LEUKEMIA & LYMPHOMA SOCIETY OF CANADA®

Access to innovative blood cancer treatment

Is it fast enough and equitable for all Canadians?

POSITION PAPER

Eric Pesarchuk & daughter, BC. Eric is living with primary mediastinal B-cell lymphoma.

A new blood cancer drug approved by Health Canada takes an average of **867** days to reach coverage by a province's public health plan. That is two and a half years for most Canadians needing a drug. That's not fast enough.

Each province and territory decide independently if they will cover the new cancer drug in their public health plan. Some do, some don't; some quickly, some after a long wait. The result is glaring inequities in treatment options between Canadians with the same blood cancer. That's not fair enough.

Joey in British Columbia has myelodysplastic syndrome (MDS), a type of blood cancer. Her treatment involves regular blood transfusions requiring a trip to the hospital every couple of weeks. That many transfusions led to an iron overload in her body. Treating that overload resulted in some hearing loss. She's had to continue transfusions with the health risks unresolved.

Joey Kerr, BC. Joey is living with myelodysplastic syndromes.

If Joey didn't live in B.C. – say she lived in Alberta or Ontario - she could take a publicly funded drug that reduces, even eliminates, the need for blood transfusions in people with MDS. But she does live in B.C. so she's out of luck since she cannot pay for the drug out-of-pocket.

Glaring inequities

New cancer drugs are very expensive. Most Canadians could never afford them without public coverage, even if they sold their homes and borrowed money from everyone they knew. Canada does not provide universal pharmacare (drug coverage). Provincial coverage decisions are complex – affected by political interests, changes in government, advocacy efforts, population size, and regional priorities.

These decisions don't just impact how well people live with cancer; they can impact if they live at all. A Canadian research team looked at 15 oncology drugs being paid for by the provinces. They used a model to predict the number of life-years lost starting from when the cancer drug received Health Canada approval, to finally being paid for by any province.

The result was startling. Their research showed that drug access delays meant 39,067 overall life-years were lost. This means that despite having cancer, collectively people died 39,067 years earlier than expected. Importantly, they died even though a treatment was available – they just were not able to get it because of the way our system is set up.[1]

Can these drug approval delays and access inequities be addressed and mitigated? That's the objective of this paper – to shine a light on the system's weak spots and explore the opportunities for improvement.

Janice Skoblenick, ON. Janice is living with small lymphocytic lymphoma.

‘Leveling up’ in Canada’s drug approval and public coverage system

To describe Canada’s drug approval and public coverage system, picture a multi-level video game - one where players don’t gain virtual loot, rather one that causes serious negative consequences for real lives. Let’s look at a new drug’s quest in Canada’s intricate, slow-moving system.

LEVEL 0: Will the drug come to Canada?

With any new treatment, the drug manufacturer needs to decide if they want to launch in Canada. It is not always an easy decision, knowing that Canada is a small market with a complex reimbursement process.

✔ Yes – Enter and start Level 1.

LEVEL 1: Is the drug safe? Does it work well?

Health Canada reviews research evidence (from large clinical trials) of the new drug’s degree of safety and effectiveness as it relates to a specific blood cancer and specific line of treatment.

✔ Approves - Advance to Level 2

LEVEL 2: What is the drug’s value versus its risk?

For every province and territory except Quebec (where the Institut national d’excellence en santé et en services sociaux (INESSS) plays the same role), Canada’s Drug Agency (CDA) assesses:

a. Does the new drug have sufficient value to be recommended for public coverage - i.e. how does it measure up against drugs already on the market for that blood cancer?

b. How sure can the CDA be that the new drug works as promised; what is the risk that it won’t?

✔ CDA recommends – Advance to Level 3

Blood cancer community advocacy groups, such as The Leukemia & Lymphoma Society of Canada, can play part here at Level 2. They can gather feedback from impacted Canadians, including healthcare professionals, and submit that to CDA with intent to influence their decision.

LEVEL 3: How much will the drug cost?

