Exploring diverse approaches to health technology assessment and reimbursement for cancer therapies:

Can new Canadian collaborations help enable timely access?

2CSENSE

CAPT Conference

Panel Session
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Disclosures

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PARTNER, **20SENSE**

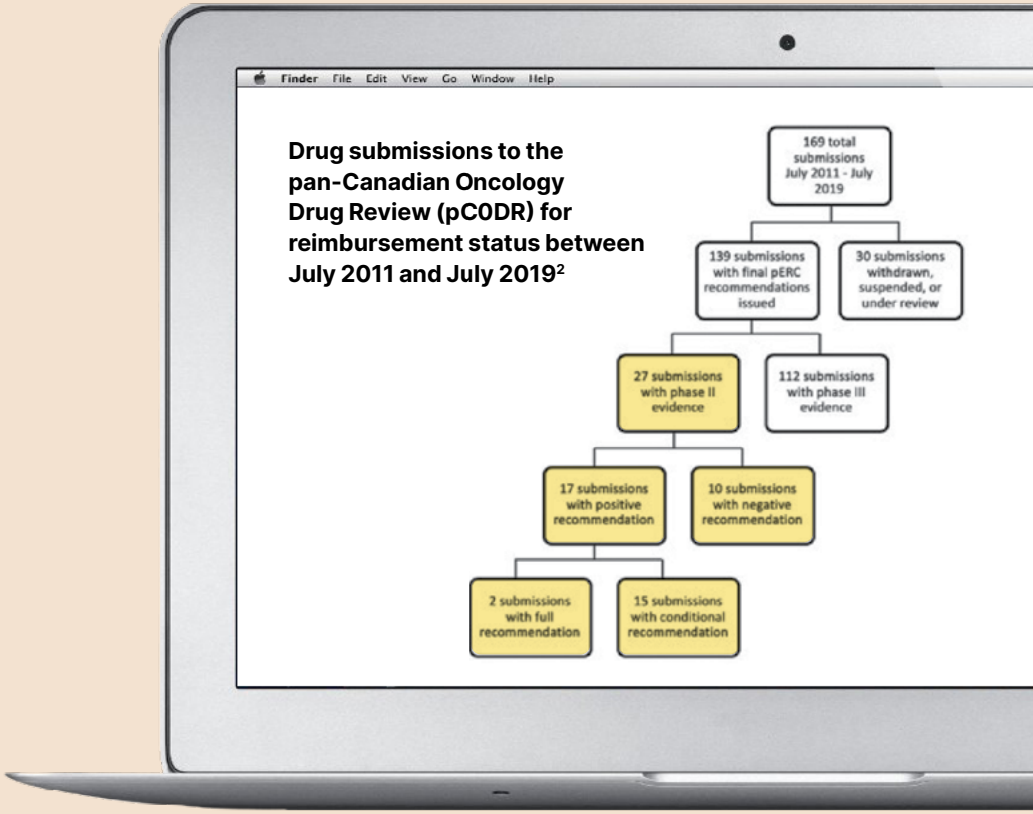
- Employed by 20Sense, which is a Canadian pharmaceutical consulting company.
- Co-chair of the *Real-World Evidence and Outcomes-Based Agreements Working Group*, which receives research support from members. Members currently include AbbVie, AstraZeneca, Janssen, Pfizer and Roche.
- This session is sponsored by AbbVie Canada

Why discuss diverse approaches to health technology assessment and reimbursement for cancer therapies?

Phase II Data

Phase II data are increasingly being used as primary evidence for public reimbursement, particularly for oncology drugs.

- In some cases, randomized trials are not possible – when the patient populations under study are too rare.[1]
- HTA entities may struggle to determine the value of products with phase II data, and therefore making recommendations is more challenging.[1]
- When compared with HTA submissions for public reimbursement having phase III data, oncology drug submissions with phase II data are less likely to be recommended by CADTH.[2]



1. CANCER TREATMENT: CANADIANS DON'T HAVE ACCESS THEY EXPECT AND DESERVE, ONCOLOGY MEDICINE ACCESS ROUNDTABLE, A.DUBUC, APR. 2022.
2. Y.Y.R. LI, MD, ET AL., REIMBURSEMENT RECOMMENDATIONS FOR CANCER DRUGS SUPPORTED BY PHASE II EVIDENCE IN CANADA, CURR ONCOL. OCT. 2020

>1.5 years

In Canada, it takes more than 1.5 years for Canadian patients to get access to a new drug in public plans.

