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Canadian public payer best practices for providing timely patient access to cancer therapies.

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Abstract

Purpose: There are concerns about the timeliness of access to innovative cancer drug treatments, as delays in treatment are known to have impacts on patient survival. Efforts have been made to accelerate regulatory and health technology assessment review times. However, delays in later stages of public reimbursement and implementation processes are impacting timely patient access to new cancer treatments. A recent analysis of time to listing for oncology therapies noted some significant differences amongst Canadian jurisdictions. A multi-jurisdictional assessment - the first of its kind - was undertaken to examine processes for integrating new therapies into cancer care systems. The goals were to better understand provincial processes for planning and implementation of new oncology therapies; and, to identify optimal practices for their timely integration into the system. **Methods:** Standardized, confidential interviews were carried out with eleven Canadian oncology payer stakeholders representing seven jurisdictions. In addition to summarizing jurisdiction-specific planning and implementation processes, data were evaluated to identify best practices for consideration by Canadian jurisdictions to optimize their approaches. **Results:** Implementation processes should focus on the needs of the patient and accelerate patient access once national undertakings have concluded. Concentrating on the needs of the patient (rather than the needs of the system) creates a "North Star" for simplifying and re-aligning processes. **Conclusion:** Adoption of proposed best practices and recommendations to proactively initiate implementation processes well before completion of national pricing negotiations could decrease delays in patient access to new oncology treatments and optimize efforts to improve patient outcomes.

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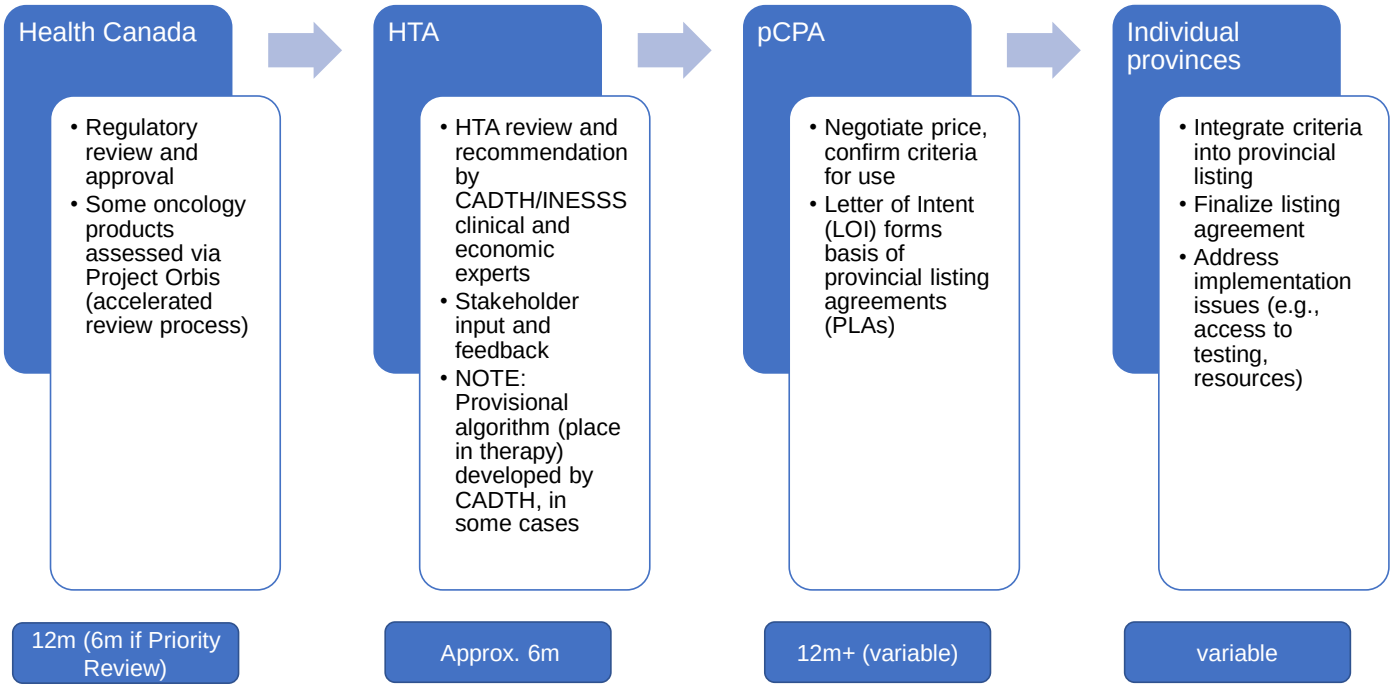
Introduction

There are a number of steps involved in the course of achieving public payer funding of new oncology therapies that ultimately enable patient access to those treatments in Canada. Figure 1 outlines the key steps in the overall process, including regulatory review by Health Canada, health technology assessment (HTA) reviews by the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS), pan-Canadian Pharmaceutical Alliance (pCPA) pricing negotiations, and listing for reimbursement in individual provinces. (The average timelines for each part of this process are also included, where available.) From regulatory approval through to eventual public payer reimbursement of the product,[a] there is a complex system of inter-related national and/or provincial administrative processes that impact how soon Canadian patients can access new oncology drug therapies.

Figure 1. Overview of national processes.



