long.

The process is made more onerous because insurers will usually authorize a maximum of three months' treatment at a time, necessitating repetition of the process several times a year. Oncologists must spend time completing time-consuming paperwork for their patients, wasting scarce resources. Service providers such as patient navigators and firms specializing in patient access have grown up because of these increasingly complex systems.

The process can also result in unnecessary delays because of the adjudicator's or the applicant's incompetence. Anecdotally, oncologists and patient access specialists report that when they receive a refusal they automatically resubmit the same information and usually get a positive response on the second try. Adjudicators complain that the paperwork is not completed correctly, necessitating a rejection. This not only puts patients through a time-consuming process, it adds stress to an already anxious situation.

A recent report by several prominent Canadian medical specialists concluded that:

> *"…implementation of the SA [Special Authorization] practice is costly and causes inequity in access, underutilization, and delays in treatment for urgently required therapies, all potentially leading to negative health outcomes."*[59]

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[57] Applied Management Consultants; *Trends and Issues in Plan Design*; Insights, Spring 2009.
[58] Ontario Drug Benefit Report Card 2005/06
[59] LeLorier, J et al.; *Drug Reimbursement Policies in Canada—Need for Improved Access to Critical Therapies*; Ann Pharmacother 2008;42:869-73.

Formulary exclusion

Another major aspect of insurance quality is the number of drugs included on the formulary, and also the time delay in making funding decisions. The question of the number of drugs on public formularies will be covered in Chapter 4. The issue of delays and plan flexibility are discussed here.

Drugs under review

The formulary decision process typically takes several months for public drug plans, and much less for private insurers. During the assessment period, the drug will usually not be covered, regardless of the patient's need. For cancer patients who may already have been receiving the drug, either as part of a clinical trial or under Health Canada's Special Access program, treatment may be cut off unless they can pay for the drug themselves. In some cases, the manufacturer may provide assistance, however there are economic disincentives for them to do so, arising from Canada's regulatory system, and this practice has been curtailed over the past two years.

Certain provinces have policies in place to provide drugs to individual patients while they are under review, under specific circumstances. Ontario, for example, recently released a Compassionate Review Policy which allows faster access for patients with life-threatening illnesses. British Columbia has a similar policy. Alberta's "Directors Privileges" program allows latitude in prescribing through a peer-review process. In smaller jurisdictions where oncologists and drug plan managers operate in close proximity, decisions can usually be worked out informally for a specific patient. The majority of provinces, however, are inflexible in this regard.

British Columbia and Ontario will also review high-priority drugs prior to their approval by Health Canada so that a funding decision can be made immediately after the drug is marketed.

Off-label use

Cancer drugs that are on the market are often prescribed by oncologists for conditions that were not included in the original submission to Health Canada. This may be because the clinical situation (including the type of cancer and/or patient's concomitant medical conditions) is so rare that the company has chosen not to file for this indication. Or, evidence of effectiveness may be available but the regulatory process is still underway.

Almost all private drug plans state they will not cover drugs for unapproved or experimental uses. Some insurers will cover the cost of an unapproved drug if it is authorized for a specific patient by Health Canada under its Special Access Program, however many do not.

Public drug formularies generally state that they do not cover unapproved uses, however, coverage can sometimes be obtained through one of the formal or informal processes described above.

Eligibility limitations

As mentioned earlier in this report, patients with pre-existing medical conditions are not eligible for private insurance coverage unless they are covered under a group plan. The list of these conditions is long, and includes having had cancer within ten years. This is of concern to all Canadians and to older citizens in particular.

Future trends

While cost-shifting to beneficiaries is a clear trend, it is difficult to predict how the quality of insurance coverage will change in the future. Employers are reluctant to sacrifice quality since this affects productivity and has the greatest impact on the most vulnerable people.

Drug plans are being encouraged to manage increasing drug costs by employing the following levers:[60]

- Mandate generic substitution
- Increase cost-sharing amounts (co-payments)
- Implement plan maxima (lifetime or annual)
- Managed formularies (i.e., special authorization)
- Proactively manage chronic diseases

The public drugs plans already tend to be less comprehensive and more bureaucratic than private ones and do not have the same pressures regarding plan quality. Whereas employers see a direct link between employee health and productivity, health and economic performance are separate portfolios in government. It is likely that, without concerted pressure from voters, the disparity in quality between private and public drug plans will grow.