- From NOC to first listing, access to oncology therapies takes approx. 580 days.
- Canada is among the slowest of the OECD20 countries to reimburse innovative new medicines through its public plans, based on the time from first global launch to public reimbursement (18th of 20; 926 days vs. median of 519 days).

SOURCES: HOSKYN S., INNOVATIVE MEDICINES CANADA, EXPLAINING PUBLIC REIMBURSEMENT DELAYS FOR NEW MEDICINES FOR CANADIAN PATIENTS, 2020.; AND IQVIA MARKET ACCESS METRICS DATABASE, SEPT. 2021.

1 or more early access pathway

Many countries, including England and Wales, France, Germany, Italy, and Australia, have established pathways for publicly-funded early access, where patients can receive treatment while evidence collection is ongoing.

0 early access pathway

Canada does not have a formalized early access pathway.

SOURCE: COWLING T, NAYAKARATHNA R, WILLS AL, TANKALA D, PAUL ROC N, BARAKAT S. EARLY ACCESS FOR INNOVATIVE ONCOLOGY MEDICINES: A DIFFERENT STORY IN EACH NATION. J MED ECON. 2023 JAN-DEC;26(1):944-953. DOI: 10.1080/13696998.2023.2237336. PMID: 37466223.

Early access for innovative oncology medicines: a different story in each nation

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REVIEW ARTICLE

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Early access for innovative oncology medicines: a different story in each nation

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ABSTRACT

Background: As innovative oncology medicines are rapidly developed, there is increasing pressure on payers to offer patients timely access to life-saving therapies. The uncertainty surrounding these therapies when phase III clinical trials are pending has necessitated new, adapted pathways to market access, with timelines that greatly vary by country. Understanding differences between pathways may identify opportunities to expedite patient access universally.

Objectives: To describe early access pathways for new oncology medicines among selected countries with established health technology assessment (HTA) frameworks and publicly funded health systems, with a special focus on real-world evidence (RWE).

Methods: We reviewed the HTA agency websites of the selected OECD countries: National Institute for Health and Care Excellence (NICE) for England and Wales; Haute Autorité de Santé (HAS) for France; IQWiG and G-BA for Germany; Agenzia Italiana del Farmaco (AIFA) for Italy; Pharmaceutical Benefits Advisory Committee (PBAC) for Australia; and CADTH and Institut National d'Excellence en Santé et Services Sociaux (INESSS) for Canada as the primary source of evidence.

Results: Processes for early patient access to innovative oncology therapies varied across selected countries; however, most countries have an established pathway for publicly funded early access (England and Wales, France, Germany, Italy, and Australia). The utilization of RWE to support earlier access (coverage with evidence) also varied by country, with some HTA organizations being actively engaged in these agreements (NICE, AIFA, and HAS) and others having no established processes in place (G-BA and CADTH/INESSS).

Conclusions: This review of early access pathways for novel oncology medicines found substantial variability between countries of interest. Coverage with evidence frameworks may provide a unique opportunity for industry and payers to collaborate on earlier access to innovative cancer therapies with life-saving potential.

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Introduction

The global cancer burden is predicted to rise to 28.4 million cases in 2040, a 47% increase from 2020[1]. Prior to the COVID-19 pandemic, the mortality rate for patients with cancer had been decreasing over time[2]; however, COVID-19 has been associated with delays in screening, diagnosis, and treatment, and is therefore expected to negatively impact this positive trend[3–5]. Prior to 2019, the remarkable improvement in patient outcomes was attributed to innovation.

Oncology is the leading therapeutic area for new medicines, with 100 new treatments expected in the next 5 years[6]. According to a recent market research report, 30 novel active substances (NASs) were launched in 2021[7]. Many of these therapies were noted as breakthroughs in immuno-oncology and many included precision biomarkers, which are now seen as a standard of care for multiple tumor types[7].

With the ever-increasing rate of innovative technologies coming to market, health systems are looking to implement processes to balance faster patient access with uncertainty from clinical trial data (e.g. single-arm trials or incomplete phase III data). Regulatory agencies in several countries have recently added new pathways to accelerate marketing authorization of innovative therapies (e.g. adaptive licensing or priority reviews) that focus on populations with high unmet needs. As a result, new oncology medicines frequently qualify for these expedited reviews due to the potential life-saving benefits of earlier access for patients[8]. The result of expedited regulatory reviews has placed increasing pressure on health technology assessment (HTA) agencies and public payers to manage a high volume of innovative technologies with immature clinical trial data but potentially life-saving benefits. Unfortunately, the availability and timelines for accelerated pathways across countries are highly variable, leading to substantial disparities in how quickly oncology patients can access innovative therapies.