Abbreviations: CADTH, Canadian Agency for Drugs and Technology Assessment; HTA, health technology assessment; INESSS, Institut national d'excellence en santé et en services sociaux; LOI, letter of intent; m, months; pCPA, pan-Canadian Pharmaceutical Alliance.

A great deal of effort goes into evaluating the clinical and economic benefits of a new product and negotiating prices in advance of provincial listings. Concerns have been raised regarding these processes and how they create delays in patients getting access to innovative cancer treatments. Research has demonstrated that delays in access to care and/or treatment can directly impact patients and their health outcomes. Specific to oncology, evidence indicates that delays in treatment access impact cancer patient survival, with a one-month delay increasing the risk of mortality by 6-13%.[1] A Canadian report estimated the human impact of regulatory and funding processes for oncology medications.[2] The total overall life-years lost associated with delays were 39,067, while progression-free life-years lost were 48,037.

While efforts have been made to accelerate regulatory and HTA review times, key areas we have ignored for their impact on patient access are the processes and policies related to the implementation of a new product within the health system. Delays in later stages of the public reimbursement process are creating barriers to how quickly products are delivered to

[a] NOTE: For the purposes of this paper, the term "product" refers to oncology therapies which may be represented by a single oncology agent used for a specific indication or a combination of oncology agents used for a specific indication.

patients in clinic. An analysis of time to listing[b] (TTL) for oncology products summarized delays in oncology negotiations at the pCPA level, noting that in addition to a lengthy negotiation process (i.e., average 160 days) there were also delays for files waiting to be picked up for negotiation (i.e.,50% were "under consideration"). A case study included in this report noted that there were significant differences in TTL amongst Canadian jurisdictions after pCPA negotiations were completed.[3] Table 1 provides several examples of differences in listing timelines between Ontario, Saskatchewan, and Alberta as outlined in the TTL paper. These differences in time to patient access raise concerns in terms of equity and uncertainty for patients, as they await government funding of new cancer therapies that have been recommended by HTA bodies.

Table 1. Examples of differences in TTL for oncology products.

Product (indication)	Ontario	Saskatchewan	Alberta
Pembrolizumab (renal cell carcinoma)	105 days	62 days	65 days
Gemtuzumab (acute myelogenous leukemia)	460 days	81 days	Not listed
Palbociclib (locally advanced or metastatic breast cancer)	240 days	115 days	160 days
Crizotinib (ROS1-positive advanced non-small cell lung cancer)	259 days	134 days	132 days

It is recognized there can be many complexities associated with the integration and reimbursement of cancer therapies, such as use of drug combinations, implementation of clinical eligibility criteria, funding of additional supportive care therapies, potential requirements for companion diagnostics, and involvement of multiple funding organizations (i.e., outpatient drug programs, provincial prescription drug programs, hospitals) which need to be managed within the cancer therapy reimbursement process. To better understand potential underlying factors for the differences demonstrated in the TTL paper, a multi-jurisdictional assessment was undertaken to survey current provincial processes and identify potential best practices associated with timely planning, implementation, and integration of new cancer therapies into Canadian cancer care systems. This is the first such cross-jurisdictional assessment of its kind in Canada with a distinct focus on implementation processes.

Methods

An assessment was undertaken across multiple provinces to determine current as well as best practices in the implementation and integration of new cancer therapies into Canadian cancer care systems. The research focused on jurisdictional activities that enable efficient implementation and decision-making during the time between completion of pan-Canadian pricing negotiations (i.e., via the pCPA) and official provincial formulary listing of the cancer therapy (ie patient access).

Processes were evaluated based on standardized, confidential interviews (see Appendix A) carried out with eleven key Canadian oncology payer stakeholders representing seven jurisdictions between July and September 2022. The interview guide was developed by the authors, who all have deep expertise in Canadian oncology evidence review and funding processes. Interviews were carried out by the authors with detailed notes being taken as part of that process.

Interviewees were selected based on their leadership role in cancer product funding and implementation within the cancer program or Ministry of Health within their jurisdiction. (NOTE: Throughout the manuscript, information related to each jurisdiction is blinded to maintain the confidentiality of research participants.) All questions were addressed by respondents during the interview process.

The jurisdictions included in the assessment (see Table 2) account for approximately 90% of the Canadian population and are representative of the different approaches to cancer treatment access used by different provinces across Canada.

[b] NOTE: For purposes of this paper, the terms "patient access" and "provincial listing" are used interchangeably to represent the point at which patients are able to gain access to new oncology therapies for treatment after all of the national and/or provincial reimbursement processes are complete.

Specifically, provinces with provincial cancer programs, provinces where there are shared responsibilities between the provincial Ministry of Health and a cancer-specific health care service delivery organization, and a province with no formal cancer system were assessed. In those jurisdictions that have two entities responsible for implementation of new oncology products, interviews were carried out with a representative of each to ensure a fulsome understanding of the roles of both organizations; and the results of the interviews were assessed and presented for the province as a whole.

Table 2. Overview of jurisdictional approach to cancer treatment access.

