Meeting Summary

COLLABORATIVE SOLUTIONS TO TIMELY PATIENT ACCESS TO CANCER TREATMENTS

Enabling timely patient access to cancer therapies in Ontario

November 2024

LIFE SCIENCES ONTARIO

J. L. Glennie Consulting Inc.

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Collaborative Solutions to Timely Patient Access to Cancer Treatments

Executive Summary

Introduction

Ontario's Premier has raised concerns related to Canada lagging behind other OECD countries in terms of timeliness of access to new therapies. There is a need to find ways to accelerate access to ensure equitable access for patients no matter where they reside.

Particularly as it relates to complex new cancer therapies, there is an opportunity to be innovative in addressing challenges in terms of their integration into the health system. A virtual multi-stakeholder meeting was held on October 3, 2024 (supported by Life Sciences Ontario and J.L. Glennie Consulting Inc.) to discuss issues and solutions to ensure timely access to cancer treatments for patients in Ontario. Specifically, the meeting objectives were:

1. To provide stakeholders with a forum to share updates on activities to improve timely access to cancer medications for patients in Ontario.
2. To collaborate in the development of ideas and actions for improving timely access to cancer treatments in Ontario, based on the research undertaken to date.

Key Take-Aways

The following summarizes the key take-aways from the day's discussions. If applied, learnings from this session would improve access for patients in the cancer system and beyond.

a) Timely patient access goes beyond the funding decision

- Timely patient access to medications has been identified as a government priority in Ontario.
- Approval of funding for a new cancer treatment is only one of the steps that need to be completed to enable actual utilization of a new product in a patient who requires treatment.
- Timely product reimbursement can only positively impact patient outcomes if health system integration and utilization also occur in a timely manner.
- The complexity of treatments in the development pipeline will continue to challenge our oncology ecosystem in terms of the implementation issues that need to be addressed to enable utilization of these products in the patients who need them.

b) Shift to system-wide planning

- Ontario should focus on improving system capacity planning processes and using system readiness planning tools, including improved and earlier information sharing practices within and/or between Ontario Health, the Ministry of Health, and cancer centres.
- Potential solutions include taking a more systems/pan-Ministry approach – particularly with complex products that have significant health system implementation issues.
- The province should also examine opportunities for policy change to enable new models for access to treatments (e.g., in appropriate alternative settings, homecare, etc.).

c) Enhance national processes

- Canada's Drug Agency (CDA) should include pathology experts on review teams to address implementation issues related to testing requirements, etc. as part of health technology assessment process.
- CDA Provincial Advisory Group members should commit to on-going implementation outreach within their respective provincial cancer systems as the norm across all provinces.

d) Stakeholder collaboration is key

- There is an opportunity to collaborate across sectors and stakeholder groups in the development of ideas and actions for improving timely access to cancer treatments in Ontario.
- It is important that all stakeholders and decision makers are at the table for discussions around improving implementation processes in Ontario, and that their deliberations are transparent.
- There is also an opportunity to expand the scope of industry engagement and education with cancer system stakeholders (e.g., Regional Vice-Presidents) regarding new therapies, to help cancer centres prepare their implementation plans.

e) Linkages to Ontario's Life Sciences Strategy

- Phase 2 of Ontario's Life Sciences Strategy reinforces the government's commitment to building a strong, competitive, and resilient life sciences sector in the province.
    - There should be further discussions on the topic of timely patient access in the context of this Strategy.
    - These discussions need to go beyond Ontario's processes for product listing agreements, etc., and should focus on resolving health system issues related to the ability to utilize new products in the patients who need them.
- Taking a holistic approach to building a vibrant life sciences sector will need to include a whole-of-government focus on ensuring that the products of the sector are integrated into the health system so that Ontarians can benefit from these advancements.

Conclusions

We know that delays in access to cancer care and/or treatment can directly impact patients and their health outcomes. We have a moral imperative to minimize delays in access to new cancer treatments to optimize patient outcomes. Proactive implementation planning and execution is a key success factor in support of timely patient access to innovative therapies.

The increasing complexity of innovative oncology products and/or regimens requires a cross-Ministry and/or cross-sectoral approach to support effective planning and implementation. Learnings from efforts to improve time to access for oncology treatments will also be applicable to the pipeline of complex non-oncology products in the cell and gene therapy space. Investment of time and effort to address the issues identified in the cancer system will ultimately benefit the health system overall.

