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Uncovering the Hidden Costs of Take-Home Cancer Drugs

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Executive Summary

The Canadian Cancer Society has reported that approximately 2 in 5 Canadians will develop cancer and about 1out of 4 is expected to die from cancer. In cancer care, patients often face increased anxiety and uncertainty about their future care pathway. This is paired with an immediate need for therapy to treat potentially aggressive disease. The uncertainties faced by cancer patients may include, but are not limited to income pressure, time to access reimbursed drugs, challenges in accessing private benefits due to co-morbidities or pre-existing conditions, travel burden, and differences in disease management across Canada.

This paper has been authored and prepared by PDCI and funded by the Canadian Cancer Society to identify the gaps in access to Take Home Cancer Drugs (THCDs) in select provinces. Using a model-based design, PDCI measured patient financial gaps in coverage and utilization for specified oral oncology drugs in the provinces of Ontario, Nova Scotia, and New Brunswick.

Canadian Cancer Society Stakeholders – Experience with Take Home Cancer Drugs from the staff at the Saint John Regional Hospital oncology department who assist patients with applications and coverage under the New Brunswick Drug Program and the New Brunswick Prescription Drug Program to have take home cancer drugs covered: "...patients ultimately never have to pay for their take home cancer drugs as there are many different 'plans' that will cover what the patients' private plan(s) will not cover." "From a patient / caregiver perspective the process of obtaining authorization and reimbursement of approved cancer medications can be time-consuming, exhausting and overwhelming if you do not have the support of the healthcare staff to do this on your behalf and you are required to complete forms and seek coverage from private plans on your own."

Pharmaceutical manufacturers frequently sponsor programs that may provide financial assistance to patients for THCDs in the form of copay support, bridging support, and compassionate use or free drug offerings. In some provinces, specialty pharmacies further assist patients with innovative programs to reduce dispensing challenges arising from communication, knowledge, counseling, or supply gaps at the community pharmacy, improving patient adherence to medication and management of adverse events. These initiatives are considered and provide additional context to the model.

PDCI explored population, age, and epidemiologically standardized provincial utilization. PDCI developed scenarios that modeled potential increases in utilization of take home cancer drugs if financial and administrative barriers to access were removed. The model then examined two scenarios of increased THCD utilization based on patients currently benefitting from comprehensive public drug coverage. The first scenario represents a conservative increase in utilization, matching potential THCD treatment levels to the most comprehensive inprovince public program offered to residents under 65 years of age. The second scenario representing a high increase in utilization was developed based on Quebec's RAMQ program for residents under 65 years of age. The analysis identified the existing costs associated with the THCD treatment and funding gap which are described below in Table 1.

The model results highlight differences in access and areas of opportunity for improvement in provincial approaches to THCD funding. PDCl's analysis of current THCD spending shows an underutilization of THCDs in provinces without comprehensive and accessible drug programs.



Table 1. Summary of results

Province	Incremental Cost (Gross)	Estimated Discount Rate*	Incremental Cost (Net)
New Brunswick	\$1.3M - \$4.1M	30%	\$0.9M - \$2.9M
Nova Scotia	\$1.1M - \$4.0M	30%	\$0.7M - \$2.8M
Ontario	\$17.5M - \$44.2M	30%	\$12.3M - \$30.9M
TOTAL	\$19.4M - \$51.9M	30%	\$13.9M - \$36.7M

^{*}The Ontario Auditor General Report (2016-2017), disclosed total pharmaceutical discounts received in Ontario was close to 30% of the total expenditures for brand-name drugs.

Today, these gaps are borne by third parties, including manufacturer sponsored patient support programs and outof-pocket costs by the patients themselves or result in reduced utilization and associated life benefits. These results estimate the net incremental cost for public payers to improve THCD coverage to be between \$14 and \$37 million (Table 1).

This research identifies important cancer information for all Canadians and a call to action for policymakers to increase services to support and improve access to drugs for people with cancer.



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Introduction

Oral prescription oncology drugs enable cancer therapy without intravenous intervention. The simplified administration can often be completed in the comfort of the patient's home with associated benefits to quality of life. These treatments reduce utilization of hospital infrastructure and associated chair-time resource costs. Oral therapies also minimize caregiver and patient disruptions in a patient's day-to-day life including travel time to clinics.

Over half of oncology medications in the global biopharmaceutical pipeline are being developed in oral formulations.³ Increasingly these therapies provide greater precision and success in cancer treatment: targeting smaller, more rare, subtypes of cancer, and/or include a predictive biomarker (i.e., requiring confirmation of a genetic subtype). These advances are leading to substantial clinical benefits, albeit at potentially higher costs and potentially for smaller patient populations.

Coverage eligibility for THCD varies significantly across Canadian provinces, creating interprovincial differences. In Ontario, Quebec, and the Atlantic provinces, THCDs do not fall under the jurisdiction of the public cancer agency budget; patients have no choice but to rely on private plans, out-of-pocket (OOP) cash payments, provincial drug programs (if eligible), or compassionate programs provided by pharmaceutical manufacturers when a drug is not covered by programs available to the patient. In contrast, Canadians living in the western provinces have their cancer drugs paid for by the provincial government regardless of their age, socioeconomic status, and the drug's route of administration.

Patients who move between different drug programs, due to changes in economic status and/or phases of disease progression, may find different reimbursement rules for the same drug. These gaps in coverage of THCD's across provinces lead to inequitable access to cancer treatments, potentially unanticipated costs to the patient and their families, and often discontinuity in their cancer treatment.

THCDs from a Patient's Perspective⁴

A patient was accessing an injectable medication through the Ontario Exceptional Access Program (EAP) which is administered through the Ontario Drug Benefit Program (ODBP). Shortly after, a more effective drug was approved in Canada and recommended to the patient by her oncologist. The drug amounted to \$5,000 per month and she worked with her pharmacist to get payment directly from her insurance company instead of paying out-of-pocket and receiving reimbursement later.

The administration behind this process became lengthy. A two-week delay accompanied the paperwork transfer between the patient, pharmacy and insurance company. Then, the pharmacy informed the patient that they could not get the medication in the specified dosage. The patient then journeyed to find a pharmacy willing to stock and dispense the medication. Once found, the administration process had to be repeated.

Unfortunately, the patient was subject to several unbearable side-effects and her oncologist requested reinstatement of the previous injectable drug. Communication with the EAP took a long time and led to the patient being without medication for four months. This experience has made the patient extremely cautious when it comes to switching treatment due to the time-consuming and labor-intensive ordeal experienced.