Jurisdiction	Description
Province A	• Stand-alone provincial cancer program responsible for funding decisions, implementation, and provision of patient access to both oral and intravenous (IV) oncology products in both inpatient and outpatient settings. • Overall drug funding via annual budget from Ministry of Health, but funding decisions for individual products rest with the program.
Province B	• The provincial cancer program is a division of the provincial health services delivery organization which reports to a board of directors and, ultimately, to the Minister of Health. • The cancer program is responsible for funding recommendations, implementation, and provision of patient access to both oral and IV oncology products in the outpatient setting. • The inpatient program mirrors the outpatient program, with funding coming from the hospital budget for cancer drugs administered to inpatients. • Final funding decision for individual products made by Ministry of Health.
Province C	• Stand-alone provincial cancer program responsible for funding recommendations, implementation, and provision of patient access to both oral and IV oncology products in both inpatient and outpatient settings and has the most comprehensive cancer drug coverage program among provinces. • Final funding decision for individual cancer products made by Ministry of Health.
Province D	• Stand-alone provincial cancer program responsible for funding recommendations, implementation, and provision of patient access to IV oncology products in both inpatient and outpatient settings. • Overall drug funding for IV oncology drugs is via annual budget from the Ministry of Health, but funding decisions for individual cancer therapies remain with the cancer program. • Provides advice to Ministry of Health regarding funding and implementation of oral oncology products. • Ministry of Health provides patient access for oral oncology medications used in the outpatient setting. • Final funding decision for individual oral oncology products is made by Ministry of Health.
Province E	• Separation of drug policy and funding decisions, implementation, and provision of patient access between the Ministry of Health and a cancer-specific health care service delivery organization. • Ministry of Health makes drug policy and funding decisions for oral and IV oncology products funded under specific government programs; and, provides patient access for oral oncology medications used in the outpatient setting. • Cancer-specific health care service delivery organization provides advice to the Ministry on funding decisions for both oral and IV oncology products; is responsible for implementation and providing patient access for IV oncology products in the outpatient setting; and, is responsible for implementation and providing patient access for select oral and IV oncology products initiated in the inpatient setting (and then continued on an outpatient basis).
Province F	• Province-specific HTA process makes recommendations to Minister of Health. • Drug program policies and negotiations are the responsibility of the Ministry of Health. • Final funding decisions are made by Minister of Health. • The provincial drug plan administrator is responsible for reimbursement primarily for inpatient and outpatient oncology products, as well as the exceptional request process for non-listed oncology products from hospitals. • Implementation and provision of patient access for funded IV products occurs via hospitals and health centres.
Province G	• Separation of drug policy and funding decisions, implementation, and provision of patient access between the Ministry of Health and a cancer-specific health care service delivery organization. • Ministry of Health makes drug policy and funding decisions for oral and IV oncology products funded under specific government programs; and, provides patient access for oral oncology medications used in the outpatient setting. • Cancer-specific health care service delivery organization provides advice to the Ministry on funding decisions for both oral and IV oncology products; and, is responsible for implementation and providing patient access for IV oncology products in the outpatient setting.

Abbreviations: HTA, health technology assessment; IV, intravenous.

Table 3. Standardized analytic framework for planning and implementation processes.

	Phase	Detailed description
Overall process		
1	Information exchange at product pipeline meetings	Product information (e.g., clinical data, etc.), implementation information (e.g., companion diagnostics, etc.), and/or budgetary information shared for one or more pipeline products.
2	Information exchange at pre-submission meetings	Product information (e.g., clinical data, etc.), implementation information (e.g., companion diagnostics, etc.), and/or budgetary information shared for specific product being submitted for HTA review.
3	PAG input into HTA submission process	Opportunity for provincial payers and/or cancer agency leads to identify issues related to clinical data, patient population, and/or implementation issues to be included in the HTA review process for the new product.
4	PAG feedback on initial HTA recommendation	Opportunity for provincial payers and/or cancer agency leads to get clarification on the HTA recommendation and/or get input from expert committee on clinical data, patient population, and/or implementation issues specific to the new product.
5	Final HTA positive recommendation issued	Final positive recommendation serves as the basis for pCPA negotiations, including clinical criteria for use and pricing negotiations.
6	pCPA negotiations	Provincial payers and/or cancer agency leads undertake negotiations with the manufacturer to finalize pricing, criteria for use, and/or any implementation issues specific to the new product or therapy.
7	Issuance of Letter of intent	The letter of intent (LOI) represents the final terms of the agreement negotiated between the manufacturer and provincial payers and/or cancer agency leads.
8	Provincial criteria and BIA finalized	Provinces finalize the clinical criteria outlined in the LOI to take into consideration any province-specific needs and determine the province-specific budget impact analysis (BIA).
9	Provincial listing agreement completed	The provincial listing agreement (PLA) represents the final listing agreement between each jurisdiction and the manufacturer, based on the terms set out in the LOI.
10	Finalize implementation activities	Represents steps taken by the provincial cancer program and/or the cancer-specific health care delivery organizations and government to ensure that all non-drug implementation issues have been addressed (e.g., companion diagnostic access and funding, resources to support drug administration, etc.).
11	Funding for product approved	Final approval for and allocation of funding via government approval processes may be required in some jurisdictions.
12	Product made available for use in patients	New cancer drug therapy available for use in patients who meet the final criteria established by each jurisdiction in the final provincial listing agreement.
Other areas of interest		
13	Changing criteria for older treatments	Processes for updating clinical criteria for older treatments when new treatments in the same therapeutic area are introduced into the system.
14	Introduction of combination therapies	Processes for managing the introduction of combination therapies (especially when the older component is not funded for the new combination).
15	Clinician and/or cancer centre engagement	Processes for clinician and/or cancer centre engagement to support implementation of new therapies.
16	IV versus oral medications	Identification of any differences in approaches to planning and implementation of intravenous (IV) versus oral oncology medications.
17	Inpatient versus outpatient cancer treatments	Processes for planning and implementation of inpatient versus outpatient cancer treatments.
18	Provisional funding algorithm process	CADTH process for the development of provisional algorithms intended to provide advice to drug programs when they have indicated that there is need to establish an appropriate place in therapy for new oncology drugs relative to alternative treatments that are currently reimbursed by the drug programs.[4] (NOTE: completion of a provisional algorithm may delay pCPA negotiations.)
Activities specific to this jurisdiction		
19		Any additional processes that are specific to the jurisdiction in question.

