Perspective

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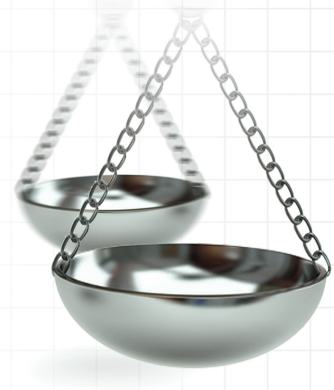

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# Time-limited reimbursement and Temporary Access Process for early access to oncology treatments in Canada: a perspective based on the epcoritamab experience

Chakrapani Balijepalli*,[1], Lakshmi Gullapalli[1], Swati Prasad[1], Nancy Paul Roc[2], Ana Rusu[2], Natalia Price[3], William Dempster[4] & Stephane Barakat[2]

[1]Pharmalytics Group, Vancouver BC V6B 2Z4, Canada
[2]AbbVie Corporation, Saint-Laurent QC H4S 1Z1, Canada
[3]AbbVie Pty Ltd, Mascot New South Wales, Australia
[4]3Sixty Public Affairs, Ottawa ON K2P 1P1, Canada
*Author for correspondence: chak.balijepalli@pharmalyticsgroup.com

For years, Canadians have faced long wait times for access to new medicines. These delays are largely attributed to complex health technology assessments, extended price negotiations and protracted provincial listing decisions. To address these challenges, in November 2023, Canada's Drug Agency (CDA) introduced its first early access program – the time-limited reimbursement recommendation (TLR) – aimed at accelerating the reimbursement of promising drugs undergoing Health Canada's Notice of Compliance with Conditions (NOC/c) process. In conjunction, the pan-Canadian Pharmaceutical Alliance developed the Temporary Access Process (pTAP) to support price negotiations for drugs that go through CDA's TLR pathway. AbbVie corporation was the first company to participate in the TLR and pTAP processes with EPKINLY (epcoritamab) – a novel treatment for advanced lymphoma. On 18 June 2024, EPKINLY became the first therapy in Canada to receive a positive CDA TLR recommendation and on 19 July 2024, AbbVie and the pan-Canadian Pharmaceutical Alliance successfully concluded pTAP negotiations. As of 1 November 2024, EPKINLY was listed in nine provinces, achieving a 10.7 month faster time-to-patient than the average time for the standard process, which is significant and meaningful to patients. This achievement demonstrates the potential of the TLR and pTAP processes to improve medicine access timelines for patients. However, an analysis of drugs that received NOC/c status from Health Canada between 2020 and 2024 reveals that very few drugs would have met the current strict eligibility criteria required to benefit from the TLR, limiting the potential benefits of these programs. While TLR and pTAP are promising initiatives, refinements are needed to maximize their impact and ensure faster access to life-saving therapies for Canadian patients.

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## Background

For some time, Canadians have looked at other countries with a mix of admiration and frustration, watching patients abroad get much faster access to new medicines, while facing lengthy delays at home.

Complex health technology assessments (HTA), extended price negotiations and protracted provincial listing decisions frequently contribute to lengthy delays to access medicines for Canadian patients.

There are two HTA agencies: Canada's Drug Agency (CDA-AMC) and Quebec's Institut national d'excellence en santé et services sociaux (INESSS). These agencies review the therapeutic value (relative to other treatments) and cost–effectiveness of new drugs and make recommendations on whether they should be publicly funded.

Once the CDA-AMC or INESSS issues a recommendation, the pan-Canadian Pharmaceutical Alliance (pCPA) – representing federal, provincial and territorial drug plans – begins negotiations with the drug manufacturer to reach terms for public reimbursement. Only after the completion of the pCPA negotiation process do individual provinces decide whether and when to fund new drugs in their jurisdictions. The duration of this process can vary significantly across the country [1].

While the CDA-AMC and pCPA have set target timelines – 180 days (6 months) for HTA review and 140 days (4.6 months) for product price negotiations – recent data show significant delays [2,3]. For instance, in 2023, the CDA-AMC's review of oncology drugs averaged 228 days (7.6 months) [4], while product negotiations added an additional 153 days (5.1 months) [4]. Even after completion of pCPA negotiations, patients faced further delays at the provincial level, where the timeline for formulary listing ranged from 65 (2.1 months) to 282 days (9.4 months) depending on the province [4].