This case is not uncommon for patients accessing cancer treatments, namely THCDs. Access in terms of general support for transitions between high-cost medicines is needed by the patient to continue treatment. In addition, support for those payer claims requirements and upfront out-of-pocket costs remain a barrier, even if the treatment has the potential to be clinically effective.



Research Objective

The objective of this report is to identify gaps in access to THCD in Canada. Using a model-based design, the analysis quantifies the financial burden to patients on oral oncology drugs in the provinces of Ontario, Nova Scotia, and New Brunswick.

Methodology

The model was designed with the objective to identify the gap or total out-of-pocket costs to patients on THCDs in three (3) key jurisdictions of Canada: New Brunswick, Nova Scotia, and Ontario. The findings provide key directional learning for other eastern provinces lacking comprehensive coverage of THCDs through public programs. The costs are based on the patient population currently receiving THCDs.

A 5-step approach was used to build the model:

- 1. Identify the cancer types, their incidence in Canada and the selected provinces.
- 2. A search for available oral THCDs covered in each jurisdiction by cancer type was conducted.
- 3. A breakdown of the components of drug plan design and coverage attributes was conducted, by age and province.
- 4. An estimate of the Canadian patient population was determined based on a stratification of patients by age, income, province, and cancer type.
- 5. The model then allocated the patient population to the coverage model to calculate costs, with details provided on primary plan spending. Utilization and treatment uptake considerations were made based on an assessment of private and public claims data.

The model assumed a comprehensive THCD program with a reimbursement design like OHIP+ in Ontario as the preferred future THCD program since it is known to have a comprehensive coverage program for those who have exhausted private coverage options.^{5, 6} The OHIP+ system in Ontario provides drug reimbursement for eligible patients under the age of 25. Validation of the results was conducted with public and private payer claims data and reporting documents from cancer agencies and public drug plans.

PDCI explored population, age, and epidemiologically standardized provincial utilization. PDCI developed scenarios that modeled potential increases in utilization due to the removal of financial and administrative barriers to access. The model then examined two scenarios of increased THCD utilization based on patients currently benefitting from comprehensive public drug coverage. The first scenario represents a conservative increase in utilization, matching potential THCD treatment levels to the most comprehensive in-province public program offered to residents under 65 years of age. The second scenario representing a high increase in utilization was developed based on Quebec's RAMQ program for residents under 65 years of age.

In support of the model, a series of primary research interviews following a short survey were conducted with Patient Support Program (PSP) Managers and Specialty Pharmacists about the current patient experience with coverage, reimbursement, and claims processing of THCDs.⁷ Five Program Managers agreed to participate in the survey.



Notable Limitations

Longitudinal data was not available to further inform the analysis to define patient treatment pathways and utilization scenarios. Epidemiological and demographic data was used to estimate plan and patient costs and utilization.

To calculate the annual cost for THCD by cancer type, a 28-day utilization cycle for each oral cancer product was included, sourced from Health Canada approved product monographs. It is assumed a constant number of patients are treated on a monthly basis representing 12 cycles of treatment per patient year.

Patients with Comprehensive Private/Underinsured were not allocated based on household income: there is evidence that patients in lower income households are more likely to have plans with high financial burdens in the form of copayments and annual maximums. This may cause our analysis to overestimate current out-of-pocket costs.

This model assumed that patients obtain all possible primary and secondary coverage for which they are eligible in order to minimize out-of-pocket costs.

The model reflects current utilization and does not consider potential future utilization effects associated with new medicines, which could be higher than the provided estimates.

Research Findings: Identifying the THCD Gap for Patients

To identify the THCD gap for patients, this research aimed to quantify the costs of the current system that represent the financial burden for patients on THCDs as out-of-pocket expenses. The model was built with consideration for patient demographics alongside plan coverage and incidence of cancer in the populations of Ontario, New Brunswick, and Nova Scotia, with Quebec as the reference province.

Cancer Incidence in Canada

In the key jurisdictions for this research, cancer incidence increases among ages 45-65+ and significantly for the 65+ age bracket. Table 17 in the Appendix presents the incidence per 100,000 individuals for various cancer types. Incidence data was accessed from Statistics Canada (Table: 13-10-0111-01). Population data was based on Statistics Canada Table 17-10-0005-01 (by age, sex, province) based on the July 1st estimate of the 2020 population.

As several drug programs implement copays and deductibles based on household income, the population in the select jurisdictions were stratified by income brackets and age in Table 18 in the Appendix, data for income was sourced from Statistics Canada tax filer data (Table 11-10-0012-01 Distribution of total income by census family type and age of older partner, parent or individual).

Drug Plan Design and Coverage Attributes

Canadians attain drug coverage through a variety of plans. These include private insurance, public plans, out-of-pocket spending, and third parties such as manufacturers financial assistance and compassionate programs. Despite an extensive array of public and private drug plans, and few Canadians without access to reimbursement options, more than 20% of Canadians' spending on prescribed drugs is paid for out-of-pocket. Error! Bookmark not defined. According to CIHI's 2019 forecast for drug spending, as displayed in Figure 1, on a regional basis, public plans in



the Atlantic provinces rank lowest amongst the provinces in the portion contributed to overall provincial drug spending, while Ontario's public contribution is also below the national average.¹

Table 19 in the Appendix provides an overview of current provincial plan terms for THCDs. Providing improved THCD public drug funding in these provinces will enhance parity in the provincial contribution to overall drug spending and reduce out-of-pocket burden for residents in these provinces.

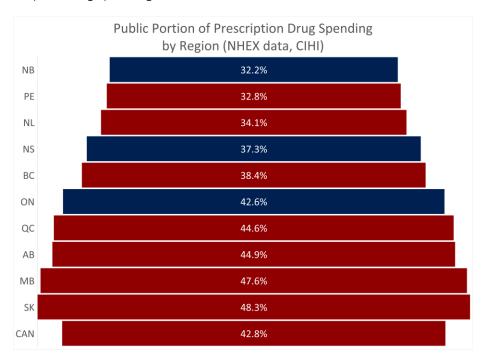


Figure 1. Public Prescription Drug Spending

The 2020 TELUS Health Drug Data Trends & National Benchmark Report⁸ finds that 69% of private plans require co-payments as a cost-sharing measure. Additionally, 20% of private plans have annual maximums, in which patients would be responsible for any costs that exceed those limits. While TELUS reports that, on average, plan annual maximums were \$28,000, some plans had annual maximums above \$50,000 and \$100,000 respectively.