Abbreviations: BIA, budget impact analysis; CADTH, Canadian Agency for Drugs and Technology Assessment; HTA, health technology assessment; IV, intravenous; LOI, letter of intent; PAG, Provincial Advisory Group; pCPA, pan-Canadian Pharmaceutical Alliance; PLA, provincial listing agreement.

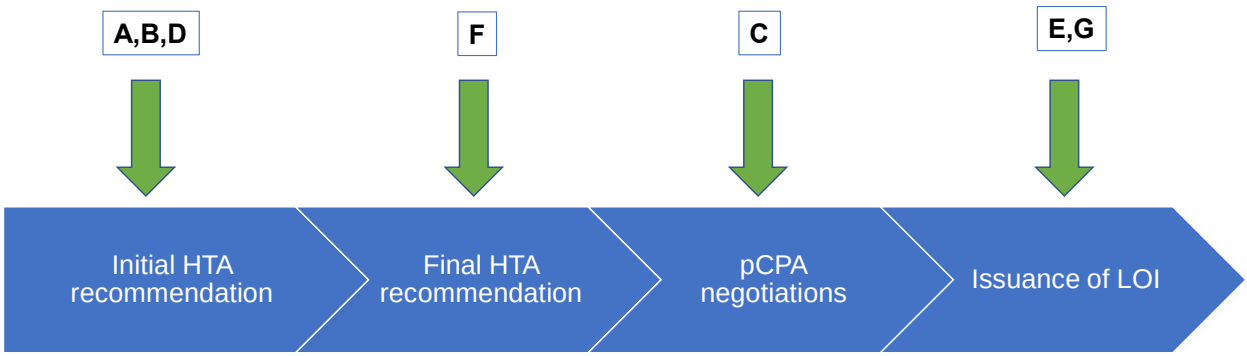
The jurisdiction-specific planning and implementation process information collected during the confidential interviews was collated using a standardized analytic framework (see Table 3). Using a framework approach helped to ensure that analysis of the information collected was done in a consistent manner. The components of the framework represent the general phases of the assessment, planning, and/or implementation processes used by most jurisdictions for new oncology products. These phases span the following time periods: prior to HTA submission; during the HTA submission process; completion of the HTA process; during the pricing negotiation process; completion of pricing negotiations; and final funding and other implementation activities at the provincial level. The findings derived for each province were then evaluated across jurisdictions to identify potential best practices. These best practices represented examples of optimized processes that could be considered for adoption by individual Canadian jurisdictions, regardless of the cancer care medication access system in place.

Results

The results presented herein focus on the best practices related to timely implementation and patient access to new oncology products identified across jurisdictions. The following outlines both the overall timing for the launch of implementation activities by each province, as well as a more detailed examination of some of the factors that affect the timing for these activities.

Figure 2 summarizes the timing of overall implementation launch activities reported by each jurisdiction across the general phases of oncology medication planning and implementation. Provinces A, B, and D were the earliest to launch their activities, doing so in concert with the release of the initial HTA recommendation from CADTH. Province F launched its implementation work in alignment with the final HTA recommendation, while Province C generally initiated in parallel to pCPA negotiations. Overall, those jurisdictions that invested in early planning and preparation, had central coordination and process standardization, and had high degrees of involvement of oncology expertise in their processes were best able to ensure that implementation and patient access moved forward quickly after completion of pricing negotiations (i.e., after issuance of LOI by pCPA).

Figure 2. Timing for launch of implementation activities.



Abbreviations: HTA, health technology assessment; LOI, letter of intent; pCPA, pan-Canadian Pharmaceutical Alliance.

On the other hand, provinces that did not typically start implementation activities until after the LOI was issued tended to reflect provinces with longer TTL (as identified in the TTL paper).[3] Specifically, Provinces E and G did not typically start implementation activities until after the completion of pricing negotiations. It should be noted that all jurisdictions have the same volume of new cancer therapies for which implementation activities are needed once national pricing negotiations are complete for that product.

A jurisdictional comparison of key points in the planning and implementation process identified practices that positively enhance implementation readiness (see Table 4). This analysis provides a more detailed assessment of select process activities where there were differences between provinces which could contribute to the timeliness of implementation launch activities. This summary articulates potential areas for improved efficiencies and/or effectiveness for Canadian jurisdictions to consider within their processes.

Table 4. Comparison of key practices across jurisdictions.