A specific facet of drug plan quality that may change in the near future, due to the influence of events in the U.S., is off-label use. In November 2008, criticism over the lack of funding by the U.S. Medicare system for off-label use of cancer drugs led to an expansion of coverage criteria. If an unapproved use of a cancer drug is included in only one of the four compendia referenced by Medicare, it will now automatically be covered. During the same period, the Food and Drug Administration (FDA) clarified the guidelines by which drug companies can inform doctors of these unapproved uses. It is expected that the implications of the U.S. experience will be watched closely in Canada.

[60] ESI Canada 2008 Drug Trend Report.

3. Catastrophic Drug Coverage

The issue defined

Although no scientific studies have been done to determine the level at which financial hardship occurs, the range of expenses defined as catastrophic in the literature and in government policy papers is between three and five per cent of net household income.

Catastrophic drug coverage has received increasing public attention over the past three years. One of the highlights of the National Pharmaceuticals Strategy, launched in 2004, was a national system for catastrophic drug coverage. Frustrated by inaction, the provinces have since moved ahead and set up separate programs. Today, only two provinces – New Brunswick and Prince Edward Island – remain without such coverage. The financial burden of coverage borne by patients, however, varies widely across the country.

As was shown in an earlier chart, one in twelve Canadian families paid more than three per cent of net household income on prescription drugs in 2006. Some provincial patterns are worth noting. In Quebec, despite government control over the parameters of insurance, one in nine families paid an amount above the "catastrophic" threshold (the same proportion as in New Brunswick). In Manitoba – a province offering universal public coverage – the ratio was one in eight and in Prince Edward Island it was one in seven.[61] Clearly, our existing models of coverage are imperfect.

Catastrophic drug programs are important to cancer patients who have no insurance coverage and, more commonly, to those with insurance who are required to pay high out-of-pocket costs.

How well do insurance plans cover catastrophic cancer drug costs?

Both public and private drug plans differ in the maximum out-of-pocket costs that beneficiaries must bear for high cost cancer drugs.

[61] Statistics Canada. *Table 109-5012 - Household spending on prescription drugs as a percentage of after-tax income, Canada and provinces, annual*, CANSIM (database). http://cansim2.statcan.gc.ca/cgi-win/cnsmcgi.exe?Lang=E&CNSM-Fi=CII/CII_1-eng.htm

Public plan coverage of catastrophic cancer drug costs

Provinces and territories cover high drug expenses either through their universal plans, where these exist, or in some cases through separate high-cost drug programs. (Public drug plans refer to high drug costs relative to income, rather than using the term "catastrophic".) The table below shows which public plans cover high cancer drug costs (for drugs included on their formularies).

Table 6 Public coverage of high cancer drug costs

Area	Type of plan	Terms
BC	Cancer agency	100% coverage
AB	Cancer agency	100% coverage
SK	Cancer agency	100% coverage
MB	Manitoba Pharmacare	100% covered after deductible of 2.7% to 6.1% of net family income
ON	Trillium Drug Program	100% covered after income-based deductible
	Ontario Drug Benefit	100% coverage for seniors (small co-payment applies) and social assistance recipients
QC	Régie de l'assurance maladie du Québec (RAMQ)	Premium + co-payment (maximum out-of-pocket expense based on income)
NB	Department of Social Development	Residents may qualify for "health card only" benefits once personal assets are exhausted
	New Brunswick Prescription Drug Plan	100% coverage (small co-payment required) for low-income seniors and social assistance recipients
PE	High Cost Drugs Program	7 specific cancer drugs partially covered for incomes <$150,000.
	PEI Pharmacare	Coverage for seniors and social assistance recipients (co-payment required)
NS	Drug Assistance for Cancer Patients	Gross family income < $15,720
	Family Pharmacare	Income-based deductible and co-payments
	Seniors' Pharmacare Program	Premium plus co-payment
NL	Assurance Plan	Cap of 5% to 10% of net household income for families with incomes $39,999 to $149,999