Based on findings in the 2020 TELUS Report, we have segmented patients with private coverage into two groups: 'Comprehensive' Private Coverage with low financial burdens, and the 'Underinsured' with high financial burdens.

We estimate that 47% of patients with Private Insurance have "Comprehensive" Private Insurance. Their weighted average copay rate equals 3.5% of drug costs. Of these patients, approximately 10% would have a plan annual maximum which averages at \$154,000.

On the other hand, we estimate that 53% of patients with private insurance would fall into the 'Underinsured' group. Their weighted average copay rate equals 20.8% of drug costs. Of these patients 29.28% have an annual maximum which averages at only \$7,516. As THCDs often exceed these costs, patients with cancer face out-of-pocket costs which may be unaffordable and impact the patient's cancer journey.

This breakdown of different plans and coverage attributes is important in assessing where the funding is coming from for THCDs, and to calculate the costs borne to the patient. Table 3 and Table 4 show the breakdown of



components for current and future designs for THCDs. The proposed THCD plan would provide a substitute source of funding comparable to non-THCD forms of cancer treatment and reduce reliance on provincial catastrophic programs, private insurance and out-of-pocket spending. Table 20 in the Appendix describes coverage plan attributes by age backet.

Table 3. Model Analysis – Breakdown of THCD Spending (Current System)

• Senior Plans

- Patient Demographics (Age)
- Product Coverage
- · Net Spending
- Catastrophic Plans
 - Patient Demographics (Age, Income)
 - Product Coverage
 - Net Spending
 - After Deductible

Private Payers

- Open Plans
 - Proportion of Private Market
 - Patient Demographics (Age)
 - Product Coverage
 - After OOP Spending
- Managed Plans
 - Proportion of Private
 - Market
 - Patient Demographics (Age)
 - Product Coverage, Use Restrictions
 - After OOP Spending
 - Plan Maximums

Out Of Pocket

- · Privately Insured
 - Deductibles
 - Copay
 - Exceeded Plan Maximums
- Uninsured
 - · Proportion of Population
 - Patient Demographics (Age, Income)
 - Catastrophic Plan Deductible

Table 4. Model Analysis – Breakdown of THCD Spending (with THCD Plan)

Provincial Payers

- Senior Plans
 - Patient Demographics (Age)
 - Product Coverage
 - Net Spending

Catastrophic Plan

- Patient Demographics (Age, Income)
- Product Coverage
- Net Spending
 - After Deductible
- THCD Plan
 - Proportion of Population (Uninsured)
 - Proportion of Population (Managed Plans)
 - Net Spending
 - Factor in Increased Utilization

Private Payers

- Open Plans
 - Proportion of Private Market
 - · Patient Demographics (Age)
 - Product Coverage
 - After OOP Spending
- Managed Plans
 - Proportion of Private Market
 - Patient Demographics (Age)
 - Product Coverage, Use Restrictions
 - After OOP Spending
 - Plan Maximums

Out Of Pocket

- · Privately Insured
 - Deductibles
 - Copay
 - Exceeded Plan Maximums

Uninsured

- Proportion of Population
- Patient Demographics (Age, Income)
- Catastrophic Plan

Provincially covered THCD therapies within the three key jurisdictions researched are identified and detailed in the Appendix, Table 21. The average annual cost per patient of publicly reimbursed THCDs, weighted by market share, is presented in Table 5 below.

To calculate the annual cost for THCD by cancer type, a 28-day utilization cycle for each oral cancer product was included, sourced from Health Canada approved product monographs. It is assumed a constant number of patients are treated on a 28-day cycle basis, representing 13 cycles of treatment per patient year.



Table 5. Current THCD Average Annual Cost per Patient by Cancer Type

Cancer Type	Average Treatment Cost per Patient Year
Brain and CNS	\$62,701
Breast	\$66,998
Kidney and Renal Pelvis	\$73,815
Leukemia	\$110,674
Liver	\$8,9801
Lung	\$103,679
Melanoma	\$106,114
Multiple Myeloma	\$121,357
Non-Hodgkin Lymphoma	\$145,112
Ovary	\$99,954
Pancreas	\$68,487
Prostate	\$36,596
Thyroid	\$75,642

Note: Cancers with no oral funded therapy were excluded from the table.

Total Out-of-Pocket Spending on THCDs

Primary plan reimbursement for patients who are prescribed THCDs can be paid by several different drug plans, both private and public. These include provincial catastrophic plans, private plans, and other public plans (i.e., Seniors, Social Assistance).

Patients with private insurance that require copayments and annual maximums typically have high out-of-pocket costs. These patients will seek secondary coverage to handle these costs, often the private insurance of a spouse (also known as Coordination of Benefits). Based on an analysis of PDCI's Private Payer Claims Database, we estimated that on average 25% of costs not paid by the primary insurer are covered by Secondary Plan coverage.

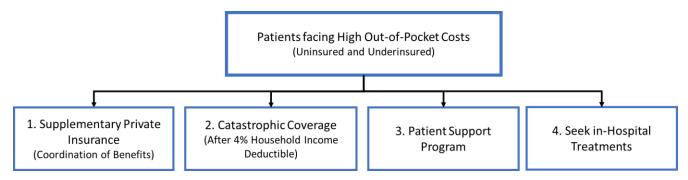
In our data analysis we also observed patients without access to sufficient private insurance seeking coverage through publicly funded catastrophic drug plans. In Ontario, Nova Scotia and New Brunswick, catastrophic plans have household-income based deductibles and / or premiums. Out-of-pocket costs exceeding the deductible limits are then reimbursed by the catastrophic plans.

Remaining out-of-pocket costs may be covered by manufacturer-sponsored patient support programs, either in the form of co-pay assistance, bridging, or compassionate use programs.

Finally, as a last resort, some patients facing high out-of-pocket costs for THCDs may instead rely upon in-hospital treatment alternatives which are fully covered.



Figure 2. Secondary coverage options for patients on THCDs



Utilization of THCDs in a population depends on several factors: age, cancer epidemiology, and medication coverage/patient access. Financial barriers were expected to negatively impact the utilization of THCDs.

In order to estimate current and future utilization of THCDs in each province, we calibrated utilization rates using age and province-specific cancer incidence rates and actual provincial spending of products listed in Table 20. Table 6 compares estimated utilization rates of the uninsured population in each province as a ratio against a) the provincial program (e.g. Seniors, Social Assistance) that saw the highest utilization rate, and b) Quebec RAMQ program for patients under 65 years of age. In the cases of New Brunswick, Nova Scotia, and Ontario, approximately 20% fewer uninsured patients received THCDs compared with patients with comprehensive public coverage. Patient utilization of THCDs under Quebec's RAMQ Under-65 program was substantially higher than the other provinces. Therefore, this points to an underutilization of THCDs in provinces without accessible and comprehensive THCD programs.