For further information regarding the stakeholder meeting and/or this report, please contact Dr. Judith Glennie, J.L. Glennie Consulting Inc. judith_glennie@on.aibn.com

Collaborative Solutions to Timely Patient Access to Cancer Treatments

Meeting Summary Report

A virtual multi-stakeholder meeting was held on October 3, 2024 to discuss issues and solutions to ensure timely access to cancer treatments for patients in Ontario. Specifically, the **meeting objectives** were:

1. To provide stakeholders with a forum to share updates on activities to improve timely access to cancer medications for patients in Ontario.
2. To collaborate in the development of ideas and actions for improving timely access to cancer treatments in Ontario, based on the research undertaken to date.

This report provides an outline of the topics discussed, with particular emphasis on constructive solutions to address the challenges identified. The report will be shared with meeting attendees as well as key decisions makers across Ontario's health system.

Summary of Key Take-Aways

The following summarizes the **key take-aways** from the day's discussions. Further details regarding the topics discussed and solutions identified are in the body of the report.

Figure 1. Key Take-Aways

Timely patient access goes beyond the funding decision

- Timely patient access to medications has been identified as a government priority in Ontario.
  - Ontario's rapid listing of epcoritamab within a month after the pan-Canadian Pharmaceutical Alliance (pCPA) Letter of Intent (LOI) demonstrated a commitment to more timely patient access.
  - The province is encouraged to apply this accelerated approach to a broader range of products.
- Approving funding for a new cancer treatment is only one of the steps that need to be completed to enable actual utilization of a new product in a patient who requires treatment.
- The complexity of treatments in the development pipeline will continue to challenge our oncology ecosystem in terms of the implementation issues that need to be addressed to enable utilization of these products in the patients who need them.
- Timely product reimbursement can only positively impact patient outcomes if health system uptake and utilization also occur in a timely manner.
  - Timely patient access is contingent upon effective and proactive implementation at the local cancer centre level, beyond the product funding decision.

Shift to system-wide planning

- Improve system capacity planning processes and use of system readiness planning tools, including improved and earlier information sharing practices within and/or between Ontario Health (OH), the Ministry of Health, and cancer centres.
- Potential solutions include taking a more systems/pan-Ministry approach – particularly with complex products with significant health system implementation issues.
  - Examine opportunities for centralization of some aspects of implementation planning at the OH and/or Ministry level, to minimize duplication of effort by individual cancer centres.
  - Improve existing processes that support implementation planning (e.g., Prescription Drug Reimbursement Programs [PDRP] pipeline meetings, provincial input into health technology assessment [HTA] processes, implementation discussions at pCPA, etc.).
- Examine opportunities for policy change to enable new models for access to treatments (e.g., in appropriate alternative settings, homecare, etc.).

Enhance national processes

- Canada's Drug Agency (CDA) should include pathology experts on review teams to address implementation issues related to testing requirements, etc. as part of the HTA process.
- CDA Provincial Advisory Group (PAG) members should commit to on-going implementation outreach within provincial cancer systems as the norm across all provinces.

Stakeholder collaboration is key

- There is an opportunity to collaborate across sectors and stakeholder groups in the development of ideas and actions for improving timely access to cancer treatments in Ontario.
    - The Lean and Continuous Improvement Office could lead this work on as an extension of their previous Lean Six Sigma work on accelerated medication access timelines.
- It is important that all stakeholders and decision makers are at the table for discussions around improving implementation processes in Ontario, and that their deliberations are transparent.
- Expand scope of industry engagement and education with cancer system stakeholders (e.g., Regional Vice-Presidents) regarding new therapies, to help cancer centres prepare their implementation plans.
    - This would help address some of the early communication and planning issues identified at the jurisdictional level, as well as ensure that more fully informed implementation planning occurs during the HTA process.
    - Industry is willing to work with PAG members (as a group or individually) and other stakeholders to create processes, etc. (e.g., workshops, expended pipeline meetings, etc.) to facilitate these enhanced approaches.

Linkages to Ontario's Life Sciences Strategy

- There should be further discussions on the topic of timely patient access in the context of Phase 2 of Ontario's Life Science Strategy.[1]
    - These discussions need to go beyond Ontario's processes for product listing agreements, etc., and should focus on resolving health system issues related to the ability to utilize new products in the patients who need them.
- Learnings from this session could help improve access for patients in the cancer system and beyond.