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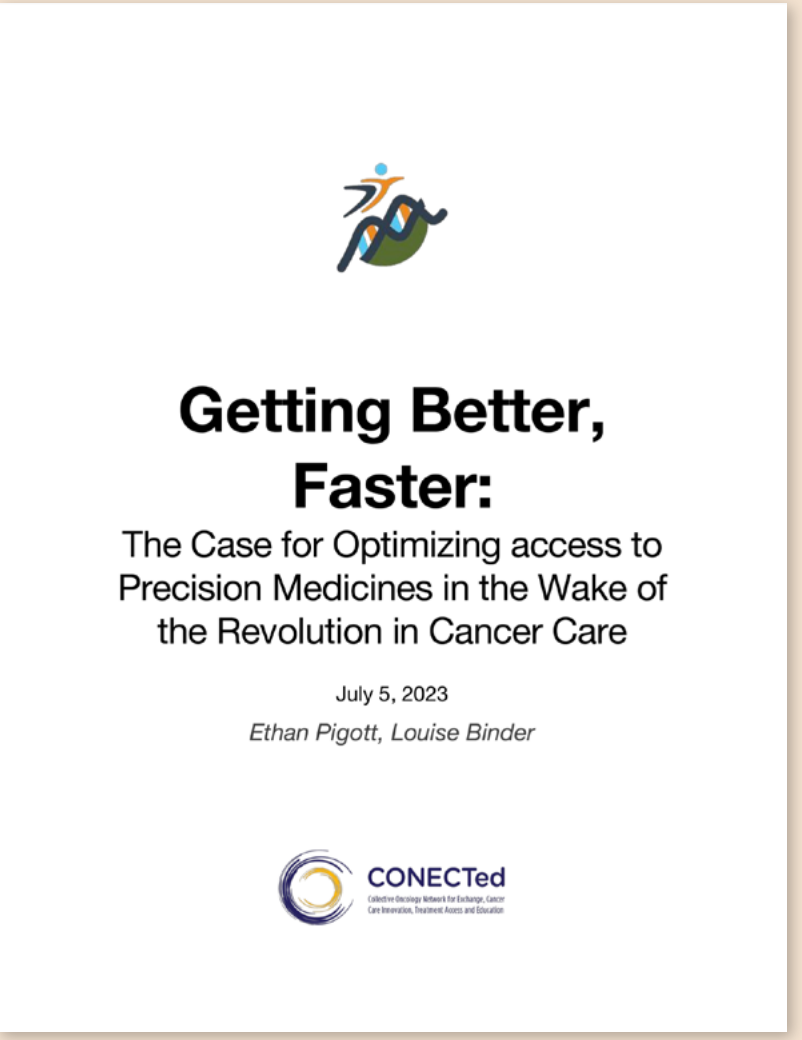
SOURCE: COWLING T, NAYAKARATHNA R, WILLS AL, TANKALA D, PAUL ROC N, BARAKAT S. EARLY ACCESS FOR INNOVATIVE ONCOLOGY MEDICINES: A DIFFERENT STORY IN EACH NATION. J MED ECON. 2023 JAN-DEC;26(1):944-953. DOI: 10.1080/13696998.2023.2237336. PMID: 37466223.

Recommendations from patient representatives include managed access-like collaboration and pathways for Canada

7. Phase II trial approvals- CADTH and INESSS should accept applications with Phase II data and should provide conditional recommendation for approval where preliminary safety and efficacy data support this decision, subject to a satisfactory pricing agreement being concluded.

10. pCPA negotiations- pCPA, now a separate incorporated agency, must work with CADTH and other relevant stakeholders to further develop a negotiation process that involves risk sharing, pay for performance, managed entry agreements… while negotiations are taking place, pCPA and the manufacturer must develop a process to ensure cost sharing so that patients obtain treatments during the period of negotiations.