These delays put Canada near the bottom among the Organization for Economic Co-operation and Development (OECD) countries. For instance, Canada ranks 19th out of 20 other OECD countries when it comes timely access to oncology treatments [5]. A 2024 Conference Board of Canada study found that, on average, it takes 736 days – more than 2 years – from Health Canada's market authorization of a drug to its first public formulary listing. This is double the average time reported in comparable OECD countries [6,7].

These access delays are also pronounced for oncology drugs, which represent a significant proportion of new therapies in development. According to the latest Patented Medicine Prices Review Board Meds Pipeline Monitor, nearly a third of drugs currently in clinical trials are oncology treatments [8]. With innovations in cancer treatment advancing rapidly, healthcare systems around the world are exploring ways to reduce time-to-patient for these therapies.

At the same time, decision-makers also face challenges when it comes to evaluating and paying for treatments with perceived uncertainty in the clinical and economic data supporting value to patients and the healthcare system. In this context, countries like England, France, Italy and Australia have implemented early access programs to reduce time-to-patient, including through the increasing use of real-world evidence (RWE) to supplement traditional clinical trial (randomized controlled trial [RCT] type) data [9–16]. Some early access programs are financed with separately allocated budgets (England and Italy) [17].

As Canadians continue to observe faster access to medicines in other countries, there is growing support for Canada to explore similar models and best practices. This paper explores Canada's recent efforts to implement early access programs and provides insights into potential pathways to expedite access. Key considerations include broadening eligibility criteria for early access programs, earmarking budgets for early access products and mandating faster timelines for reimbursement decisions [8].

## Early access programs in Canada: time-limited reimbursement recommendation

Acknowledging the need for an early access scheme, the CDA-AMC formally introduced its first early access program, the time-limited reimbursement recommendation (TLR), in November 2023. Prior to the launch of TLR, drug sponsors were allowed to make reimbursement submissions to CDA-AMC for their drugs with phase II data that had received a Notice of Compliance with Conditions (NOC/c) from Health Canada; however, there were no specific guidelines for phase II submissions related to an early access reimbursement scheme [18]. The drugs followed the same review and reimbursement pathways process as submissions for drugs with phase III data. Due to the uncertainty associated with phase II data, a significant proportion of files either received very high price discount recommendations or negative reimbursement recommendations due to uncertainty related to the clinical trial data. This often resulted in situations where a drug is reimbursed in other countries that recognize its promise of value while it remains unreimbursed in Canada [17].

The TLR initiative creates a path for CDA-AMC to provide a reimbursement recommendation to fund a drug for a time-limited period while the drug sponsor collects additional data from a phase III trial to establish clinical efficacy addressing uncertainties [19]. In order to be eligible for the TLR process, drugs must meet the following conditions:

- The drug has been or is undergoing review through Health Canada's advance consideration process under the NOC/c policy or the approval is accompanied by terms and conditions.
- Evidence generation is planned through a phase III trial that is being planned or conducted in the same patient population, with the same indication (e.g., same line of treatment), same intervention and same dosage as

specified in the product monograph for the indication being reviewed by CDA-AMC, and with an expected study completion within 3 years.
- The drug sponsor is expected to file a reassessment application with CDA-AMC within 270 calendar days after the completion of the phase III trial.
- The evidence-generation plans described in Health Canada's Qualifying Notice are expected to address the gaps in the evidence identified by CDA-AMC's expert committee.

Upon the sponsor's submission for a reassessment, CDA-AMC reviews the new evidence and issues an updated reimbursement recommendation to supersede the original time-limited recommendation that was based on phase II trial data. Of particular note are the requirements that the drug sponsors be able to complete the phase III trial within 3 years and file for reassessment within 270 days from the completion of the phase III trial. The results of the phase III trial must confirm the results of phase II trial data to secure a positive final reimbursement recommendation from CDA-AMC.