	Access Plan	Low income families (income-based deductible)
	65Plus Plan	Seniors receiving GIS and OAS (beneficiary pays dispensing fee)
	Foundation Plan	100% coverage for social assistance recipients.
YT	Chronic Disease Program	100% coverage above deductible
NT	Specified Diseases (including cancer)	100% coverage
NU	Extended Benefits	100% coverage
Federal	Health Canada, Veterans Affairs, RCMP, Correctional Services Canada, National Defence and Citizenship and Immigration Canada	100% coverage

How much do Canadians pay under public plans?

To understand how much Canadians who rely on the public system for catastrophic coverage would have to pay, two types of families were used as examples:

- a non-senior (working-aged) family of average net income ($75,000) with three dependants, and
- a senior couple with average net income ($54,200).[62]

The example uses the average cost per patient for oncology drugs introduced since 2006 which is $65,000 per year.[63] The table below shows the amount a patient would have to pay out-of-pocket in each jurisdiction (assuming that the drug is listed on the public formulary).

Table 7 Out-of-pocket expense for average family without private insurance for newer cancer drugs

P/T	Type of family	Out-of-pocket expense	Percentage of Income
BC	Both	$0	0%
AB	Both	$0	0%
SK	Both	$0	0%
MB	Senior	$2,655	4.9%
	Non-senior	$3,207	4.3%

[62] Statistics Canada. *Average income after tax by economic family types*; 2007.
[63] Presentation by Bob Kamino, Brogan Inc. to the Group Insurance and Pharmaceutical Committee, 8 April 2009.

ON	Senior	$124	0.2%
	Non-senior	$2,764	3.7%
QC	Senior	$1,908	3.5%
	Non-senior	$1,908	1.3%
NB	Both	$65,000	87% – 120%
	Health card only benefits	$0	0%
PE	Senior	$84	0.2%
	Non-senior	up to $65,000*	up to 87%
NS	Senior	$806	1.5%
	Non-senior	$24,536	32.7%
NL	Senior	$4,065	7.5%
	Non-senior	$7,500	10%
YT	Both	$500	0.9%
NT	Both	$0	0%
NU	Both	$0	0%
Federal	Both	$0	0%

* The High Cost Drugs Program will assist if the drug is included on a specific list

The comparison shows a significant variability among plans. Although there have been improvements in recent years, Canadians living in Atlantic Canada remain vulnerable to high cancer drug costs.

In addition, cancer patients who require drugs that are not on the public formulary (due to rejection, funding decision not yet made, or unapproved use) are liable for the entire cost of the drug.

Private plan coverage of catastrophic cancer drug costs

Drug plans were originally designed to cover predictable drug costs of a few dollars a day. The advent of very high cost treatments that are taken at home has revealed previously unrecognized gaps in coverage. Initially, these situations were managed as exceptions by plan sponsors, but now that specialized drugs have become more widely used, the parameters of coverage are being re-evaluated.

As discussed in the previous section, private plans sometimes set a maximum out-of-pocket expense, above which the plan pays 100 per cent of prescription drug costs. However, one in five plans set a cap above which the beneficiary pays 100 per cent of the costs.

New insurance products have emerged to address these new needs. Some companies now also offer separate coverage for high prescription drug expenses. For example, Manulife offers a Catastrophic Plan which covers health services costs and drug expenses over $4,500 per year. Critical illness insurance, which pays out a lump sum

for patients who are diagnosed with one of a predefined list of serious illnesses, including cancer, can be used to pay for cancer drugs.

How much do privately insured Canadians pay?

Private insurance plans vary widely in their financial terms, so the cost to the patient for a catastrophic drug expense is not uniform. One way to understand the financial burden is to look at averages.

Using the data as cited previously, the average cost per patient for newer oncology drugs is $65,000 per year and an average co-insurance amount is 20 per cent, equating to an annual out-of-pocket expense of $13,000 for the patient. (This scenario assumes that the plan has neither a maximum out-of-pocket expense nor a ceiling of coverage within this range.) The table below shows the percentage of net income[64] required by three types of working families to cover this amount under a private plan.