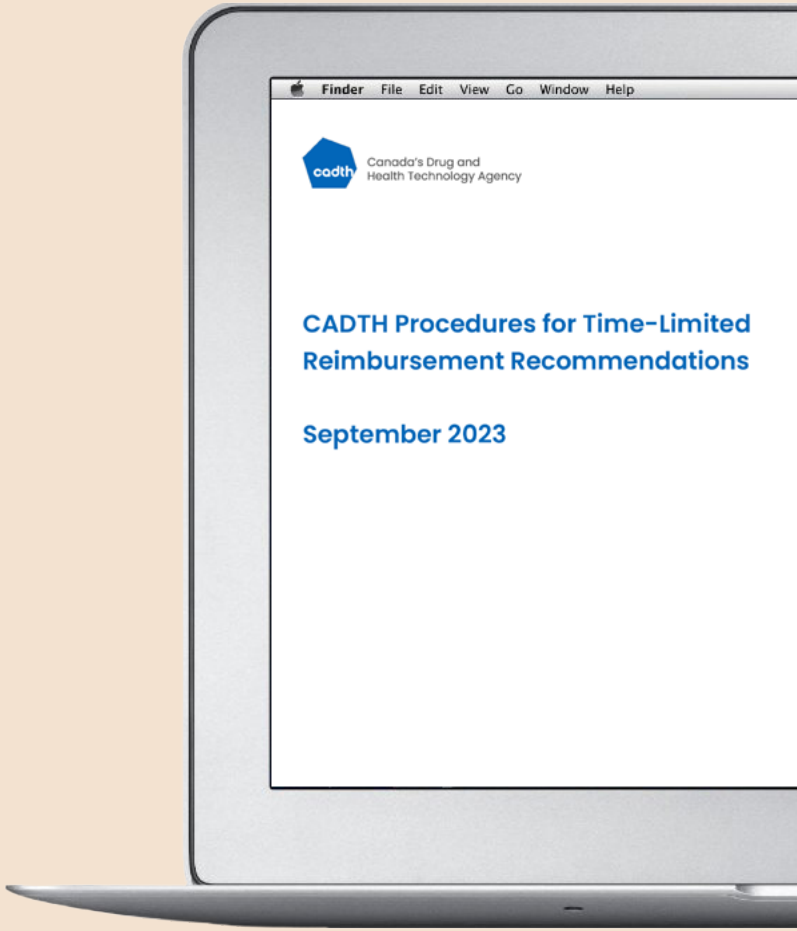


SOURCE: GETTING BETTER, FASTER: THE CASE FOR OPTIMIZING ACCESS TO PRECISION MEDICINES IN THE WAKE OF THE REVOLUTION IN CANCER CARE. CONNECTED. JULY 5, 2023.

Canada's Drug and Health Technology Agency

New process for time-limited reimbursement recommendations for drugs which receive Notice of Compliance with Conditions (NOC/c) regulatory approval.

"A time-limited recommendation is a recommendation to publicly fund a drug or drug regimen for a certain period of time. This recommendation is based on the condition the manufacturer will conduct ongoing clinical studies to address uncertainty in the evidence. CADTH will conduct a future reassessment of that additional evidence, which will lead to a final reimbursement recommendation."

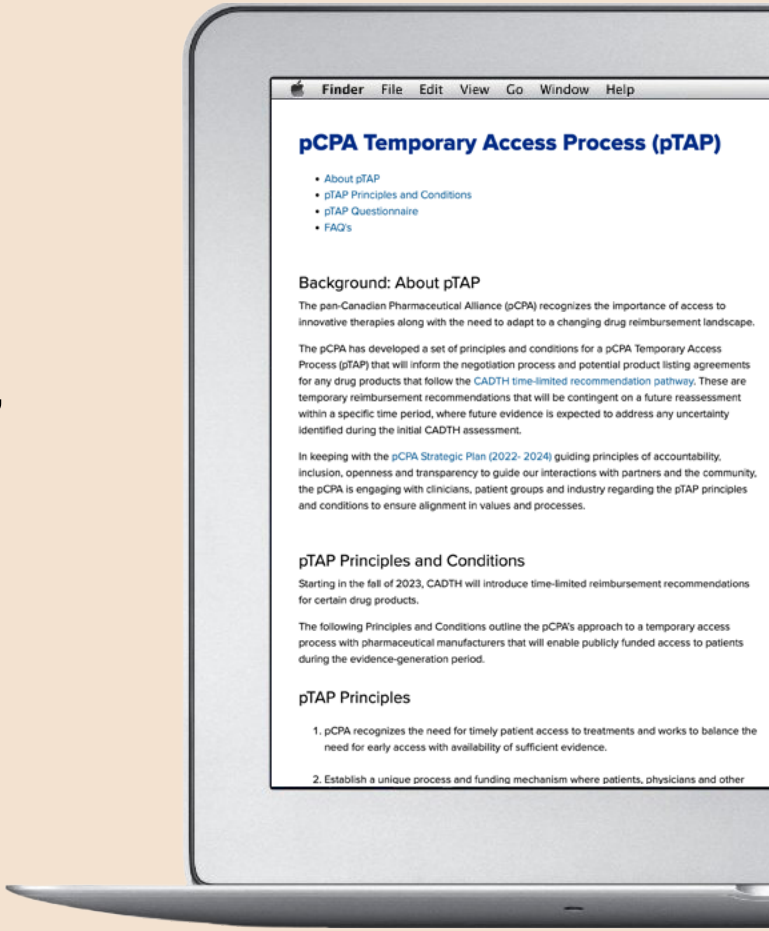


SOURCE: CADTH'S TIME-LIMITED RECOMMENDATION CATEGORY AIMS TO SUPPORT EARLIER ACCESS TO PROMISING DRUGS. SEPT 2023.

pCPA pan-Canadian Pharmaceutical Alliance

"The pCPA has developed a set of principles and conditions for a pCPA Temporary Access Process (pTAP) that will inform the negotiation process and potential product listing agreements for any drug products that follow the CADTH time-limited recommendation pathway."