Table 6. Utilization ratios for THCDs of catastrophic plans

	NB	NS	ON	QC*
Catastrophic plan vs. Highest in Province	0.82	0.83	0.78	1.21
Catastrophic plan vs. RAMQ Under 65	0.45	0.48	0.62	1.00

^{*}In terms of patient demographics, Quebec's equivalent of a catastrophic program is the RAMQ Under-65 program

Table 7 to Table 10 for the provinces of New Brunswick, Nova Scotia, and Ontario, with Quebec as a benchmark. The breakdown of these costs is presented by provincial catastrophic, other provincial programs and private plan spending.

Table 7. New Brunswick – Total Plan Spending and Patient Out-of-Pocket Costs

Total OOP Costs	



	THCD Drug Costs	Primary Plan Spending	Deductible Costs	Co-Pay Costs	Plan Maximum Costs	Secondary Plan Spending	Total Out-of- Pocket Spending
New Brunswick Drug Plan**	\$1.7M	\$1.7M	-	-	-	-	-
Other Public Plans*	\$14.16M	\$14.16M	-	-	-	-	-
Private Plan	\$6.13M	\$4.49M	<\$0.01M	\$0.77M (13%)	\$0.87M (14%)	\$1.06M (17%)	\$0.58M (9%)

^{*}Other public plans include: Seniors, Social Assistance

Table 8. Nova Scotia – Total Plan Spending and Patient Out-of-Pocket Costs

	THCD	Primary	Total OOP Costs			Total	Total Out-of-
	Drug Costs	Plan Spending	Deductible Costs	Co-Pay Costs	Plan Maximum Costs	Secondary Plan Spending	Pocket Spending
Take Home							
Cancer Drug			\$0.09M	-	-	-	
Fund	\$2.08M	\$2M	(4%)				\$0.09M (4%)
Other Public							
Plans	\$16.86M	\$16.86M	-	-	-	-	-
Private Plan				\$0.94M	\$1.06M	\$1.79M	
	\$7.47M	\$5.47M	<\$0.01M	(13%)	(14%)	(24%)	\$0.21M (3%)

Table 9. Ontario – Total Plan Spending and Patient Out-of-Pocket Costs

	THCD	Primary	Total OOP Costs			Secondary	Total Out-of-	
	Drug Costs	Plan Spending	Deductible Costs	Co-Pay Costs	Plan Maximum Costs	Plan Spending	Pocket Spending	
Trillium Program	\$36.76M	\$35.18M	\$1.58M (4%)	-	-	-	\$1.58M (4%)	
Other Public Plans	\$366.56M	\$366.56M	-	-	-	-	-	
Private Plan	\$150.06M	\$109.99M	\$0.02M (0.01%)	\$18.84M (13%)	\$21.21M (14%)	\$35.75M (24%)	\$4.32M (3%)	

Table 10. Quebec – Total Plan Spending and Patient Out-of-Pocket Costs

^{**}The New Brunswick Drug Plan requires the payment of premiums in place of cost-sharing measures



	THCD	Primary	Total OOP Costs			Secondary Total Out-of-	
	Drug Costs	Plan Spending	Deductible Costs	Co-Pay Costs	Plan Maximum Costs	Plan Spending	Pocket Spending
RAMQ	\$38.3M	\$37.66M	\$0.12M (0.3%)	\$0.52M (1%)	-	\$0.52M (1%)	\$0.13M (1%)
Other Public							
Plans	\$235.2M	\$235.2M	-	-	-	-	-
Private Plan	\$404.5014	**	\$0.41M	\$1.8M	\$0 (0%)	\$1.93M	\$1.8M
	\$131.59M	\$129.37M	(0.3%)	(1%)	. ()	(1%)	(1%)

Figure 3. Factors leading to out-of-pocket costs for THCDs

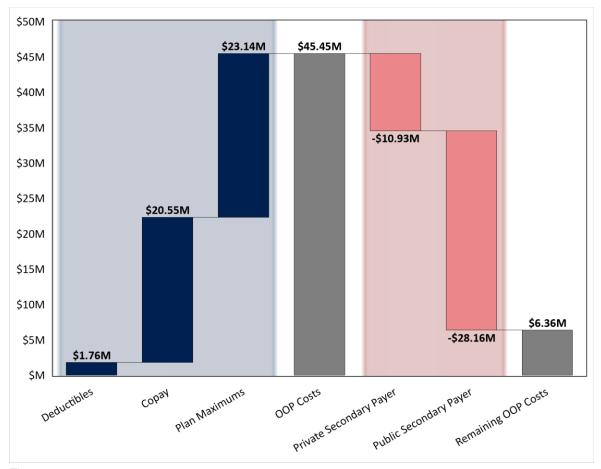


Figure 3 presents a waterfall chart of potential out-of-pocket costs associated with underinsurance and uninsured, for New Brunswick, Nova Scotia, and Ontario. The light blue shaded region of the graph represents potential out-of-pocket costs associated with primary private and public insurance sources. The red shaded region of the graph represents potential secondary sources of insurance that reduce out-of-pocket costs for THCDs. The remaining portion \$6.36 million (gray shaded) represents the shortfall that would be addressed by the modeled THCD program prior to any consideration of the effects of enhanced coverage on utilization.



Patient Support Considerations

Patient Support Program (PSP) services are offered to patients and providers nationally for specific specialty drugs and therapies sponsored by manufacturers to help facilitate the reimbursement investigation process, provide patient education and understanding of their disease, ensure compliance and adherence, and/or may provide financial assistance for high out-of-pocket costs.¹ These programs are offered by individual product manufacturers and may reduce financial barriers that would otherwise impede patients' access to THCDs in the provinces studied.

While in western Canada patients can rely on government reimbursement of listed THCDs, patients in Ontario and the Atlantic provinces face a patchwork of reimbursement cobbled together by manufacturer support. The THCD patient requires financial, administrative, and adherence support that may currently be provided by manufacturer sponsored programs for certain high-cost oral oncology products. These third party supports enable the patient to stay on therapy when insurance or public coverage is insufficient. While these programs offer value for patients, their families and treating physicians, that value may mask critical gaps that exist in eligible patients' access to treatment and highlights inequities in cancer care between the provinces.