Table 8 Percentage of net income required for co-insurance of $13,000

Type of family	Net Household Income	Co-Insurance Percentage of Income
Non-senior family	$75,000	17%
Lone-parent family, male	$52,100	25%
Lone parent family, female	$39,500	33%

These figures are in stark contrast to the public plans and to the commonly accepted three to five per cent of net household income that qualifies drug costs as catastrophic. In all provinces except New Brunswick and Prince Edward Island, the public drug plan will pay for a portion of these costs under its high drug cost program.

The future

The insurance industry recognizes the emerging trend of high cost specialized drugs and the pressures from employers to maintain reasonable coverage for their employees.

Incremental changes in plan design using the levers described earlier will be part of the remedy. A multi-stakeholder approach is also being pursued by the industry to

[64] Statistics Canada. *Average income after tax by economic family types*; 2007.

address the need for sustainable catastrophic coverage. In June 2009, the Canadian Life and Health Insurance Association presented its position in a policy paper:

> *"The federal, provincial and territorial governments must ensure that no Canadians need take on undue financial hardship as a result of prescription drug costs. Our industry further recommends that catastrophic drug coverage be established for all Canadians, that drug pricing be equitable across private and public programs, and that a healthy generic drug program that is open to competition be created. Consistent access to the most cost-effective drugs and the establishment of a minimal formulary are vital in order to achieve fiscal benefits and improve health outcomes for individuals regardless of where they live."*[65]

[65] Canadian Life and Health Insurance Association. *CLHIA Report on Health Care Policy: Towards a Sustainable, Accessible, Quality Public Health Care System.* June 3, 2009

4. Disparities in coverage of specific cancer drugs

There are no pan-Canadian criteria for coverage of cancer drugs. Disparities exist between the public and private plans and among the 19 public plans regarding which cancer drugs are covered and under what conditions.

How do disparities arise?

Differences between drug plan coverage of specific cancer drugs arise from two sources. The plan's decision whether or not to include a new drug on its list of covered drugs, or formulary, is one area of potential difference. The second area relates to the conditions under which the drug will be reimbursed.

Both the decision to include a new drug on the formulary and the determination of approved uses depend on clear demonstration of clinical and economic benefits. Drug plans differ in both the methodologies and the standards used for these evaluations. There are variations around how the quality of evidence is judged, what clinical guidelines or criteria are used, what economic parameters are included in the analysis and budget availability relative to competing priorities.

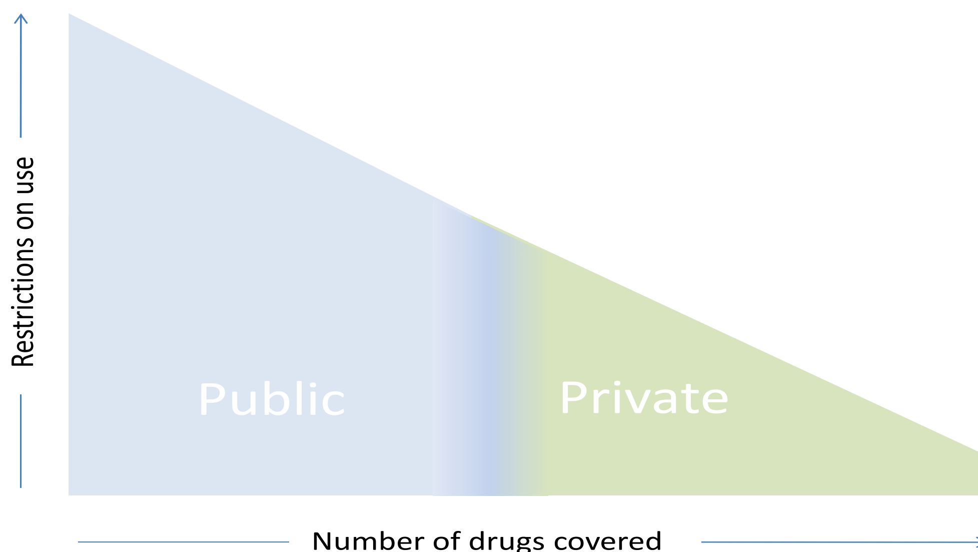
Although Health Canada has already determined through its approval process that a new drug offers a positive clinical benefit, the drug plan will take a somewhat different view based on its own realities. Regulatory approval usually relies on the outcomes of clinical trials comparing the new cancer drug to best available treatment, which may not be the same as that used in a particular jurisdiction. Also, patients for clinical trials are selected based on the absence of other potentially confounding illnesses and do not necessarily reflect the patient population covered by the drug plan. Therefore, both the clinical and economic analyses will be based on data that differs to some degree from the ideal requirements of the drug plan.