## pCPA Temporary Access Process (pTAP)

Recognizing the need to adapt and provide timely access to innovative treatments for patients, the pCPA developed a set of principles and conditions to inform the price negotiation process for drugs that go through the CDA-AMC's TLR pathway. These principles and conditions are referred to as the pCPA Temporary Access Process (pTAP). In addition to receiving a TLR designation from CDA-AMC, participation in pTAP requires that several other criteria be met [20]:

- A time-limited recommendation from CDA-AMC does not guarantee pCPA will agree to temporary access. pCPA will assess each file individually and determine whether it will pursue a negotiated agreement in the interim while further evidence is developed. There may be instances where pCPA does not negotiate a temporary reimbursement agreement.
- For temporary access, drug products are required to be priced according to established cost–effectiveness criteria to offset clinical uncertainty and a risk-share agreement between payer and manufacturer is required.
- Funding during the interim period is considered temporary. Funding beyond the interim period is subject to the final CDA-AMC reassessment recommendation and the final pCPA negotiated agreement.
- During the temporary access process, pCPA may negotiate for the period after the final CDA-AMC reassessment has been issued.
- Manufacturers must agree to submit for HTA-reassessment, regardless of the outcome of the phase III clinical trial, within the designated time period as prescribed by CDA-AMC. If the manufacturer does not submit updated clinical trial data within the agreed-upon time, then time-limited funding will be terminated, and any existing patients will become the responsibility of the manufacturer.
- In the following situations, the manufacturer will assume funding for patients who started on the drug product during the interim period:
  - Manufacturer fails to comply with CDA-AMC reassessment; or
  - CDA-AMC final recommendation is to not reimburse; or
  - CDA-AMC provides a final recommendation to reimburse, but pCPA negotiations do not result in a long-term agreement between pCPA and the manufacturer; or
  - CDA-AMC final recommendation further restricts criteria which results in patients becoming ineligible for public funding.
- If CDA-AMC has issued a time-limited recommendation for a product, pCPA and public drug plans require the manufacturer of that product to abide by the principles and conditions outlined above.

Although the TLR and pTAP processes now offer Canadian patients an official early access pathway, there are clear differences with the more established programs available in other countries, such as England and Italy. Of note, in England, managed access agreements for oncology therapies are accompanied by a set budget from the Cancer Drug Fund that covers innovative cancer drugs with promise of value while data are collected to support permanent reimbursement [21,22]. Similarly, in Italy, there is an Innovative Drug Fund for both oncology and nononcology drugs that allows new drugs with promising value to be covered for a period of 36 months, while additional data on the new drug are collected using a national registry [16]. In contrast, in Canada, there is no specific committed


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budget from public drug plans for drugs that are assessed under the TLR program. While TLR offers a valuable step toward early access, the lack of a guaranteed budget means that each drug listing depends on available funds and individual provincial decisions, which may limit the reach and speed of access to TLR therapies for Canadian patients.

## Drugs with NOC/c status & feasibility of qualifying for TLR/pTAP

According to Health Canada, a NOC/c is a conditional market approval given to products that target serious or life-threatening illnesses, contingent upon additional clinical trials to confirm the anticipated benefits [18].

With the recent launch of the TLR program, an analysis of NOC/c drug submissions using publicly available data outlined in CDA-AMC's reimbursement review reports [23] was conducted to understand the following:

- What proportion of drugs with NOC/c status are submitted for HTA review with phase Ib/ phase II data?
- What proportion of drugs with NOC/c status using phase Ib/phase II data also have a phase III trial ongoing?
- Of the drugs with NOC/c status and an HTA submission, how many received a positive recommendation?
- What are the ranges of recommended price reductions associated with the positive HTA recommendations for NOC/c drugs?

Since 2020, CDA-AMC has recommended price reductions for drugs that fail to meet an efficiency frontier with the $50,000/ quality-adjusted life year threshold (although this policy may be under revision). This analysis includes submissions from 2020 onward to determine hypothetically what proportion of NOC/c drugs would have been eligible for the TLR-pTAP pathway if it had been available since 2020.

From 1 January 2020 to 16 August 2024, it was found that a total of 30 new drug submissions received an NOC/c designation from Health Canada (with two more under review). Of these, 11 (37%) were submitted to the CDA-AMC based on phase 1b/phase II data.