Meeting Design

The meeting agenda (see Table 1) was designed to provide attendees with a common grounding on the topic of timely access to cancer medications, with a focus on recent research carried out in this area. Patient, clinician, and health system administrator perspectives were also shared, to provide additional insights on the challenges encountered in the current Ontario system. Participants then engaged in a broad-ranging discussion of potential solutions for improving the timeliness of patient access to new innovations in cancer.

Table 1. Meeting Agenda

Item/time	Topic	Leads
1) 930-940am	**Opening Session:** • Welcome • Opening remarks • Overview of attendees • Agenda	Dr. Judith Glennie, facilitator Dr. Alison Symington, Chair – Life Sciences Ontario (LSO)
2) 940-1040am	**Research Overview and Panel Discussion:** • Overview of research and the environment • Panel discussion ○ How can we work together to improve health system readiness to implement and provide access to important new therapies? • Q&A/Discussion	Judith Glennie Sophiya Gasaria, Conference Board of Canada (CBoC) Bob Bick, CanCertainty Dr. Geoff Lui, PMH Neil Johnson, Juravinski Hospital and Cancer Centre
3) 1040-1055am	**BREAK**	
4) 1055-1155am	**Workshop/Plenary discussion: How do we continue to improve the timeliness of patient access to new medications?** • Plenary discussion and brainstorming of potential solutions	Judith Glennie, facilitator
5) 1155-12noon	**Closing Remarks** **Wrap-up, Next Steps**	Dr. Christine Williams, Ontario Institute for Cancer Research (OICR) Judith Glennie, facilitator
12noon	Adjournment	

[1] Government of Ontario. Driving growth in life sciences and biomanufacturing: Ontario's strategy (October 15, 2024). https://www.ontario.ca/page/driving-growth-life-sciences-and-biomanufacturing-ontarios-strategy?utm_campaign=%2Fen%2Frelease%2F1005175%2Fontario-launches-next-phase-of-life-sciences-strategy&utm_medium=email&utm_source=newsroom&utm_term=public

Session attendees (see Figure 2) included individuals from various sectors, providing varied perspectives and great insights regarding the topics discussed at the meeting.

Figure 2. Meeting attendees

Bukun Adegbembo, CBCN	Dr. Geoff Lui, PMH
Bob Bick, CanCertainty	Lisa Maslanka, Amgen
Louise Binder, Save Your Skin	Onai Muvezwa, Lung Health Foundation
Flay Charbonneau, Sunnybrook	Stephen Piazza, Canadian Cancer Society
Dr. Abby C. Collier, Prostate Cancer Foundation Canada	Ann-Marie Romanin, PROCURE
Stuart Edmonds, Canadian Cancer Society	Christina Sit, Leukemia & Lymphoma Society of Canada
Dr. Harriet Feilotter, OICR	Lily Spasic, Royal Victoria Regional Health Centre
Dr. Jason Field, LSO	Lucy Su, MEDJCT
Sophiya Gasaria, CBoC	Dr. Alison Symington, Chair – LSO
Sabrina Hanna, Cancer Colab	Dr. Mina Tadrous, UofT Pharmacy
Jennifer Hansford, Novartis	Tracey Taylor, J&J Innovative Medicine
JK Harris, CBCN	Shenthuraan Tharmarajah, UofT Pharmacy
Neil Johnson, Juravinski Hospital and Cancer Centre	Stefani Vukmanovic, Rubicon
Oliver Johnson, Pfizer	Dr. Christine Williams, OICR
Harold Just, Abbvie	

Meeting Details

Opening Remarks

In her opening remarks, Dr. Alison Symington, Chair – LSO reflected on Premier Ford's comments[2] related to Canada lagging behind other OECD countries in terms of timeliness of access to new therapies. Particularly as it relates to complex new therapies, there is an opportunity to be innovative in addressing challenges in terms of their integration into the health system. There is a need to find ways to accelerate access to ensure equitable access for patients no matter where they reside. Innovation in the access pathway can happen when there is collaboration amongst all sectors, as was demonstrated with COVID vaccines. The process from regulatory approval to funding and patient access for cancer therapies is lengthy and there is an opportunity to build on existing efforts to improve its efficiency and timeliness.