Another aspect of the evaluation process is that the economic analysis may not take into consideration unique factors that are important to cancer but may not apply to other diseases. For example, because cancer is often an acute life-threatening illness, the time horizon over which economic benefit is calculated should be longer than the often narrow period of treatment and recovery. By the same token, the scope of economic analysis should be broad enough to encompass the increased productivity of cancer patients who return to work after successful treatment.

Disparities between public and private insurance

In general, private coverage is more comprehensive than public, both in terms of the number of drugs covered and the restrictions placed on their use. The chart below illustrates in very broad terms the differences between public and private drug plan coverage of cancer drugs.

Chart 3 Disparities in public and private cancer drug coverage



The number of drugs covered is defined by the plan's formulary. Presently, all public drug plans – but only one out of six private plans – has an actively managed formulary.[66] The majority of private plans accept all new cancer agents once they are approved by Health Canada, following an application by the manufacturer.

Disparities among public plans

Although the situation has improved during the past two years with the implementation of the interim Joint Oncology Drug Review, there remain significant disparities among the public drug plans in terms of which drugs are approved, the times to approval and restrictions on use.

[66] ESI Canada 2008 Drug Trend Report.

The table on the next page shows the present approval status of newer cancer drugs by province and territory and for the largest federal drug plan, the Non-Insured Health Benefits (NIHB) covering registered First Nations and Inuit. Coverage is broadly defined as availability for at least some patients, since some provinces will pay for a medication although it is not on formulary through an Exceptional Access mechanism.

Reasons for disparities

Examination of the table reveals several types of disparities.

Some drugs, such as Abraxane, Alimta (for mesothelioma), Avastin and MabCampath are funded in some provinces and have been rejected in others. Although the drug plans reviewed the same clinical and economic data, they came to different decisions based on their interpretations of clinical benefit and affordability relative to other options.

Other drugs, such as Bexxar and Zevalin, are not available in all provinces because they are radiopharmaceuticals and require special facilities to administer.

Differences in review times account for many discrepancies. More than two years after their approval by Health Canada, several drugs still have not been reviewed by some provinces.

A final difference between provinces is the drug plan's policy regarding unapproved drugs. British Columbia, for example, has already reviewed and rejected Avastin for the treatment of brain cancer even though it has not yet received marketing authorization in Canada. Ontario has a similar policy of allowing reviews of urgently needed drugs prior to Health Canada approval.

Role of the Joint Oncology Drug Review

The interim Joint Oncology Drug Review (JODR) was initiated in 2006 by two western premiers who felt that interprovincial disparities in cancer drug coverage should be eliminated. During its two years of operation, the interim JODR has succeeded in moving toward this goal by engaging all provinces (except Quebec) in a single drug review process which results in a recommendation for funding approval.

The Ontario review system was adopted as a starting point for the Joint Oncology Drug Review in early 2007 and since that time modifications have been made to strengthen the clinical and pharmacoeconomic evaluations. The process has also been made somewhat more transparent by including a list of drugs reviewed on the Ontario Public Drug Programs' website, however the recommendations themselves are not posted. The impact of the JODR reviews is apparent when the actions of individual provincial formularies are monitored over time — similar funding decisions are made by several provinces within a few months of each other.