Of these 11, five (45%), were not recommended for reimbursement by CDA-AMC (four had ongoing phase III trials, and at least two appeared to meet TLR eligibility).

Meanwhile, of the six submissions that did receive a positive recommendation from CDA-AMC, four had price reduction recommendations of 35–95%. Notably, two of the six submissions that received a positive recommendation also had ongoing phase III trials and appeared to fulfill the TLR eligibility criteria.

Thus, based on this analysis and the current TLR eligibility criteria, only four out of 30 drugs receiving an NOC/c designation since 1 January 2020, would have been eligible for TLR if the scheme had existed as of that date.

This analysis also shows that phase Ib/phase II submissions often fail to receive a positive HTA recommendation. Almost half of the submissions in this study did not receive a positive reimbursement recommendation due to study design limitations (e.g., small sample sizes, lack of comparative data or insufficient evidence of long-term benefits). For the remaining 50% of submissions that received a positive recommendation with phase Ib/phase II data, a majority received price reduction recommendation greater than 70% which may reflect the cautious approach taken with early-phase data.

## The Epkinly experience with TLR

Since the launch of the TLR and pTAP initiative in November 2023, AbbVie became the first company to participate in this early access initiative. AbbVie received an initial NOC/c designation from Health Canada for Epkinly (epcoritamab), a novel treatment for advanced lymphoma, on 13 October 2023, with a subsequent revision to the product monograph on 23 April 2024 [24].

Following receipt of an NOC/c for Epkinly, AbbVie made a submission to CDA-AMC on 14 November 2023, seeking a TLR for Epkinly to treat adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL transformed from indolent lymphoma, high-grade B-cell lymphoma, primary mediastinal B-cell lymphoma or follicular lymphoma grade 3B after two or more lines of systemic therapy and who have previously received or are unable to receive chimeric antigen receptor T-cell therapy. On 18 June 2024, EPKINLY became the first therapy in Canada to receive a positive CDA-AMC TLR recommendation and on 19 July 2024, AbbVie and the pCPA successfully concluded pTAP negotiations [23,25].

Epkinly was eligible for a TLR submission given that AbbVie submitted evidence from the ongoing EPCORE NHL-1 trial, a phase I/II, open-label, single-arm study, that included 157 patients with relapsed or refractory large

B cell lymphoma, and also agreed to file the results of the phase III EPCORE DLBCL-1 trial to CDA-AMC in accordance with TLR timelines and reassessment requirements. During the review of Epkinly, the pan-Canadian Oncology Drug Review Expert Review Committee (pERC) determined that the trials EPCORE NHL-1 and EPCORE DLBCL-1 were similar enough with regard to population, indication and dosage of epcoritamab and therefore the Epkinly submission met the criteria for a TLR submission. Furthermore, the pERC found that evidence from the EPCORE NHL-1 trial suggested that treatment with epcoritamab may result in clinically meaningful improvements in median overall survival and progression free survival. Also, additional landmark analyses of overall survival and progression free survival at 12 and 18 months were supportive of survival analyses. Epcoritamab also showed a clinically meaningful response and a durable response with no detriment in health-related quality of life [26].

As of September 2024, Epkinly is the first and only drug to be reviewed and approved by CDA-AMC for a TLR designation. The analysis described above indicates that since the launch of TLR in November 2023, only two other new drug submissions to Health Canada have received a NOC/c designation and, out of the two submissions, only one may have been potentially eligible for the TLR process.

## Lessons learned from the Epkinly experience & how to enhance TLR & pTAP

Based on AbbVie's experience with the first TLR, early engagement is critical for manufacturers to understand whether a new drug is eligible for TLR. Even when a file passes the initial eligibility screening, TLR-eligibility is not confirmed until the draft recommendation is published. Further clarity is needed to increase the overall transparency of the process to determine TLR eligibility. This additional guidance would allow manufacturers to know the status of the file (TLR or standard recommendation) in advance of the draft recommendation and better prepare for subsequent pCPA negotiations. This is important, as each step in the reimbursement process can impact time-to-patient.