Practices	Provinces						
	A	B	C	D	E	F	G
Early engagement with manufacturers (e.g., pipeline and/or pre-submission meetings) to support budget forecasting and/or implementation planning (Y/N/S)*	S	S	S	S	S	N	S
Timing of launch of implementation activities	Initial HTA	Initial HTA	Parallel to pCPA	Initial HTA	Post LOI	Final HTA	Post LOI
Level of consistent clinician involvement in implementation processes (H-M-L)	H	H	H	H	M-L	M	M-L
Degree of clinician accountability for implementation processes (H-M-L)	M	H	M	M	L	L	L
Degree of updating of criteria for use from HTA/LOI when incorporating into PLA (H-M-L)	L	L	L	L	H	L	L
Ministerial funding approval required for each product (Y/N)	N	Y	Y	Y – oral N - IV	N	Y	Y
Need for PLA modifications with criteria changes (Y/N/S)	N	S	N	N	Y	N	S
Implementation process differences between IV and oral oncology medications (Y/N)	N	N	N	Y – but minor	Y	N	Y
Implementation process differences between inpatient and outpatient use of oncology medications (Y/N)	N	Y	N	Y	Y	N	Y
Cancer agency pharmacy department resources invested in supporting clinician input into the HTA process (Y/N/S)	N	N	N	N	Y	N	N
Degree to which implementation processes understood by external stakeholders (H-M-L)	H	H	H	H	L	H	M

Abbreviations: Y, yes; N, no; S, sometimes; H, high; M, medium; L, low; HTA, health technology assessment; IV, Intravenous; LOI, letter of intent; pCPA, pan-Canadian Pharmaceutical Alliance; PLA, product listing agreement.

In addition to the differences in implementation activity launch timing outlined in Figure 2, a number of other notable areas of differentiation that contribute to timely implementation processes were identified. For example, the degree of clinician and/or oncology pharmacist involvement contributed to timely processes, reflecting the importance of having deep oncology expertise available to optimize implementation activities.

Several process activities that were more administrative in nature were assessed to determine if they contributed to timely implementation or lack thereof. For instance, the degree to which jurisdictions make modifications to the criteria for use outlined in the HTA assessment and/or LOI can significantly impact the timeliness of implementation activities and patient access to new medications (i.e., more modifications to criteria = increased delays). In addition, the need for modifications to older listing agreements when new cancer treatments are funded varied across the jurisdictions evaluated. There may be opportunities for efficiencies in those jurisdictions that require PLA updates in all cases where criteria are modified. It was interesting to note that the need for ministerial funding approval for new oncology products did not necessarily impede the time to access to new medications. For instance, Provinces B, C, and F require Ministerial and/or Ministry funding approval but were seen by stakeholders as having the most efficient and timely processes for patient access.

A key finding of this research was the identification of major differences in the level of process complexity between jurisdictions. This was particularly true in terms of how oral versus IV medications and outpatient versus inpatient medications were funded and managed. Those provinces that manage access to both IV and oral medications through the same process were seen to have low process complexity, were typically more efficient, and tended to provide more timely patient access to new oncology therapies. In addition, the presence of separate processes and/or funding mechanisms for inpatient versus outpatient cancer medications introduced significant complexity to the implementation process, as well as potential misalignment of and/or significant time delays to the patient access process.

Discussion

This research represents the first cross-jurisdictional assessment of planning and implementation processes for new cancer medications in Canada. The Canadian oncology reimbursement system is unique compared to other countries and is a reflection of the different approaches to cancer drug funding and overall cancer care in each province. This initiative had a particular focus on identifying how those processes may contribute positively or negatively to timely patient access to new oncology treatments.

The TTL paper which prompted this research identified significant variability in the timelines for both national pricing negotiations as well as individual provincial listing processes.[3] There were also some important differences in TTL amongst Canadian jurisdictions. This degree of variability creates uncertainty for patients, as they await access to new medications recommended by the HTA process. It also introduces inequity in access to important new medications, with patients in some provinces having access earlier than those in other provinces. Once national pricing negotiations have concluded, differences in timing of provincial access to new oncology therapies can largely be attributed to the extent that advanced planning activities have occurred and the efficiency of administrative processes.

A recent analysis[5] evaluated overall drug reimbursement timelines (i.e., from Health Canada approval to provincial listing) in Canada versus the Organisation for Economic Co-operation and Development (OECD) average (oncology and non-oncology). In 2019-2020, the mean time to provincial listing was over 700 days, while the OECD mean was 368 days. On average, Canadian patients are waiting twice as long to get access to new medications compared to their counterparts in other countries.

While it is well understood that earlier stages of the access process (e.g., national pricing negotiations) contribute to access delays after a positive HTA recommendation,[6,7] the variability in final funding timelines across jurisdictions significantly impacts inequities in medication access between provinces.

As noted above, there can be many complexities associated with the integration and reimbursement of cancer therapies (e.g., drug combinations, clinical eligibility criteria, additional supportive care therapies, companion diagnostics, and involvement of multiple funding organizations [i.e., outpatient drug programs, provincial prescription drug programs, hospitals]). If these complexities and processes are not managed proactively and effectively, they add incremental delays in provincial listing and, thus, patient access to new cancer treatments. Ensuring that all phases of the medication access system function efficiently and with a view to timely patient access is important to optimizing patient outcomes.

