Assessing the Utilization of Early Access Pathways and Implementation of Time-limited Reimbursement and Temporary Access Process in Canada

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INTRODUCTION

- Health Canada first issued the Notice of Compliance with Conditions (NOC/c) Policy in May 1998, which provides earlier conditional regulatory approval to promising novel therapies that treat life-threatening/ debilitating diseases with limited therapeutic options based on immature evidence.
- Effective Sept. 28, 2023, Canada's Drug Agency (CDA) introduced the time-limited recommendations (TLR) process to accelerate review and support timely access to these promising new therapies.

OBJECTIVE

We aimed to understand utilization and impact of early access programs, by reviewing Canadian health technology assessment (HTA) decisions and pricing negotiations of products that received an NOC/c designation from Health Canada (HC) following the introduction of the TLR/pan-Canadian Pharmaceutical Alliance (pCPA) Temporary Access Process (pTAP).

METHODS

- HTA reports of products that received an NOC/c designation from HC from September 2023 (i.e., when CDA introduced the TLR process) to December 2025 were retrieved from the CDA website.
  - Corresponding *Institut national d'excellence en santé et services sociaux (*INESSS) submissions for these products were also retrieved from the INESSS website.
  - The status of pCPA negotiations for CDA submissions retrieved were also obtained from the pCPA website.
- Information on the following were extracted from the CDA final recommendation report:
  - Product information (brand or generic drug name, manufacturer, dosage, route of administration, and indication).
  - NOC status at the time of filing (i.e., pre-NOC, post-NOC submission).
  - Trial design.
  - Potential for meeting TLR eligibility criteria (i.e., the product is anticipating or was issued an NOC/c, a robust evidence-generation plan such as a Phase 3 clinical trial is planned.
- Reimbursement decisions were also extracted

RESULTS

- 15 products were identified that received an NOC/c from HC during the period Sept. 2023–Dec. 2025.
  - Of these, 10 were submitted for CDA review, of which 7 had completed reviews.

RESULTS (*Cont.*)

- Among the completed reviews, 6 products received a positive CDA recommendation (**Fig. 1**).
- One submission (Talvey™) received a negative CDA recommendation due to uncertainties around clinical benefit demonstrated in the Phase 1/2 single-arm trial submitted.
  - When assessing for TLR eligibility, the product appeared to have met the criteria for undergoing the early access process.

Figure 1. Drug submissions with NOC/c designation from HC and submitted for CDA review between September 2023 and December 2025

Abbreviations: CDA: Canada's Drug Agency; HC: Health Canada; NOC/c: Notice of Compliance with Conditions.

- As of Dec. 31st, 2025, Enhertu® and Epkinly™ were the only products to enter the early access TLR process; both received a TLR from CDA and a pTAP agreement pCPA.
  - While Epkinly™ received a positive recommendation from INESSS and is reimbursed by public drug programs across Canada, Enhertu® received a negative recommendation from INESSS and is not listed in Quebec and PEI public drug plans.
  - Comparing CDA and INESSS recommendations, 3 drugs received positive decisions with concordance from both agencies (Epinkly, Elrexfio, and Tagrisso; **Table 1**). Discordant decisions between the agencies were observed for Enhertu, Imdelltra, Talvey, and Iqirvo, while Braftovi, Leqembi, and Lyvdelzi remained under review or not yet submitted at the time of this investigation (**Table 1**).

Table 1. CDA/INESS recommendations concordance for drugs submissions with NOC/c designation

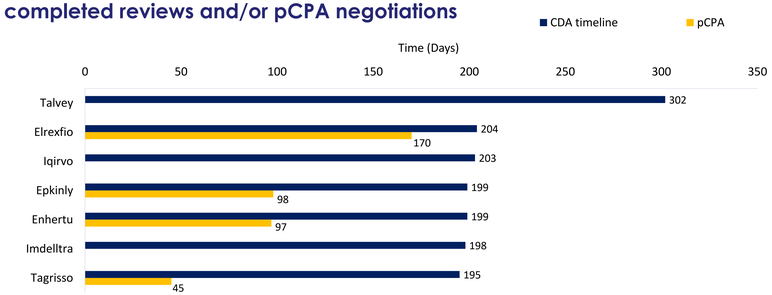
Drug	CDA recommendation	INESSS recommendation	Concordance/ Discordance
Enhertu[1]	Reimburse	Do not reimburse (currently under re-evaluation)	Discordant
Epinkly[2]	Reimburse	Reimburse with conditions	Concordant (Positive)
Elrexfio[3]	Reimburse with clinical criteria and/or conditions	Reimburse with conditions	Concordant (Positive)
Imdelltra[4]	Reimburse with clinical criteria and/or conditions	Do not reimburse	Discordant
Talvey[5]	Do not reimburse	Reimburse with conditions	Discordant
Braftovi[6]	Under review	Under review	N/A
Leqembi[7]	Under review	Not yet submitted	N/A
Lyvdelzi[8]	Under review	Under review	N/A
Tagrisso[9]	Reimburse with clinical criteria and/or conditions	Reimburse with conditions	Concordant (Positive)
Iqirvo[10]	Reimburse with clinical criteria and/or conditions	Do not reimburse (currently under re-evaluation)	Discordant

Abbreviations: CDA: Canada's Drug Agency; INESSS: *Institut national d'excellence en santé et en services sociaux*; N/A: not applicable.

RESULTS (*Cont.*)

- For 7 completed reviews, CDA review timelines ranged from 195 days (Tagrisso) to 302 days (Talvey), with an average time from submission to recommendation of 214 days.
- For pCPA negotiations, the timelines ranged from 45 days (Tagrisso) to 170 days (Elrexfio) for 4 concluded negotiations. Enhertu and Epinkly had similar negotiation timelines of 97 and 98 days, respectively, while Imdelltra, Iqirvo, and Talvey did not have concluded negotiations at the time of this review (**Fig. 2**).
- Total CDA/pCPA timelines for the 4 products that completed pCPA negotiations were 504 days (Elrexfio), 248 days (Epinkly), 220 days (Enhertu), and 273 days (Tagrisso).

Figure 2. CDA submission and pCPA negotiation timelines for drugs with completed reviews and/or pCPA negotiations



Note: CDA timelines measured as days from submission to recommendation issued; pCPA timelines measured as days from engagement letter to negotiation process. Abbreviations: CDA: Canada's Drug Agency; pCPA: pan-Canadian Pharmaceutical Alliance.

DISCUSSION & CONCLUSIONS

- Early access pathways present opportunities for accelerated access to promising therapies.
- However, utilization of these processes has been limited, with only two products that underwent these processes since introduction. Products receiving an NOC/c designation from HC meeting the TLR eligibility criteria should consider submitting through the early access process.
- Additional requirements for TLR/pTAP, such as a robust, time bound Phase 3 evidence generation plan, alignment with CDA identified evidence gaps, and a commitment to reassessment within 270 days of Phase 3 completion, may be seen as creating additional burden, complexity and risk for manufacturers.

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DISCLOSURES

All authors listed are employees of Amaris Consulting, and do not have any conflicts of interest to declare.

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