CASE STUDY - THCD from a Specialty Pharmacy Perspective

The time it takes to obtain coverage for medications varies based on the drug plan involved. In an interview for this research with a McKesson Specialty Pharmacy, the experience with time to treatment for specialty drugs reveals that it usually takes a few weeks to obtain coverage for medications that require special authorizations (prior authorizations) or Exceptional Access Program approvals (in the case of Ontario Drug Benefit patients). In all cases the request for funding must be initiated by the prescribing physician. The paperwork must then be sent to the insurer which must be reviewed prior to granting a special authorization/prior authorization (in the case of private plans) or an EAP approval (in the case of public plans in Ontario).

While patients wait for drug plan approval, the PSP will often facilitate access to the drug product at no cost to the patient. This facilitated access is called "bridging", where the pharmaceutical company, through the sponsored PSP, ensures continuity of care from the time a prescription is written to the time of reimbursement decision from the drug plan. How much drug a patient receives while bridging varies based on the patient support program. Each has their own rules as to how much bridge supply they will approve at a time. For example, for one manufacturer program for an oral capsule taken once daily, the drug is always approved bridging for three weeks at a time. Another approves three months for an initial bridge. The bottom line: manufacturer bridging support is utilized by patients on oral oncology therapies to help fill the financial gaps in the cost of care, but access varies program to program. While intended to help ensure appropriate patients gain timely access to the treatment they need, the support may mask the size of the actual gap in access faced by patients. Where public and private drug programs may not offer equitable access to needed treatments, patient support programs offer a stop-gap level of access to innovative cancer treatments.

In this research, a short survey was conducted of oncology PSPs. Five Program Managers agreed to participate in the survey. A key similarity among all respondents found financial support offered by all the PSPs is used by a considerable portion of the registered patients. Compassionate access to treatment is generally provided when the patient has no coverage or does not fall within public and/or private eligibility criteria. A summary of the survey results is presented in Table 11.

¹ Financial assistance may take the form of copay support, bridging support, and compassionate use or free drug offerings.



Table 11. Summary of the Results of All the Oncology PSP Surveys

Oncology PSP Component	Reported Survey Results (Range if available)
In which provinces does the program operate?	All programs operate nationally
Average time to reimbursement approval <u>for all</u> <u>patients</u> in the PSP	1-4 weeks range
% patients in the PSP who have decided to pick-up their oral oncology drug from the retail pharmacy	23% average
Does the program follow-up with retail patients (adherence calls)?	No, programs do not generally follow-up with retail patients
Patient age group	40-65+ range
Copay Support	
Does the program offer copay support?	Yes, all programs offer copay support
Bridging Support	
Does the program offer bridging support for oral oncology patients?	Yes, all programs offer bridge support
How many weeks of product does the bridging program cover?	Programs generally offer bridge support until reimbursement investigation is complete or "as needed"; and often extended due to COVID delays in processing requests at the payer
% Active patients getting bridging support	Up to 70% average
Compassionate Use	
Does the oral oncology program offer compassionate support (free drug)?	Yes, all programs offer compassionate support
% Active patients currently accessing compassionate drug	Up to 45% average with one outlier of up to 90% for new drug pending coverage
Number of weeks on compassionate support	52 weeks+ on average
·	<u> </u>
Does compassionate support end?	All programs report that compassionate access is either re-assessed at the end of a select period and/or never ends once the patient is registered. The goal for some programs is for the patient to transition to provincial funding.
Primary reason for compassionate program?	No coverage for the patient is the main reason or unable to access due to eligibility criteria.

Results: Implementation of a THCD Plan

The research explored the implementation of a THCD plan and estimate its related costs. This THCD plan would seek to eliminate out-of-pocket costs and equalize product coverage between provinces. It is assumed the formulary would reflect the most generous provincial plan in terms of THCD coverage. The model also accounted for increases in utilization once out-of-pocket costs are eliminated.

The characteristics of this plan are summarized in Table 12. The THCD coverage model is based on the OHIP+ system in Ontario, which provides drug reimbursement for eligible patients under the age of 25. Costs for public, private, and out-of-pocket related to THCD are calculated under this comprehensive THCD program. The model was costed out to replace "Trillium"-like (catastrophic) programs and capture patients without alternative coverage.



The analysis suggests a total THCD financial gap between \$19.4 and \$51.9 million in New Brunswick, Nova Scotia, and Ontario in 2020 dollars. Gaps in coverage were identified with patients that rely primarily on private and catastrophic drug coverage. Table 13 details the current THCD drug cost and associated gaps in coverage by province.

Table 12. THCD Plan Parameters

THCD Plan Param	THCD Plan Parameters				
Beneficiary	Patients without or with insufficient drug insurance benefits				
Eligibility					
Replaces	'Trillium-like' drug programs				
Drug Coverage	Secondary payer, i.e., supplemental to existing benefits				
Model Basis	Coverage based on OHIP+ system in Ontario				
Limitation	Plan coverage is limited to existing provincial formulary coverage				

Table 13. Total THCD Gap in Coverage for Public and Private Plans (excluding Seniors and Social Assistance plans)

	Product Cost	Cov	erage	THCD Fin	ancial Gap
Province	THCD Drug Costs	Primary Coverage Spending	Secondary Coverage Spending	Gap in Coverage	Financial Gap %
New Brunswick	\$7.8M	\$6.2M	\$1.1M	\$0.6M	7.4%
Nova Scotia	\$9.6M	\$7.5M	\$1.8M	\$0.3M	3.1%
Ontario	\$186.8M	\$145.2M	\$34.8M	\$5.9M	3.2%
Quebec (benchmark)	\$169.9M	\$167.6M	\$0.6M	\$1.7M	1.0%

In this analysis, PDCI estimates a gap in current spending on THCDs of \$0.6 million in New Brunswick, \$0.3 million, in Nova Scotia, and \$5.9 million in Ontario. These costs cover the THCD financial gap after all current payer spending that is represented as 7.4% in New Brunswick, 3.1% in Nova Scotia, and 3.2% in Ontario.

Formulary differences can represent another gap in access for patients. Appendix Table 20 shows differences in product coverage between provinces by cancer type. A THCD plan would seek to equalize these formulary differences. Expanding coverage in New Brunswick, Nova Scotia, and Ontario to account for nine (9) additional products covered in Quebec would present some additional costs. None of these additional products treat cancer types without THCD alternatives, however these newer products tend to be more expensive than alternatives. Therefore, there would be some incremental costs over a baseline formulary. These amount to an additional \$45,000 in New Brunswick, \$48,000 in Nova Scotia, and \$865,000 in Ontario.