Table 9 Funding Status of Selected Newer Cancer Treatment Drugs (as at August 2009)

Legend: • *Covered for at least some patients* × *Denied listing on formulary* **R** *Under review*

Brand Name	Generic Name	Cancer Type	Form	NOC	BC	AB	SK	MB	ON	QC	NB	PE	NS	NL	YK	NIHB
Abraxane	alb. paclitaxel	Breast	IV	06/06	•	•	•	R	•	•	•	R	R	R		
Alimta	pemetrexed	Mesothelioma	IV	07/04	•	•	•	•	×	•	•	×	×	•		
Alimta	pemetrexed	Lung	IV	01/07	•	•	R	R	•	×	R	R	•	R		
Arimidex	anastrozole	Breast	oral	08/96	•	•	•	•	•	•	•	•	•	•	•	•
Aromasin	exemestane	Breast	oral	08/00	•	•	•	•	•	•	•	•	•	•	•	•
Avastin	bevacizumab	Colorectal	IV	11/05	•	•	•	×	•	•	×	×	•	•		
Avastin	bevacizumab	Breast	IV	02/09	R	R	R	R	R	R	R	R	R	R		
Avastin	bevacizumab	Lung	IV	04/09	R	R	R	R		R	R	R	R	R		
Avastin	bevacizumab	Brain	IV	not yet	×		×	R								
Bexxar	tositumomab	Lymphoma	IV	04/06	•	×	×	×	×	×	×	×	×	×		
Erbitux	cetuximab	Colorectal	IV	09/05	•	×	×	•	×	×	×	×	×	×		
Erbitux	cetuximab	Head and neck	IV	09/08	•	R	R	R	•	•	R	R	•	R		
Femara	letrozole	Breast	oral	09/97	•	•	•	•	•	•	•	•	•	•	•	•
Gleevec	imatinib	ALL, GIST	oral	10/01	•	•	•	•	•	•	•	•	•	•	•	•
Herceptin	trastuzumab	Breast	IV	08/99	•	•	•	•	•	•	•	•	•	•		
MabCampath	alemtuzumab	CLL	IV	11/05	•	×	×	•	×	×	×	×	•	×		
Nexavar	sorafenib	Kidney	oral	08/06	•	•	•	•	•	×	•	•	•	•	R	R
Nexavar	sorafenib	Liver	oral	01/08	•	•	•	•	•	R	•	•	•	•	R	R
Revlimid	lenalidomide	5q-MDS	oral	01/08	•	R	R	R	•	•	•	R	R	R	R	R
Revlimid	lenalidomide	Myeloma	oral	10/08	•	R	R	R	•	×	R	R	×	R	R	R
Rituxan	rituximab	Lymphoma	IV	04/00	•	•	•	•	•	•	•	•	•	•		
Sprycel	dasatinib	CML, ALL	oral	03/07	•	R	•	R	•	•	•	•	•	•	R	R
Sutent	sunitinib	Kidney	oral	06/06	•	•	•	•	•	•	•	•	•	•	R	×
Sutent	sunitinib	Gastrointest.	oral	05/06	•	•	•	•	•	•	•	•	•	•	R	•
Tarceva	erlotinib	Lung	oral	07/05	•	•	•	•	•	•	•	•	•	•	R	•
Tasigna	nilotinib	CML	oral	11/08	•	R	R	R		R	R	R	R	R	R	R
Temodal	temozolomide	Brain	oral/IV	10/99	•	•	•	•	•	•	•	•	×	•	•	•
Torisel	temsirolimus	Kidney	IV	12/07	•	R	R	R	×	×	R	R	•	R		
Tykerb	lapatinib	Breast	oral	05/09	R	R	R	R	R	R	R	R	R	R	R	R
Vectibix	panitumumab	Colorectal	IV	04/08	•	R	R	•	•	×	R	R	R	R		
Velcade	bortezomib	Myeloma	IV	02/05	•	•	•	•	•	•	•	•	•	•		
Xeloda	capecitabine	CRC, breast	oral	10/98	•	•	•	•	•	•	•	•	•	•	•	•
Zevalin	ibritumomab	Lymphoma	IV	06/06	•	×	×	•	×	•	R	×	×	•		

Notes: NWT and Nunavut use the NIHB formulary. Territories use provincial formularies for hospital-administered drugs (YT/BC, NWT/AB).
Sources: Provincial/territorial drug plan managers, except BC, AB, QC, NS. Cancer agency/drug plan formularies on websites were used for these provinces.