With regard to the TLR eligibility criteria, as noted above, only four out of 30 NOC/c drugs would have been eligible for TLR over the past 4 years, and only one has received this designation since the program was launched in November 2023. This underscores the need to broaden eligibility criteria to ensure more therapies qualify for TLR.

One recommendation is to align the TLR criteria with Health Canada's eligibility criteria for the NOC/c pathway. This could help streamline regulatory and reimbursement pathways in Canada and remove redundancy in the process. Without wider eligibility for TLR, the TLR program will have limited impact on the speed of patient access to promising new therapies.

An additional limitation pertains to TLR's reassessment requirements. The reassessment requirements within the TLR process should offer manufacturers greater flexibility to adapt their subsequent submission packages to include phase III clinical data and/or RWE. This flexibility during HTA reassessment would help manufacturers align their evidence with evolving standards and expectations, may reduce redundancy in the evaluation process to secure permanent patient access.

To summarize, broadening the eligibility criteria, and allowing manufacturers greater flexibility in the required second submission to CDA-AMC for the removal of the time-limited recommendation with a final recommendation will help ensure the long-term viability of this emerging early access pathway in Canada.

## A note on cost–effectiveness thresholds

When evaluating the implementation of a new intervention, decision-makers must estimate both the health benefits that could be obtained through alternative uses of the required resources and the health losses likely to occur if the new intervention is not implemented. This is assessed using cost–effectiveness thresholds [27].

One of the key eligibility criteria for pTAP is to meet a predefined cost–effectiveness threshold, which effectively requires manufacturers to price their drugs at a level that offsets the uncertainty in clinical benefit. However, this pTAP condition may act as an additional deterrent to participation in the TLR/pTAP pathway. It may limit the number of submissions made and ultimately limit the number of treatments made available to patients via early access.

A previous descriptive analysis of CDA-AMC submissions for oncology products showed that submissions with higher incremental cost–effectiveness ratios receive higher price reduction recommendations. High price reduction recommendations risk lengthening the price negotiation which, in turn, may delay access to new innovative medicines [28]. To help support early patient access to medicines with promising value, therapeutic innovation

should be recognized, and policy makers should consider other factors beyond cost–effectiveness in the negotiation process, such as disease severity or small patient volumes to enhance the uptake of the early access process [28].

## Remarkable acceleration achieved through the TLR & pTAP processes versus the regular reimbursement process

The good news is that the new TLR/pTAP evaluation and funding processes significantly accelerated the 'time-to-patient' for Epkinly. The entire TLR and pTAP process took just 248 days (8.2 months). This is significantly faster than the average time of 568 days (18.9 months) for oncology drugs and 617 days (20.6 months) for nononcology drugs through the standard evaluation and reimbursement processes for the drugs completing the CDA review in 2022 [4]. TLR and pTAP accelerated the process by at least 10.7 months. This magnitude of acceleration is significant and meaningful to patients.

It is important to note that CDA-AMC has introduced a Target Zero initiative, which aims to improve time-to-patient by achieving zero days between Health Canada's regulatory approval of a drug and CDA-AMC's draft reimbursement recommendation [29]. Target Zero, combined with policies such as rolling review submissions, has the potential to accelerate the HTA process even further for future TLR assets. Rolling reviews could lead to even faster time-to-patient by allowing manufacturers to submit the required clinical and economic evidence as soon as it is available, rather than waiting to assemble all required documentation into a single application package [30].

## Experiences with public formulary listings for Epkinly

As of 1 November 2024, Epkinly is listed in nine provinces. Listing decisions were taken much faster than for drugs that go through the standard CDA-AMC review process. The faster funding timelines in the provinces of Ontario and Quebec are particularly notable. The first provincial listing occurred only 273 days (9 months) following the submission to CDA-AMC. On average, it takes 568 days (18.9 months) for oncology treatments to reach first listing following submission to CDA-AMC. This means the TLR/pTAP process reduced the overall time-to-patient by 295 days (9.8 months)

Notably, for some provinces, formulary listings came within 57 days (2 months) after the HTA recommendation, and 1 month after the successful pTAP negotiation [31]. The experience with Epkinly showed that novel treatments can move rapidly through the listing process when they go through TLR and pTAP, illustrating how these pathways support significantly faster timelines compared with the standard reimbursement process.