PDCI developed scenarios that modeled potential increases in utilization due to the removal of financial and administrative barriers to access. The model then examined two scenarios of increased THCD utilization based on patients currently benefitting from comprehensive public drug coverage. The first scenario represents a conservative increase in utilization, matching potential THCD treatment levels to the most comprehensive inprovince public program offered to residents under 65 years of age. The second scenario representing a high increase in utilization was developed based on Quebec's RAMQ program for residents under 65 years of age. As summarized in Table 14, the introduction of a THCD program would potentially increase the number of patients



treated. Our model predicted a range of 18 - 68% between all provinces with an increased utilization gap ranging between \$12.1M and \$44.6M.

PDCI's analysis of current THCD spending shows an underutilization of THCDs in provinces without comprehensive and accessible drug programs.

Table 14. The increased utilization gap from utilization rate scenarios for best in province plans covering THCDs

Utilization Effects	Province	Utilization Ratio	Incremental Treated Patient-Years	Increased Utilization Gap
Lower Range (based on Utilization associated with	New Brunswick	1.23	+19	+\$0.6M
Best in Province Coverage	Nova Scotia	1.20	+21	+\$0.7M
	Ontario	1.28	+363	+\$10.8M
Upper Range (based on Utilization associated with	New Brunswick	2.25	+102	+\$3.5M
RAMQ Under 65 program)	Nova Scotia	2.08	+112	+\$3.7M
	Ontario	1.62	+930	+\$26.6M
Total Utilization Increase	Lower Range		+403 (18%)	+\$12.1 (17%)
	(Equivalent to Best in Province)			
	Upper Range (Equivalent to RAMQ Under 65)		+1,507 (68%)	+\$44.6 (61%)

When accounting for product coverage inequities between the provinces and the potential increase in utilization of THCDs, with details presented in Table 15, PDCI estimates a total incremental cost of the gap at \$19.4 to \$51.9 million for all three provinces.

Table 15. Incremental Government Costs for implementation of a THCD Plan

	Current	Incremental Costs of the THCD Gap				Total THCD	
Province	Government Costs	Current Spending Gap	ding Product Utilization		Total Incremental Costs (Gross)	Plan Cost (Gross)	
New Brunswick	\$2.4M	+\$0.6M	+\$0.05M	+\$0.6M - +\$3.5M	\$1.3M - \$4.1M	\$3.6M - \$6.5M	
Nova Scotia	\$3.3M	+\$0.3M	+\$0.05M	+\$0.7M - +\$3.7M	\$1.1M - \$4.0M	\$4.3M - \$7.3M	
Ontario	\$59.9M	+\$5.9M	+\$0.9M	+\$10.8M - +\$37.4M	\$17.5M - \$44.2M	\$77.5M - \$104.1M	
TOTAL	\$66.0M	+\$6.4M	+\$1.0M	+\$12.1M - +\$44.6M	\$19.4M - \$51.9M	\$85.4M - \$117.9M	



Provincial payers negotiate confidential reimbursement agreements with drug manufacturers through the pan-Canadian Pharmaceutical Alliance. These agreements invariably include some confidential financial terms and other arrangements (e.g. public clinical criteria) for drugs. While the terms of each negotiated agreement remain confidential, for the purpose of modelling we assumed a publicly disclosed average discount rate to arrive at a net expenditure reduction across all costs. Net expenditures will vary depending on actual financial terms of product listing agreements between the provincial drug plans and pharmaceutical manufacturers. In Table 16, we present an estimate of the associated net incremental costs for implementing the THCD plan.

Table 16. Incremental costs after consideration of discount

Province	Incremental Cost (Gross)	Estimated Discount Rate*	Incremental Cost (Net)
New Brunswick	\$1.3M - \$4.1M	30%	\$0.9M - \$2.9M
Nova Scotia	\$1.1M - \$4.0M	30%	\$0.7M - \$2.8M
Ontario	\$17.5M - \$44.2M	30%	\$12.3M - \$30.9M
TOTAL	\$19.4M - \$51.9M	30%	\$13.9M - \$36.7M

^{*}The Ontario Auditor General Report (2016-2017), disclosed total pharmaceutical discounts received in Ontario was close to 30% of the total expenditures for brand-name drugs.

Conclusions

Across Ontario, New Brunswick, and Nova Scotia, the total perceived THCD gap is estimated to be between \$19.4 million and \$51.9 million. It is estimated that the provincial breakdown cost to implement a THCD plan to cover the gap would be as follows: a range of \$1.3 and \$4.1 million in New Brunswick, \$1.1 and \$4.0 million in Nova Scotia, and \$17.5 and \$44.2 million in Ontario.

In a small survey of oral oncology PSPs, it is reported that significant financial and drug access support is currently being provided to patients aged 40-65 years and older, which is funded by the drug manufacturer. Patients on oral oncology therapies will likely always be subject to prior authorization requirements, which take a few weeks to process to obtain and maintain coverage and reimbursement. PSPs provide access to therapies while patients await approval.

This research highlights the financial gaps, and variability of coverage for patients based on where they live or their type of cancer. As the concern access to THCDs continues to evolve, cancer advocacy organizations expect to continue to help shape health policies to support those living with the disease. This research identifies important cancer information for all Canadians and a call to action for policymakers to increase services to support and improve access to drugs for people with cancer.

As we advance our understanding of the underlying defects at the genomic and cellular level that can lead to cancerous tumors, biopharmaceutical research is delivering more precise and potentially curative treatments. The trade-off is often treating smaller populations with greater success but at a greater cost per patient. Those greater costs will place increasing stress on patients facing larger out of pocket costs; and may hasten more annual and lifetime caps across private drug plans – all leaving potentially larger gaps in actual access to new advanced cancer treatments. While the range of costs needed to implement universality of THCD coverage may seem large (relative to each province's population), other provinces' experience demonstrates the coverage gaps can be filled, removing the financial stress and burden from patients.



Further research in this area may help to better define the model. For example, access to more granular data that payers may collect would represent an additional research opportunity to develop additional insights into the actual THCD gap for policymakers and address the limitations and assumptions that form the basis of the model. The opportunity exists to address potential future utilization effects associated with new medicines since the model reflects current utilization. This additional information could help policymakers forecast future costs and utilization of THCDs.