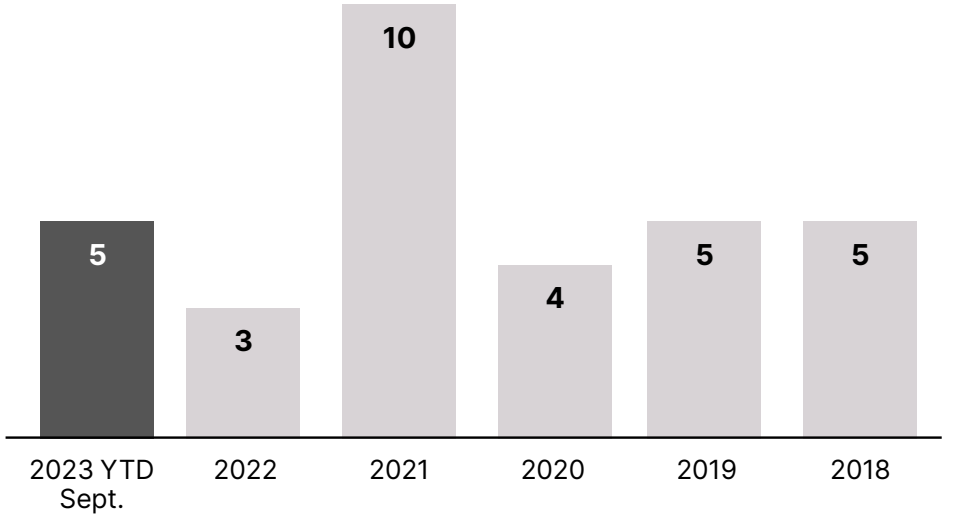
Principle 2: "Establish a unique process and funding mechanism where patients, physicians and other stakeholders are made aware that coverage of the medication is temporary, conditional on manufacturer's agreement to a risk-share arrangement, and subject to change dependent on subsequent evidence review."



SOURCE: PCPA TEMPORARY ACCESS PROCESS (PTAP), PCPA. ACCESSED OCTOBER 5, 2023.

Notice of Compliance with Conditions (NOC/c) Approvals from 2018-2022 & year-to-date Sept. 2023

Number of Health Canada NOC/c approvals by year



Health Canada NOC/c approvals in 2023 (Jan. - Sept.)

Medicinal Ingredient(s)	Therapeutic Area	Submission Concluded	Outcome of Submission
Teclistamab	Antineoplastic agents	Jul-23	NOC/c
Abiraterone acetate, niraparib	Endocrine therapy	Jun-23	NOC/c
Andexanet alfa	All other therapeutic products	Jun-23	NOC/c
Glofitamab	Antineoplastic agents	Mar-23	NOC/c
Ciltacabtagene autoleucel	Antineoplastic agents	Feb-23	NOC/c

SOURCES: HEALTH CANADA SUBMISSIONS FORMERLY UNDER REVIEW: NEW DRUG SUBMISSIONS AND HTTPS://WWW.CANADA.CA/EN/HEALTH-CANADA/SERVICES/DRUG-HEALTH-PRODUCT-REVIEW-APPROVAL/SUBMISSIONS-UNDER-REVIEW/NEW-DRUG-SUBMISSIONS-COMPLETED.HTML ACCESSED SEPT. 22, 2023.

Panelists

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Session Objectives

1. Explore how international jurisdictions have employed collaborative health technology assessment approaches to enable timely access to oncology therapies, with a focus on the opportunity to use such approaches for Canada.

2. Discuss CADTH's recently launched time-limited recommendation process to understand its potential impact on timely access for novel oncology therapies.

3. Hear perspectives from patient and physician communities on the potential impact of these new Canadian collaborations on patient access.

4. Discuss next steps required to appropriately support timely access to novel oncology therapies for Canadian patients.

Panel Discussion

Can new Canadian collaborations in health technology assessment and reimbursement help enable timely access to cancer therapies?

Moderator

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Audience Q&A

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