It is believed that, based on an independent evaluation of the JODR conducted in 2008, a recommendation was made in early 2009 to the sponsoring provincial governments that the Review should become a permanent structure. However, the status and details of this proposal have not yet been communicated. It is unknown what role patient representatives may have in the permanent structure, should it be approved. In a presentation to the Canadian Oncology Societies in April 2009, Dr. Tony Fields, Chair of the JODR Advisory Committee, stated that the patient representatives had provided invaluable insights and that he would not in future undertake any major project without patient consultation and representation.[67]

Disparities within provinces

Even within a particular province there are disparities in cancer drug access. Two major ones are:

- lack of alignment between clinical guidelines developed by oncologists and funding decisions made by public drug plans; and
- absence of policy dealing with the administration in public hospitals of cancer drugs that are privately paid.

Clinical guidelines and funding

There are no pan-Canadian standards of treatment for the various types of cancer. While several cancer agencies have developed their own guidelines, the websites of some provincial cancer agencies refer either to the B.C. Cancer Agency chemotherapy guidelines or to Cancer Care Ontario's Program in Evidence-Based Care (PEBC). The National Comprehensive Cancer Network, a U.S.-based organization representing 21 leading cancer centres, is also an authoritative reference for clinical guidelines.

Two provinces – British Columbia and Ontario – are used here to illustrate the varying degrees of alignment between clinical guidelines and funding decisions among the provinces. This comparison is intended not as an evaluation of different systems but to illustrate a concern that cancer patients find particularly frustrating: why a treatment recommended by their oncologist is not funded by the public health system.

In the B.C. Cancer Agency's system, clinical guidelines and funding approvals are closely linked and very few regimens are not supported. New cancer drugs are reviewed quickly, often in advance of their approval by Health Canada if they are urgently needed. Clinical practice guidelines are developed in consultation with oncologists throughout the province and are used to manage utilization. Requests to the ministry for funding are prioritized by the Agency, ensuring that new regimens with the greatest expected benefits are funded first. An override system of

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[67] Presentation by Dr. Tony Fields to the Canadian Oncology Societies, Toronto, 30 April 2009.

Compassionate Access allows oncologists to apply to use unfunded treatments for patients in unusual circumstances. As a result of this system, it is rare for an oncologist in British Columbia to recommend a treatment protocol that is not funded by the Agency.

In Ontario — another of the small number of provinces whose clinical guidelines and drug formulary are transparent to the public — there are several examples where chemotherapy protocols that are recommended in clinical guidelines are not funded. The following cancer treatments, for example, are listed on Cancer Care Ontario's website as "core" (meaning that they are recommended based on evidence) but are unfunded:

- MabCampath (alemtuzumab) for the treatment of chronic lymphocytic leukemia
- Bexxar (^{131}I-tositumomab) and Zevalin (^{90}Y- ibritumomab) for the treatment of lymphoma
- Torisel (temsirolimus) for renal cell carcinoma.

(Ontario has recently allowed compassionate access to drugs that have not yet been reviewed for patients who are in life-threatening clinical situations.[68] This step may help to alleviate some of the discrepancies experienced by patients.)

Patients elsewhere in Canada likely experience similar gaps in alignment as do those in Ontario, however a full comparison could not be conducted because few provinces publish both their clinical guidelines and their lists of funded cancer drugs.

Administration of privately paid cancer drugs in the public health system

Another area of disparity centres around the options available to patients who want to receive an unfunded intravenous drug and are willing to pay privately. Provinces have varying policies and practices differ even within some provinces.

Most intravenous drugs that are unfunded are either under review or have been reviewed and denied funding. Erbitux for the treatment of advanced colorectal cancer, for example, is marketed in Canada but is listed on only one provincial formulary. A patient whose oncologist recommends this drug has the option of paying for it privately.

Any patient with private means can elect to receive the drug outside Canada. Provinces such as Ontario, in some cases, have paid for out-of-country treatments with unapproved drugs through the health insurance plan rather than through the public drug program. (This practice has been criticized for its lack of consistency and has been under review in Ontario since 2007.)