Appendix

Table 17. Cancer Incidence per 100K by Age Cohort

Cancer Type	ICD-10 Codes	Age	Incidence per 100K
		0-24	0.2
		25-34	0.9
Diaddan	007	35-44	3.3
Bladder	C67	45-54	12.7
		55-64	39.7
		65+	120.9
		0-24	2.6
		25-34	3.1
Brain/CNS	070 070	35-44	4.3
	C70-C72	45-54	7.1
		55-64	12.2
		65+	18.6
		0-24	0.9
		25-34	10.8
Dunnat	050	35-44	45.2
Breast	C50	45-54	89.8
		55-64	135.2
		65+	190.5
		0-24	0.8
		25-34	3.8
On main	050	35-44	7.2
Cervix	C53	45-54	6.4
		55-64	5.1
		65+	4.4
		0-24	1.4
		25-34	5.0
Coloractal	C18-C20,	35-44	16.6
Colorectal	C26	45-54	45.7
		55-64	99.6
		65+	228.0
		0-24	0.0
		25-34	0.1
Ecophague	C15	35-44	0.8
Esophagus		45-54	4.0
		55-64	11.2
		65+	22.6

Cancer Type	ICD-10 Codes	Model Ages	Incidence per 100K
		0-24	0.2
		25-34	0.9
Luna	004	35-44	5.0
Lung	C34	45-54	32.3
		55-64	112.2
		65+	295.2
		0-24	1.4
		25-34	5.1
Malanama	C43	35-44	12.6
Melanoma	C43	45-54	22.3
		55-64	38.1
		65+	69.1
		0-24	0.0
		25-34	0.3
Multiple	000	35-44	1.4
myeloma	C90	45-54	5.4
		55-64	13.9
		65+	34.4
		0-24	2.1
		25-34	4.2
Non-Hodgkin's	C82-	35-44	9.5
Lymphoma	C86, C96	45-54	20.5
		55-64	41.3
		65+	89.2
		0-24	0.5
		25-34	1.4
Over	CEG	35-44	4.1
Ovary	C56	45-54	8.3
		55-64	13.3
		65+	21.1
		0-24	0.1
		25-34	0.6
Paparasa	C25	35-44	2.2
Pancreas	020	45-54	8.3
		55-64	22.7
		65+	58.3



Cancer Type	ICD-10 Codes	Age	Incidence per 100K
		0-24	0.6
		25-34	1.6
Head and neck	C00-C14,	35-44	5.9
nead and neck	C30-C32	45-54	18.2
		55-64	36.4
		65+	52.2
		0-24	2.6
		25-34	3.1
Hodgkin's	C81	35-44	2.8
lymphoma	Col	45-54	2.3
		55-64	2.5
		65+	3.4
Vida ov/Donol		0-24	0.6
		25-34	2.1
	C64-C65	35-44	7.5
Kidney/Renal	C64-C65	45-54	18.2
		55-64	34.0
		65+	53.6
		0-24	3.8
		25-34	3.5
Leukemia	C90, C91-	35-44	4.9
Leukeiiiia	C95	45-54	11.1
		55-64	23.5
		65+	55.7
		0-24	0.2
		25-34	0.3
Liver	C22	35-44	1.0
LIVEI	022	45-54	4.8
		55-64	14.1
		65+	24.4

Cancer Type	ICD-10 Codes	Model Ages	Incidence per 100K
		0-24	0.0
		25-34	0.1
Droototo	C61	35-44	3.3
Prostate	Col	45-54	36.3
		55-64	135.2
		65+	238.1
		0-24	0.1
		25-34	0.6
Ctomoob	C16	2.4	
Stomach	C16	45-54	7.1
		55-64	16.0
		65+	37.6
		0-24	2.8
Testis		25-34	5.2
	C62	35-44	5.7
	C62	45-54	2.9
		55-64	1.4
		65+	0.7
		0-24	3.9
		25-34	11.4
Thyroid	C73	35-44	22.3
Thyroid	073	45-54	26.1
		55-64	26.0
		65+	21.3
		0-24	0.1
		25-34	1.4
Litoruo	C54-	35-44	6.5
Uterus	C55	45-54	21.6
		55-64	44.1
		65+	52.6
		0-24	4.7
		25-34	7.5
OTHER	All other	35-44	16.2
OTTIER	sites	45-54	35.9
		55-64	74.2
		65+	198.5



Table 18. Gross Household Income by Age Cohort

AGE	Gross Household Income	NB Population	NS Population	ON Population	QC Population
	\$0-\$40K	46,233	62,185	933,405	475,022
	\$40-60K	32,340	38,259	549,099	330,387
0-24 years	\$60-80K	30,135	34,685	497,518	318,995
	\$80-100K	24,639	29,575	442,780	283,754
	\$100K+	65,570	87,218	1,797,481	897,567
	\$0-\$40K	19,610	29,760	434,970	220,610
	\$40-60K	12,270	15,290	241,560	138,350
25-34 years	\$60-80K	10,083	11,960	194,107	119,837
	\$80-100K	7,987	9,680	149,393	101,813
	\$100K+	14,920	18,710	365,980	215,700
	\$0-\$40K	15,600	20,650	295,380	173,510
	\$40-60K	11,750	14,220	215,890	134,520
35-44 years	\$60-80K	11,913	13,333	206,573	139,460
	\$80-100K	10,887	12,567	186,287	133,360
	\$100K+	34,190	41,290	788,590	480,990
	\$0-\$40K	16,280	20,470	277,660	161,180
	\$40-60K	11,080	12,990	183,710	114,700
45-54 years	\$60-80K	11,050	12,543	181,430	117,040
	\$80-100K	10,700	12,327	163,300	110,120
	\$100K+	44,120	53,200	927,620	495,790
	\$0-\$40K	24,950	31,410	362,800	249,360
	\$40-60K	16,420	18,510	206,780	165,370
55-64 years	\$60-80K	16,723	18,243	202,853	155,727
	\$80-100K	14,487	16,187	185,667	140,833
	\$100K+	41,740	55,620	919,350	485,260
	\$0-\$40K	68,110	77,170	817,720	699,360
	\$40-60K	38,530	45,010	507,330	389,860
65 years+	\$60-80K	27,993	33,760	386,853	255,747
	\$80-100K	17,467	22,200	281,507	163,213
	\$100K+	26,320	38,650	687,260	280,370