It is worth mentioning that provincial drug plans do not have timeline targets for TLR/ pTAP products. To ensure the success of Canada's early access initiative, all provinces should be prepared to rapidly list products that complete the TLR and pTAP processes. Provinces should consider developing listing protocols for drugs that are eligible for TLR across various therapeutic areas, including oncology.

Efforts to accelerate timely access to new treatments should also be informed by best practices in other countries, including dedicated drug funds such as those in England and Italy. These types of funds help jurisdictions pay for medicines, enabling faster access to innovative therapies.

## Conclusion

The new TLR and pTAP processes serve as a significant positive first step toward the goal of providing faster access to life saving medications in Canada. AbbVie has appreciated the opportunity to collaborate with CDA-AMC and the pCPA on the first application of TLR and pTAP. However, there are significant barriers to participation in this process. Broadening the eligibility criteria for TLR (so more treatments can pass through this process), addressing current barriers related to cost–effectiveness pricing, and considering the creation of a dedicated fund for drugs going through the TLR and pTAP processes could help accelerate access to more medicines with the promise of value. The integration of TLR with initiatives like Target Zero offers the potential for even greater acceleration, but the success of this process requires collaboration from all parties involved. Provincial drug plans should also establish protocols that include firm timelines for funding medicines that complete the TLR and pTAP processes.

This article is intended to serve as a starting point for discussions to improve emerging Canadian accelerated access programs with the hope of it being able to make a meaningful contribution to the shared goal of expediting Canadians' access to valuable new medicines.

## Summary points

- In November 2023, Canada's Drug Agency (CDA) introduced its first early access program, the time-limited reimbursement recommendation (TLR).
- This process is designed to accelerate the reimbursement of new drugs with promising value that are undergoing Health Canada's Notice of Compliance with Conditions (NOC/c) process.
- To support the price negotiation of drugs that enter the TLR, the pan-Canadian Pharmaceutical Alliance developed the Temporary Access Process (pTAP).
- Epkinly (epcoritamab), a novel treatment for advanced lymphoma from AbbVie, was the first therapy to receive a positive TLR recommendation from CDA-AMC on 18 June 2024, followed by a successful pTAP negotiation on 19 July 2024.
- As of 1 November 2024, Epkinly was listed in nine provinces, achieving a time-to-patient that was 10.7 months faster than the average duration required for the standard CDA review process.
- The TLR and pTAP processes represent significant positive first steps toward the goal of providing faster access to life-saving drugs in Canada.
- Although TLR and pTAP have the potential to reduce the time-to-patient for new drugs, the current eligibility criteria for the TLR process appear to be a barrier for many drugs.
- To enable more therapies to qualify for TLR/pTAP criteria, CDA-AMC should broaden eligibility and revise reassessment requirements. By allowing the inclusion of phase III data that may differ from phase II data and incorporating real-world evidence, manufacturers gain flexibility to meet evolving clinical practice standards, enhancing the evaluation process's effectiveness. Additionally, the pan-Canadian Pharmaceutical Alliance should address cost–effectiveness pricing barriers to create a more flexible pathway, reducing the industry's risk in pursuing TLR/pTAP processes.

### Author contributions

AbbVie conceived the project, C Balijepalli conducted formal analysis, wrote the original draft and revisions. L Gullapalli worked on data curation, conducted formal analysis and wrote the original draft and revisions. S Prasad worked on data curation and wrote the original draft. S Barakat, NP Roc, A Rusu and N Price provided analysis and insights to the original draft and revision and supervised the work. W Dempster provided analysis and insights. All authors have read the final version of the manuscript.

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C Balijepalli and L Gullapalli are shareholders of Pharmalytics Group, a company that has served as a consultant to AbbVie and has received research funding from AbbVie. S Prasad is an employee of Pharmalytics Group. NP Roc, A Rusu, N Price and S Barakat are employees of AbbVie. W Dempster co-leads 3Sixty Public Affairs, a company that has served as a consultant to AbbVie and has received policy research funding and speaking fees from AbbVie. The authors have no other competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript apart from those disclosed.

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