This level is especially complicated. A group called the pan-Canadian Pharmaceutical Alliance (pCPA) represents the public payers (the provinces, territories and federal government) and negotiates with the brand name and generic drug manufacturers – the interests of a dozen or more players at the table – to agree on the price that will be paid for the new cancer drug.

- ✔ pCPA and manufacturer agree 'the price is right' – Advance to Level 4

LEVEL 4: Will the drug be covered by the provinces?

Each province or territory can now decide, independently, if it will include the new drug in its public health coverage for residents.

- ✔ Province says 'yes' – Advance to public coverage of new treatment

It's worth nothing that none of these levels can be played concurrently. Each level must wait for the level ahead of it to conclude its committee meetings, reviews and voting before the new drug can move forward through the system.

How long does it take a new blood cancer drug to move through these levels?

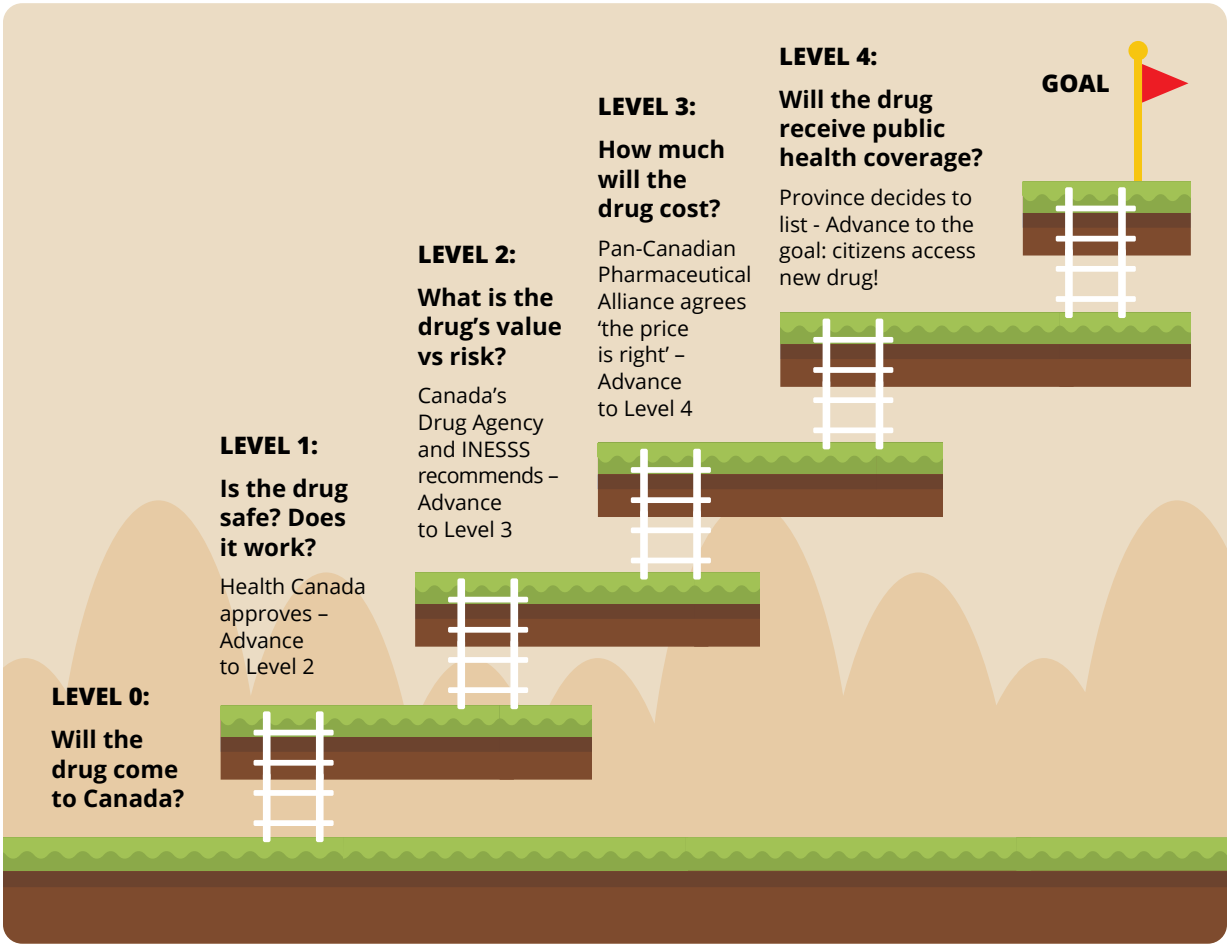
That depends on…

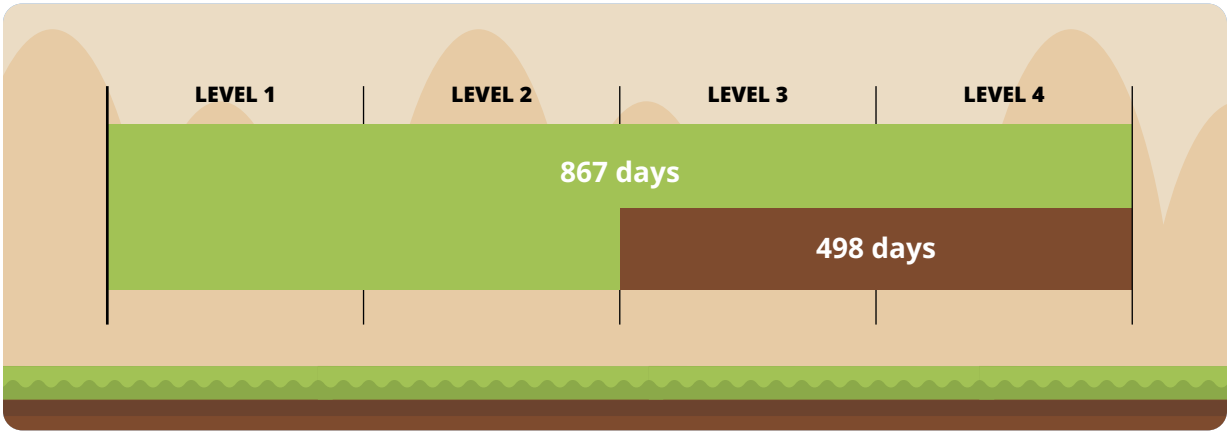
- ⏳ How long it takes Health Canada reviewers to decide on approval
- ⏳ How long it takes the CDA to make recommendation
- ⏳ How long it takes all the negotiating parties in pCPA to agree on a price
- ⏳ What the political will and budgets are for each province
- ⏳ How many other new drugs are queued up ahead, at one or more of the levels

As well, at any point in Levels 0 through 4, the process can result in a negative outcome – no approval or recommendation to move onto the next level.

Laura and James Lawson, AB. James is living with myeloproliferative neoplasms.

'Leveling up' in Canada's drug approval and public coverage system





The data story

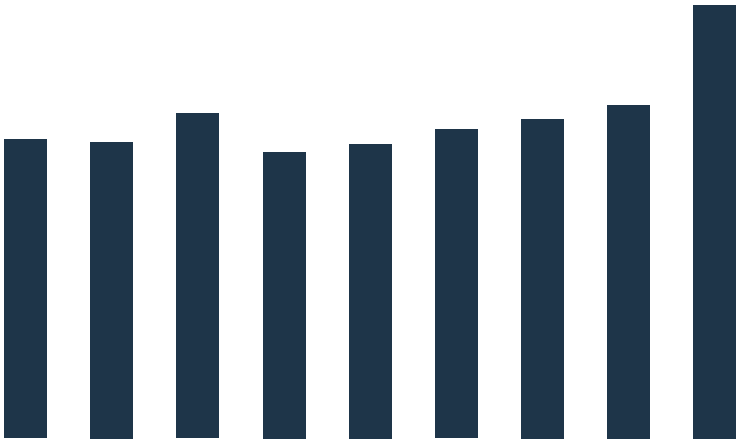
LLSC analyzed recent data[2] on wait times for new blood cancer drug approval, comparing how those wait times compare province to province (excluding the 3 territories and Quebec).