As noted previously, each jurisdiction needs to manage the implementation of the same number of new cancer therapies after completion of the national pricing negotiation process. In addition, all jurisdictions need to address the same issues when drug therapies that are associated with implementation challenges come through the system (e.g., companion diagnostic funding coordination, incremental human resource requirements for administration, unique requirements, complicated drug issues, etc.). Whether a file is challenging or not, the TTL paper and this research demonstrate that there are differences in timelines for provinces that start their implementation planning early versus starting at the time of completion of national pricing negotiations. It is more logical to attribute this variability to effective versus suboptimal province-specific processes, as drug therapy-specific challenges will be the same regardless of jurisdiction.

The solution to improving medication access timelines at the provincial level is not to solely focus on how to address drug therapies that pose implementation challenges, but rather to improve implementation processes overall for all oncology products. This philosophy mandates having a consistent approach that leverages oncology expertise, thus enabling the jurisdiction to identify local issues early in the HTA review and reimbursement process; and, having processes that promote collaboration to resolve the issues prior to final issuance of the pCPA LOI. With appropriate planning and early engagement, no jurisdiction should ever be learning about the challenges associated with a file after the LOI has been issued.

Process complexity is also a key issue. For instance, Province E was seen to have the highest degree of complexity in its overall oncology implementation and listing processes compared to the other jurisdictions evaluated. It is not clear that this increased complexity provides value to patients, clinicians, or the health care system. Examples of process complexity in this jurisdiction include:

- Development of criteria for use goes back and forth between the Ministry and the cancer organization;
- PLA negotiations are spearheaded by the Ministry with only *ad hoc* involvement of the cancer organization responsible for the implementation of funding, often resulting in an important gap in oncology expertise during these discussions; and,
- Recently introduced programs have been positive steps for patients but continue the trend of increasing the complexity of Province E's approach to funding and managing oncology products. For instance, there are separate funding sources, separate PLA development and contracting processes, and separate Ministry signatories for inpatient versus outpatient use of the same oral oncology product for the same indication. This contributes to duplication of effort overall and results in delays to patient access.

To this end, a key output of this assessment was the identification of best practices that appear to facilitate the introduction of new medications into the Canadian cancer system. Overall, those jurisdictions that invested in early planning and preparation, had central coordination and process standardization, and had high degrees of involvement of oncology expertise in their processes were best able to ensure that implementation and patient access moved forward quickly after completion of national pricing negotiations.

Table 5 provides a summary of the key learnings identified based on insights gleaned from the interviews and subsequent analysis and are summarized below:

a) Early identification of issues and implementation planning
b) Importance of oncology treatment and practice expertise
c) Consistent representation
d) Collaboration
e) Process standardization
f) Simplification of processes

These represent best practices that have been implemented by some jurisdictions, which allow them to be able to move forward quickly with the implementation and integration of new cancer therapies into their cancer care systems. These should be considered by all jurisdictions as it relates to optimizing their processes for implementation and integration of new cancer therapies into Canadian cancer care systems.

In addition to the above noted best practices, Table 6 outlines specific recommendations that represent areas that all decision-makers - regardless of the type of cancer medication access system in place - should address as they work optimize their cancer medication access systems. Of key importance in these recommendations is the focus on creating an organizational culture that has as its focus the needs of the patient (see Figure 3). Starting with the patient in mind creates a level of commitment that fosters a focus on accountability for ensuring optimization of patient outcomes through processes that ensure timely patient access to new products. While somewhat nebulous, organization culture is the foundation of attitudes that put patients first so that processes flow to achieve that focus.

There were certainly limitations to this assessment. For instance, additional steps that may need to be taken the cancer centre level (e.g., education of staff [physicians, nurses, pharmacists], the development of patient information materials, education of drug access navigators, etc.) may not be considered as part of the implementation process by some jurisdictions but can certainly contribute to a delay in patient access. One of the other factors not evaluated in a more targeted manner was the potential role of budget impact is a source of delay in patient access for some provinces. (The budget impact issue was captured more generally in interview questions related to the overall provincial listing process.) Further insights into these additional factors in the future would help to give us a more complete understanding of barriers to patient access.

Table 5. Best practices in planning and implementation.