Table 19. Canadian Provincial Public Coverage Terms for THCD

PROVINCE	DRUG PROGRAM FOR ELIGIBLE THCD COVERAGE	DRUG PLAN DETAILS: COST TO THE PATIENT				
British Columbia	BC Cancer	Free of charge for THCD on formulary ⁹				
Manitoba	Cancer Care Manitoba	Free of charge for THCD on formulary9				
Saskatchewan	Saskatchewan Cancer Agency	Free of charge for THCD on formulary ⁹				
Alberta	Outpatient Cancer Drug Benefit Program	Free of charge for THCD on formulary ⁹				
Ontario	Trillium Drug Program	Deductible: 4% of household income after taxes Co-pay: Up to \$2 per eligible drug dispensed ¹⁰				
Quebec	RAMQ	Annual premium: \$0-\$662 based on net family income Monthly deductible: \$22.25 Monthly OOP maximum: \$95.31 Annual OOP maximum: \$1,14411				
Nova Scotia	Family Pharmacare	If annual income is less than \$25,000 annually, the provincial government will cover the entire cost involved in cancer treatment ⁹				
	Take Home Cancer Drug Fund	If out-of-pocket costs are greater than 4% of net family income, the remaining drug cost may be reimbursed under this program ¹²				
New Brunswick	New Brunswick Drug Plan	Annual premiums based on income (\$200-\$2000), along with a 30% copay to a maximum per prescription, also based on income (\$5-\$30) ¹³				
Newfoundland & Labrador	The Access Plan	Coverage of prescription medications for those with low incomes (individual: under \$27,151; couples without children: \$30,009; families with children: \$42,870) ¹⁴				
	Assurance Plan	0-40k Annual Income: 5% of net annual income 40k-75k Annual Income: 7.5% of net annual income 75k-150k Annual Income: 10% of net annual income ¹⁴				
Prince Edward Island	Catastrophic Drug Program	0-20k Annual Income: 3% of annual income 20-50k Annual Income: 5% of annual income 50-100k Annual Income: 8% of annual income 100k+ Annual Income: 12% of annual income ¹⁵				



Table 20. Coverage Plan Attributes by Age Cohort

Age	Primary Coverage	NB %	NS %	ON %	QC %
	Comprehensive Private	32%	32%	31%	31%
	Underinsured Private	37%	36%	36%	36%
0-24	Social Assistance	3%	3%	4%	3%
years	OHIP+	0%	0%	29%	0%
	Uninsured	28%	29%	0%	0%
	RAMQ Under 65	0%	0%	0%	30%
	Comprehensive Private	29%	29%	29%	29%
05.04	Underinsured Private	33%	34%	33%	33%
25-34 years	Social Assistance	6%	5%	8%	6%
yours	Uninsured	32%	32%	30%	0%
	RAMQ Under 65	0%	0%	0%	33%
	Comprehensive Private	35%	35%	35%	35%
05.44	Underinsured Private	40%	40%	40%	40%
35-44 years	Social Assistance	6%	5%	8%	6%
years	Uninsured	19%	19%	17%	0%
	RAMQ Under 65	0%	0%	0%	20%
	Comprehensive Private	34%	34%	34%	34%
45.54	Underinsured Private	39%	39%	39%	39%
45-54 years	Social Assistance	6%	5%	8%	6%
years	Uninsured	21%	21%	19%	0%
	RAMQ Under 65	0%	0%	0%	22%
	Comprehensive Private	32%	32%	32%	31%
55.04	Underinsured Private	36%	36%	36%	36%
55-64 years	Social Assistance	6%	5%	8%	6%
years	Uninsured	27%	27%	24%	0%
	RAMQ Under 65	0%	0%	0%	27%
	Comprehensive Private	0%	0%	0%	0%
	Underinsured Private	0%	0%	0%	0%
65	Social Assistance	0%	0%	0%	0%
years+	Seniors	100%	100%	100%	100%
	Uninsured	0%	0%	0%	0%
	RAMQ Under 65	0%	0%	0%	0%



Table 21. Provincially Covered THCD Therapies

			Re	Pul imbui	blic rseme	nt
CANCER TYPE	Brand Name	Active Ingredient	QC	ON	NB	NS
Brain and CNS	Afinitor	Everolimus				
	Afinitor	Everolimus				
Breast	Ibrance	Palbociclib				
	Kisqali	Ribociclib				
	Nerlynx	Neratinib				
	Tykerb	Lapatinib				
	Verzenio	Abemaciclib				
Colorectal	Lonsurf	Trifluridine				
Colorectal	Stivarga	Regorafenib				
	Calquence	Acalabrutinib				
Non-Hodgkin's Lymphoma	Imbruvica	ibrutinib				
Lympnoma	Zydelig	Idelalisib				
	Afinitor	Everolimus				
W: do	Cabometyx	Cabozantinib				
	Inlyta	Axitinib				
Kidney and Renal	Lenvima	Lenvatinib				
Kenui	Nexavar	Sorafenib				
	Sutent	Sunitinib				
	Votrient	Pazopanib				
	Bosulif	Bosutinib				
	Calquence	Acalabrutinib				
	Daurismo	Glasdegib				
	Iclusig	Ponatinib				
Leukemia	Idhifa	Enasidenib				
	Imbruvica	ibrutinib				
	Rydapt	Midostaurin				
	Venclexta	venetoclax				
	Zydelig	Idelalisib				

			Re		blic rseme	ent
CANCER TYPE	Brand Name	Active Ingredient	QC	ON	NB	NS
	Cabometyx	Cabozantinib				
Liver	Lenvima	Lenvatinib				
Liver	Nexavar	Sorafenib				
	Stivarga	Regorafenib				
	Alecensaro	Alectinib				
	Alunbrig	Brigatinib				
	Giotrif	Afatinib				
	Iressa	Gefitinib				
	Lorbrena	Lorlatinib				
Lung	Rozlytrek	Entrectinib				
	Tagrisso	Osimertinib				
	Tarceva	Erlotinib				
	Vizimpro	Dacomitinib				
	Xalkori	Crizotinib				
	Zykadia	Ceritinib				
	Cotellic	Cobimetinib				
Malanama	Mekinist	Trametinib				
Melanoma	Tafinlar	Dabrafenib				
	Zelboraf	Vemurafenib				
na litala	Ninlaro	Ixazomib				
Multiple Myeloma	Pomalyst	Pomalidomide				
Wycioma	Revlimid	Lenalidomide				
Overv	Lynparza	Olaparib				
Ovary	Zejula	Niraparib				
Pancreas	Afinitor	Everolimus				
rancicas	Sutent	Sunitinib				
	Erleada	Apalutamide				
Prostate	Nubeqa	Darolutamide				
Prostate	Xtandi	Enzalutamide				
	Zytiga	Abiraterone				
Stomach	Lonsurf	Trifluridine				
	Caprelsa	Vandetanib				
Thyroid	Lenvima	Lenvatinib				
	Nexavar	Sorafenib				



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