Our data, reviewed by manufacturers of new blood cancer drugs, included those drugs that, between January 2018 and December 2023, either:

- Received Health Canada approval (Level 1); or
- Received a recommendation from CDA (Level 2); or
- Were listed by a province for public health coverage (Level 4).

Average timelines to go through the entire process varies across Canada

Our data analysis showed that it took an average of 867 days – two years and four months – to go through the entire process, that is, to level up from Health Canada approval to the provinces paying for a new drug. (See Figure 1.)



	BC	AB	SK	MB	ON	NS	NB	NFLD	PEI
Average number of days	813	809	885	779	805	840	870	904	1,178

Figure 1: Average number of days from Health Canada approval to provincial funding of new blood cancer drugs.

Keegan Morin, ON.
Keegan is living with Burkitt's lymphoma.

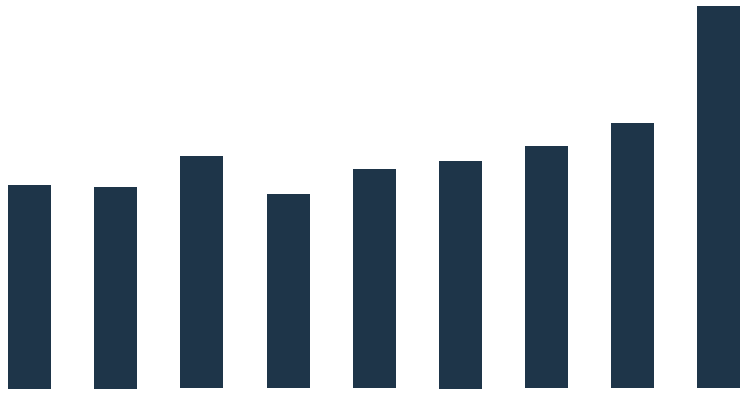
Time to provincial funding varies between provinces

There is variation between the provinces in the average number of days it takes to get from the CDA recommendation to fund a new blood cancer drug, to actual provincial funding. (See Figure 2.)

The average number of days between CDA recommendation and provincial funding is **498** but the range between provinces is wide. On average, Manitoba is the fastest to fund with an average of 411 days and PEI is the slowest with an average of 803 days.

The CDA makes a recommendation for all of Canada (except for Quebec), and the pCPA also negotiates a price that is valid for the entire country. This inequity and variation happen at Level 4, after the price is negotiated, because each province decides when to fund the treatment.

When you dig deeper and look within each province, you can see that some drugs can get funded quickly and other drugs can take a very long time. (See Appendix for a table indicating the range minimum and maximum range for each province.)



	BC	AB	SK	MB	ON	NS	NB	NFLD	PEI
Average number of days	432	424	493	411	464	476	510	558	803

Figure 2: Average number of days from CDA recommendation to provincial funding.

Efforts to ‘power up’ the system

Some efforts have been made to speed up time to get new cancer drugs approved faster.

In the U.S., the Food and Drug Administration (FDA) Oncology Centre of Excellence is working with partner countries – including Canada – to get patients faster access to promising cancer treatments in a program called Project Orbis.

Fifteen blood cancer drugs have qualified for Project Orbis. The good news is that Project Orbis has significantly shortened the average number of days between Health Canada approval and funding in each of the provinces. (See Figure 3.)