Best practice	Details
a) Early identification of issues and implementation planning	• Jurisdictions that invest the time to identify local issues early and begin their implementation activities in parallel to the HTA and/or pCPA process tend to demonstrate shorter timeframes to patient access for new cancer medications. • Many provinces leverage manufacturer meetings to forecast their costs and/or initiate funding requests at least 6 to 12 months in advance.
b) Importance of oncology treatment and practice expertise	• Having individuals with deep oncology expertise (i.e., front-line clinicians and/or senior level pharmacists) involved throughout all review and/or reimbursement processes appears to be highly related to efficient, effective, and timely execution of implementation processes. a. For instance, the expertise of the oncology organization lead is relied upon heavily in Province G, with that individual representing the province in all aspects of the HTA process and being very closely involved in PLA development. b. Having people with expertise in cancer therapeutics involved early in the process is very helpful in identifying and addressing implementation challenges in a timely manner. • Several jurisdictions noted the importance of clinician involvement and the opportunity to improve clinician education related to the HTA process and expanded engagement to further improve local implementation processes.
c) Consistent representation	• The consistent involvement of a single provincial representative across the full access journey ensures that challenges identified on a national basis can be addressed and resolved early within the provincial implementation process. a. Provinces A, B, C, and D model this approach, such that involvement of a single "point person" across the HTA, pCPA, and implementation processes means that issues are not "lost" as might be seen in those provinces where there is hand-over from cancer program to Ministry staff. • This is also linked to the success of jurisdictions that have centralized approaches to implementation planning, with the same people covering off budget forecasting and funding approvals, HTA input and feedback, pCPA negotiations, and development and execution of implementation activities. This contributes significantly to simplification of processes (see below).
d) Collaboration	• Collaboration amongst teams (e.g., pharmacy, nursing, medicine, laboratory medicine) within cancer programs and/or between cancer-specific health care delivery organizations and government is critical to ensuring timely access to new cancer treatments. • Those jurisdictions that promote sharing of information and collaboration within teams (pharmacy, medical, nursing) and/or between organizations (labs, cancer organization, Ministry) tend to demonstrate more efficient and/or effective implementation processes.
e) Process standardization	• Many of the jurisdictions evaluated used PLA templates to standardize their approach to listing agreements and minimize the time for review (e.g., by legal, finance, etc.). a. This practice also supports alignment of agreements, in those cases where separate agreements might be needed for inpatient and outpatient use. • Several jurisdictions actively use planning and implementation check lists and standardized communication processes with the internal and external departments involved. a. This helps to ensure clear accountability (to promote trust and collaboration) as well as alignment and coordination within their teams and/or with collaborators within or outside their organization. b. Accountability is linked to ownership and completion of responsibilities, but also provides authority over decision-making within the scope of responsibility, so that required activities are not omitted or left to others to address. • Province F was identified as a jurisdiction that provides clear deadlines for their PLA process, including expected listing timelines based on those deadlines. This helps to improve the predictability of the listing process for stakeholders. However, this also creates pressure on existing resources and can lead to challenges in the implementation process.
f) Simplification of processes	• Overall, Provinces A, B, C, D, and F appear to have developed the most efficient and practical processes to ensure timely transition from LOI to provincial PLA. a. This has been achieved through a combination of early planning activities (see above) as well as simplification of processes with the goal of ensuring consistency and decreasing complexity. b. Undertaking activities in parallel rather than sequentially also helps prevent delays in access for patients. c. Coordinated funding of oral and injectable oncology products contributes to lower levels of complexity. • Province G has developed a strong and highly collaborative relationship between the cancer organization and Ministry and takes a very pragmatic approach to addressing any challenges that arise with specific oncology products. • Province E is seen to have the highest degree of complexity in its overall oncology implementation and listing processes compared to the other jurisdictions evaluated and would benefit from efforts to simplify its approach.

Abbreviations: HTA, health technology assessment; LOI, letter of intent; pCPA, pan-Canadian Pharmaceutical Alliance; PLA, provincial listing agreement.

Table 6. Recommendations for optimal planning and implementation.

Recommendation	Details
a) Organizational culture	• Create a culture that places a priority on ensuring timely patient access to new oncology products, in an effort to optimize patient outcomes (see Figure 3).
b) Transparency	• The degree to which there is transparency regarding processes for implementation and integration of new oncology therapies into the cancer care system is a challenge in many jurisdictions. • Transparency is important for building trust with all stakeholders invested in achieving timely access to new therapies for patients. • Those jurisdictions that have developed implementation checklists could consider sharing blank versions with stakeholders to improve the level of transparency and understanding of the complexity of implementation processes for new cancer medications. • Other tools to support transparency include: clear and transparent processes and accountabilities for all steps; and, public performance standards and reporting.
c) Resources	• Provinces should place priority on ensuring timely patient access to new oncology products by investing their resources in a manner that enables efficient implementation processes and leverages oncology expertise (e.g., via process simplification, accountabilities, removing complexity, etc.). a. Provincial listing agreements are a key tool in achieving cost savings for the health care system. b. With the increasing volume and complexity of new oncology products coming to market[8] and the need to monitor and/or update access to already funded products, the workload associated with the efficient and timely provision of cancer medicines will continue to increase. c. Integrating and providing accountability to staff with strong oncology expertise into the process will improve efficiencies, as - by virtue of their knowledge, understanding, and experience - they will be more efficient in identifying and resolving issues. • Resources need to be allocated in a manner that enables efficient implementation and PLA processes in support of timely patient access. a. The time and effort invested in pCPA, PLAs, and other implementation activities are directly linked to savings accrued to the province over time.

Abbreviations: pCPA, pan-Canadian Pharmaceutical Alliance; PLA, provincial listing agreement.

Figure 3. Patient-focused organizational culture.

Conclusion

The best practices identified through this research represent current practices and opportunities that could be useful for individual jurisdictions to adopt, regardless of the current system of cancer care medication access in place.

There are significant opportunities for learnings across jurisdictions to improve the efficiency and timeliness of implementation processes that allow for faster patient access to new oncology products. These improvements would decrease delays in the timeframe between completion of national pricing negotiations and official provincial funding of a product.

Timely and comprehensive patient access to cancer care has a direct impact on patient outcomes, and delays have been demonstrated to lead to higher risk of death. It has been argued that many of the processes put in place to manage the integration of new products into the system are primarily administrative in nature and provide no added value to patients or the overall health care system. The potential health impact on Canadian patients from delays as a result of these administrative processes is substantial. This should motivate policy makers to consider the implications of treatment access delays for patient health outcomes and take action to improve their procedures.