[68] Ontario Public Drug Programs. *Compassionate Review Policy.* April 2009.

Private insurance plans state that they do not cover drugs that are given in hospital, since this contravenes the *Canada Health Act*. On an exceptional basis, however, some private plans have agreed to cover an unfunded drug since, by its rejection, the province has determined that the drug is not medically necessary and it is therefore outside the terms of the Act.

If the private insurer will not cover the costs, a patient may decide to pay the expense out-of-pocket. (Numerous newspaper articles about community fundraising events and generous donors illustrate that this situation is not unusual.)

Once the source of private funding is determined, an infusion facility must be located. In some parts of the country, private clinics provide this service. Provis Infusion Clinic, located in downtown Toronto, was the first to open its doors in 2005. This facility infuses drugs for cancer and other illnesses provided they are not funded by the public health system. Cancer drugs manufactured by Hoffmann-LaRoche are available at Bayshore Infusion Clinics located in approximately 20 cities across Canada. Other manufacturers have contracts with various pharmaceutical distributors for these services.

The public healthcare system may also allow unfunded drugs to be infused in its facilities for private payment, although this practice is controversial and information is not publicly available in some jurisdictions.

Table 10 Provincial policies regarding administration of self-pay cancer drugs by public hospitals

Province	Private pay policy
BC	Formal policy
AB	Formal policy
SK	Formal policy
MB	No formal policy
ON	No formal policy*
QC	No formal policy
NB	No formal policy
PE	No formal policy
NS	No formal policy
NL	No formal policy

* The Provincial Working Group recommendations were submitted to government in 2006, however no formal policy has been released. Individual cancer centres and hospitals make their own decisions and some have published policies on their websites.

The future

As can be seen from the previous examples, there are many areas in which there are disparities in access to specific cancer drugs, depending on where Canadians live and on their employment status. Significant attempts have been made through the Joint Oncology Drug Review to ameliorate the situation. However, because health care is a provincial matter, discrepancies will continue to exist as long as there are no pan-Canadian standards of coverage.

Several organizations have called for a pan-Canadian approach to clinical guidelines linked to funding. This would ensure that, regardless of where they live, all Canadians receive cancer drug treatments that are accepted by leading authorities in the field. While individual provinces and private insurers would remain free to cover additional treatments, Canadians would be reassured that their health system will cover essential medicines for the treatment of cancer. This approach may also reduce the number of arbitrary decisions associated with prior authorization processes. Timely and clear guidelines would greatly streamline funding approvals.

Conclusions

Equity in access to cancer drugs in Canada is based to a great extent on our system of coverage. There are major gaps between the experiences of cancer patients and the system that Canadians believe should be in place to ensure that all citizens can obtain drug treatments recommended by oncologists in a timely manner and without undue financial hardship.

The gaps and disparities outlined in this report reflect the multifaceted nature of the issue. Our patchwork "system" has reached an almost impenetrable level of complexity due to the different standards and decision-making processes of multiple drug programs, and in some areas a marked lack of transparency. Gaps and disparities that have been exposed by the emergence of high-priced oral cancer drugs in recent years have resulted in enormous burdens being placed on the end-user: the patient. Many cancer patients and their families are shouldering heavy financial costs and are being denied access to important cancer drugs as drug plans struggle to contain burgeoning expenditures.

Just as the issues are multifaceted, potential solutions must involve actions from multiple sources. Gaps in the insurance status of Canadians must be eliminated. Costs of insurance should be distributed more equitably. No Canadian should experience financial hardship for such an essential medical service. Also, inequities in coverage of accepted standards of treatment between jurisdictions and between privately and publicly insured Canadians need to be resolved.

Beyond these factors, steps need to be taken to ensure the sustainability of the system of coverage. The twin drivers of spiralling drug costs – utilization and prices – must be examined to ensure that Canadians receive value for money today and so that future generations can continue to afford a high quality drug funding system.

Because of the multifaceted nature of these issues, actions must be concerted and leadership is essential to make progress on these concerns. Timely and effective measures to tackle the challenges we face today will benefit all Canadians – now and in the future.