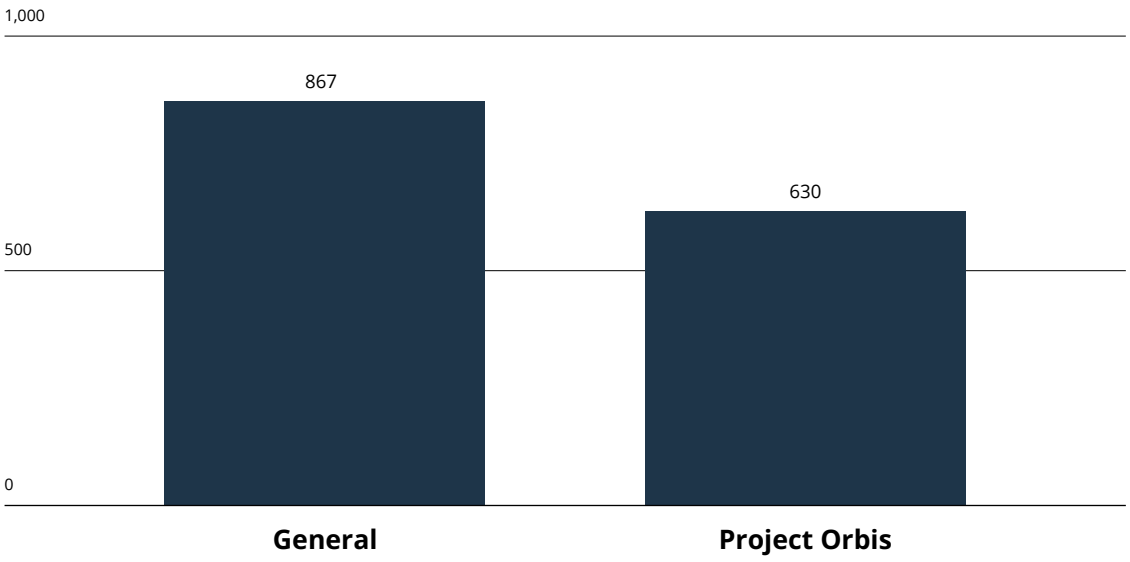


Figure 3: Average number of days from Health Canada approval to provincial funding, comparing outside of Project Orbis (“general”) to within Project Orbis.

Jovanna Sauro with Ellie, BC. Jovanna is living with Hodgkin’s lymphoma.

System improvements can help

Canadian agencies have taken some recent steps to try to expedite the drug approval process. In 2023, Canada's Drug Agency – Level 2 - introduced its Time Limited Recommendations (TLR) program. If a drug qualifies for TLR, that triggers its inclusion in the Temporary Access Pathway (pTAP) at Level 3, the pan-Canadian Pharmaceutical Alliance. Both steps are conditional on the drug manufacturer providing sufficient data to meet the agencies' requirements.

Since the criteria for TLR-pTAP are very strict, many drugs are ineligible. Only one blood cancer drug has gone through that program so far — epcoritimab, a new drug used to treat diffuse large B cell lymphoma (DLBCL) — and the resulting time to approval has been significantly improved.

Most provinces have listed epcoritimab for coverage in their provincial health plans within 1 year of the drug entering the Canadian drug approval system. A record time: half of what our system usually takes end to end! (See Figure 4.)

Figure 4: Coverage timeline for epcoritimab through the Time Limited Recommendations (TLR) + Temporary Access Pathway (pTAP)

In 2024, the CDA also announced Target Zero. Their intention with this initiative is to achieve zero days between Health Canada approval of a drug and a CDA recommendation for reimbursement[3]. When this happens, drugs can go through two levels at the same time!

Other barriers to timely, equitable treatment

On top of the delays and inequities in the drug approval system, Canadians with a blood cancer have other barriers to treatment. Take chimeric antigen receptor (CAR) T-cell therapy – a treatment that equips your own immune system with tools to better detect and destroy the cancer cells in your body. It has shown better clinical and quality of life outcomes, and more durable results, for certain types of blood cancer.[4]

However, not every Canadian eligible for CAR-T is given the chance. The lengthy wait time between referral for CAR T and start of treatment is an issue. If someone is fortunate enough to qualify and start CAR T in time for it to be effective, then there is the barrier of where the treatment happens.