It is time to focus efforts on the needs of the patient rather than the needs of the provincial funding system. To ensure that provincial processes related to the implementation and integration of new cancer therapies do not interfere with patient access once national processes have concluded, jurisdictions should examine their alignment with the best practices and recommendations identified herein. Efforts to proactively improve implementation processes well before completion of national pricing negotiations could help to accelerate patient access to oncology treatments and optimize patient health outcomes.

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Appendix A - Summary of Best Practices Interview Guide

Jurisdictional Processes for Implementation and Adoption of HTA-Recommended Cancer Therapies

Core Information:

Date of interview:	
Name of interviewee:	
Organization:	
Province:	
Name of interviewer:	

Preamble:

- This interview is part of a policy research project intended to better understand provincial processes related to planning and implementation of new CADTH/INESSS-recommended oncology drug therapies into the cancer care systems across Canadian jurisdictions.
- We are hoping to be able to identify some overall optimal practices that lead to efficient implementation – and we will share our findings with all participants when the project is complete.
- This is a structured interview and I will be asking you - on behalf of your organization - to describe various processes and their time dependencies within your jurisdiction. The scope of information requested is no different from what you would share with any other stakeholder.
- Your participation in the interview will be anonymous to those outside the project team.

Questions:

a) General planning questions

1. In general, please describe the various departments that are involved in your process for moving forward with integrating a new HTA-recommended cancer therapy into the cancer system after an LOI has been achieved?
2. The following questions are meant to elicit additional details about your processes and when they occur, as part of reimbursement and implementation of a new cancer therapy in your jurisdiction.
    a. At what stage of the product reimbursement process do you start the process for addressing and planning for the implementation of a new cancer therapy into your local cancer system? (e.g., with HTA submission and/or jurisdictional PAG input? with the HTA recommendation (initial/final?), at the time of pCPA engagement? post-LOI?)
    b. Why do you choose to start your implementation planning at this stage?
    c. Are there any factors that affect the process timelines for implementation of new cancer therapies within this process?
    d. What do you find works well with your current approach to implementation planning?
    e. What could be improved based on your current approach to implementation planning?
        i. What would it take to achieve these improvements?
3. Do you think there are any opportunities to make the process of integrating a new HTA-recommended cancer therapy (including new products, new indications, combination therapies, etc.) into the cancer system more efficient?

b) Manufacturer meetings

1. Does your organization participate in payer meetings with pharmaceutical companies to receive more in-depth information (contextualized for Canada and your province) regarding upcoming therapies being submitted to HTA in the very near future?
    i. What is the ideal timeframe for you to receive this information?
    ii. What kind of information do you want from companies at these meetings?
    iii. What do you do with that information?
    iv. How do you use this information for budgetary planning?
    v. How do you use this information for patient access planning?

vi. At what point in your planning processes do you start factoring the information from these meetings into your budgetary and patient access planning activities?

2. Please describe any other types of manufacturer meetings (e.g., pipeline meetings) you hold with pharmaceutical companies to help facilitate your budgeting and/or planning activities for new cancer therapies.

c) HTA submission process

1. Does your organization regularly provide input into the HTA process?
2. Do you keep close track of submissions as they are going through the HTA process?

d) HTA recommendation process

1. Does your organization regularly provide input in response to initial HTA recommendations?
2. Does your organization use the initial HTA recommendation for internal planning or other purposes?

e) pCPA negotiation process

1. Does your organization regularly provide input into the pCPA negotiation process?
2. Does your organization have mechanisms for providing access to new HTA-recommended oncology therapies while they are going through pCPA negotiations and/or prior to final provincial listing – outside of a manufacturer PSP?
3. How does your jurisdiction support access to new cancer products via a manufacturer's patient support program (PSP)?

f) Provincial listing process

1. Please describe your organization's/jurisdiction's overall PLA development and reimbursement approval process, including communication processes between organizations, as applicable.
2. Are there differences in this process based on whether the oncology product is administered orally or intravenously?
3. Does your organization have a formal process for addressing implementation issues as part of the provincial product listing process (e.g., inpatient vs outpatient use, chemotherapy workload/chair time, dosing issues, place in therapy (algorithm), grandfathering patients, transition of patients from pCPA)?
4. Does your organization have a process in place for changing criteria for older treatments in the same therapeutic area as the new product?

g) Expert clinical input

1. Please describe the role of local clinicians (oncologists/hematologists) and/or cancer centre committee engagement as part of implementation planning for and adoption of new cancer therapies (i.e., how it works, who is involved, committee processes, timelines, etc.)

h) Wrap-Up Question:

As a wrap-up to our best practices discussion, we thought it would be useful to think about what an ideal process might look like.

- So, if you had unlimited resources and were able to make changes to the drug funding process (i.e., between pCPA LOI and provincial funding), what would you change? What would you want this future state to look like?

Thank you

- Thank you so much for your time and participation today, and for sharing this information with me.
- Under the auspices of this project, we will be collating the information and generating a report, which will for the basis of a manuscript.
- Our goal will be to publish the outputs of this project in Winter 2022-23. You will receive a copy of this report after publication.