There are only seven facilities in Canada that provide CAR T-cell therapy. Rod Delaney, the mayor of Cupids, Newfoundland, for example, had to fly to Ottawa, Ontario and live there for weeks for his CAR T treatment for diffuse large B-cell lymphoma. (His wife drove the 2700 kms one way to meet him there with their dogs because they couldn't find anyone to take care of them at home.)

Conclusions

In this paper, we looked at two key elements of Canadians' access to blood cancer treatment: 1) Is it fair enough? 2) Is it fast enough? Our conclusions are, sadly, a resounding 'no' on both fronts.

To best serve the community, and improve inequity, our systems need to modernize. We need faster access to medications, and to have more of them covered by public insurance. (The cost of a month's supply of a new blood cancer drug is often more than a month's salary for the average Canadian.) On the payer side, the healthcare system often attributes its delays to the need to increase "value" and decrease "risk" for the system. There are opportunities to satisfy both sides of this dilemma.

Rod and Joanne Delaney, NL. Rod is living with diffuse large B-cell lymphoma.

Opportunities for improvement

1. Use advancements in the drug discovery process to decrease the cost of research and decrease risk for the payers. For example:

   a. New and emerging technologies such as Artificial Intelligence (AI) can provide an opportunity to analyze data from past research and current treatments to predict the success of new discoveries. AI can be used to reduce both the time and cost of drug development.

   b. Genomic testing that can determine if a drug will work for an individual is called pharmacogenomics. Investing in this form of research will help us better match people to treatments that work for them. This gives people who need the treatments, and governments that pay for them, more assurance that it is the right treatment.

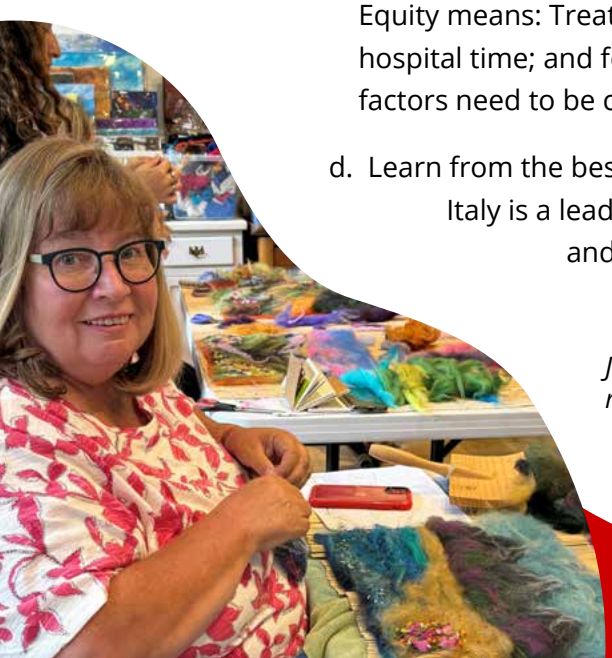
2. Further evolve our health technology assessment (HTA) systems to better serve the population.

   a. Canada's Drug Agency has introduced new processes, but at the time of this publication, only ONE blood cancer drug has completed this process. It is not enough. We need to re-examine the criteria for new processes so that more treatments can qualify.

   b. Capture the cost of a treatment beyond price. The value of the drug isn't just related to the hard cost. Caregiver time away from work, lost productivity, and travel to treatment all have costs that are not being captured in cost models used by the CDA.

   c. Define and truly include equity in considerations of drug coverage. Equity is often a concept that doesn't have set criteria new treatments can be measured against. Equity means: Treatment in home communities instead of distant cancer centres; less hospital time; and fewer out of pocket expenses associated with treatment. Those factors need to be considered by decisionmakers and payers.

   d. Learn from the best of proven models for drug approval and coverage. For example, Italy is a leader in outcomes-based agreements. They look at individual cases and only pay for treatments that work.



Jane Burns, AB. Jane is living with myeloproliferative neoplasms.

3. Expand the definition of “meaningful” data.

a. Real-world evidence: Data captured after a treatment is approved for sale by Health Canada can inform the system’s decision makers as to which drugs continue to work. (There is a myth that the cancer community wants all treatments funded. That isn’t true; the cancer community only wants the treatments that work to be funded.)

b. Develop the systems to capture the data and get agreement from individual hospitals and provinces to share. It is not their data – it is the community’s data.

4. Close the gap between wide variations in blood cancer drug coverage between provinces.

a. Explore ways to instate more equity across Canada. Currently, the national pharmacare model covers only diabetes and contraceptives; could cancer drugs be included?

5. Create ‘made in Canada’ solutions to address changes in geopolitical and health-related issues globally.

a. For example, in the recent past the COVID pandemic revealed deficits in Canadian manufacture of vaccines.

b. The current administration in the United States is slowing clinical research and as a result, drug development. The discussed Project Orbis program, with its promise of faster cancer drug approval in Canada, is led by the FDA and therefore faces an uncertain future.

Change takes time but it will never happen unless the community speaks up and decision makers listen. As a cancer community, we can use our voices to champion change and equity. Decision makers need to listen, adapt and innovate the system. The overall goal is to deliver the right blood cancer treatment to the right person at the right time in the right place. Individuals’ lives depend on getting the most effective drug as soon as possible, regardless of where they live in Canada.

We can do better. We **need** to do better - for Joey, and for all Canadians impacted by a blood cancer.

Sarah Moroz, ON. Sarah is living with acute promyelocytic leukemia.

APPENDIX

Days from Health Canada approval to provincial funding of new cancer drug

	BC	AB	SK	MB	ON	NS	NB	NFLD	PEI	AVERAGE (all provinces):
AVERAGE:	813	809	885	779	805	840	870	904	1,178	**867**
Range (min):	65	244	248	89	26	89	111	124	131	
Range (max):	5,615	5,611	5,618	5,622	5,594	5,625	5,630	5,635	5,639	

Number of drugs covered:	39	39	39	39	40	39	38	37	30	
Number of drugs not covered:	29	29	29	29	28	29	30	31	38	
Not covered minus those still under consideration 8 drugs under consideration	21	21	21	21	20	21	22	23	30	

References / Footnotes

1. Gotfrit, J.; Shin, J.J.W.; Mallick, R.; Stewart, D.J.; Wheatley-Price, P. Potential Life-Years Lost: The Impact of the Cancer Drug Regulatory and Funding Process in Canada. *Oncologist* 2020, 25, e130–e137.
2. Information was gathered from the website of Canada's Drug Agency (then CADTH) from March 2023 to November 2023. Drug manufacturers were asked to review the data between November 2023 and July 2024. The information used in the analysis consists of drugs that: received a CDA recommendation between January 2018 and December 2023, or; were paid for by the province (a provincial listing) between January 2018 and December 2023, or; received Health Canada approval between January 2018 and December 2023. The number of drugs included: 68 drugs that received Health Canada's Notice of Compliance (NOC) met our criteria for inclusion and analysis: 50 out of 68 drugs received a positive CDA recommendations; and 15 out of 68 were Project Orbis drugs. At the time of analysis, only 8 Project Orbis drugs had positive recommendations. The number of days from NOC to CDA n* = 54. *Only with a CDA recommendation (not considering "not pursued" (4),"no information" (1), "no indication" (1) or "pending" (8) - total14
3. https://www.cda-amc.ca/news/new-target-zero-initiative-aims-help-improve-access-new-drugs)
4. Cappell, K.M., Kochenderfer, J.N. Long-term outcomes following CAR T cell therapy: what we know so far. *Nat Rev Clin Oncol* 20, 359–371 (2023). https://doi.org/10.1038/s41571-023-00754-1

Access to new medications allows for meaningful life moments. Thank you to our community for sharing their photos and experiences so that we can highlight the real-life impact of treatment access.

This publication was made possible thanks to the support of

July 2025