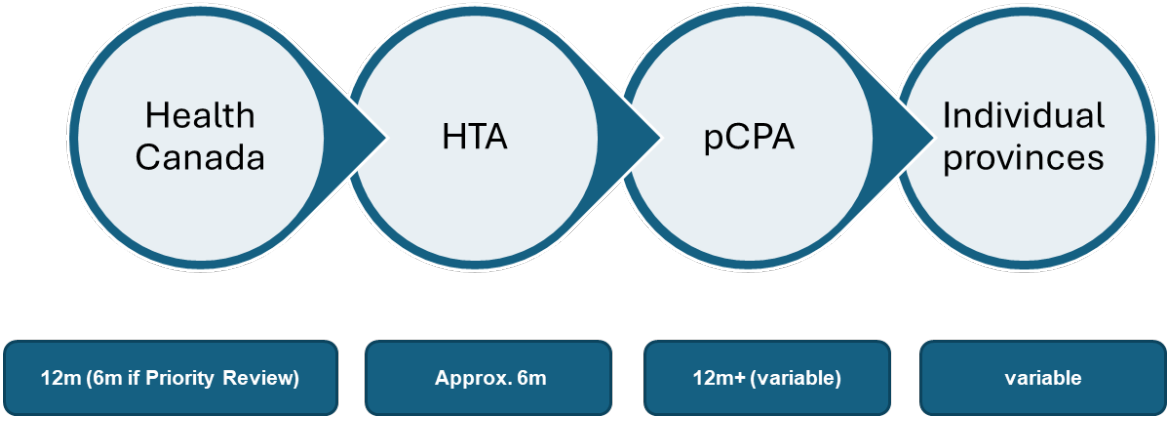
Research and Policy Overview

This portion of the meeting provided a summary of the overall patient access process in Canada (see Figure 3), including the timelines associated with each of these steps. A recent analysis[3] of listing timelines for oncology products identified delays in negotiations for these products at the pCPA level, due to holdups in files being picked up to start negotiations as well as the length of the overall negotiation process. A case study included in the analysis also found delays in final funding decisions for cancer therapies in Ontario compared to many other jurisdictions.

[2] Rushowy K. Doug Ford to focus on getting medications approved faster at annual premiers' conference. Toronto Star *july 14, 2024). https://www.thestar.com/politics/doug-ford-to-focus-on-getting-medications-approved-faster-at-annual-premiers-conference/article_5e8af906-3ef1-11ef-980e-5fedf2bc45f7.html#:~:text=As%20Premier%20Ford%20takes%20over%20as%20chair%20of

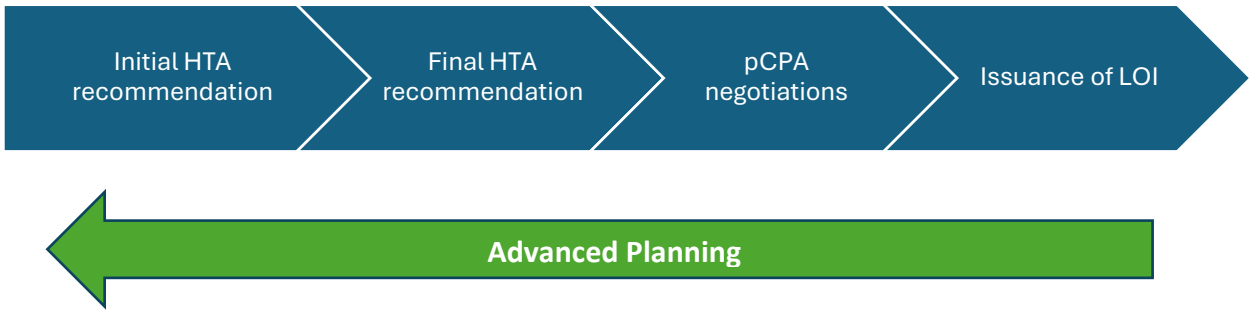
[3] Glennie JL, Duon L, O'Quinn S. Assessment of Listing Timeframes for Oncology Products in Canada. Provincial Reimbursement Advisor. 2022;25(1):12-25.

Figure 3. Patient access process and timelines



Findings from the case study prompted a follow-up assessment[4] to examine processes for integrating new therapies into cancer care systems across Canada. Research was undertaken to better understand provincial processes for planning and implementation of new oncology therapies, with the goal of identifying optimal practices associated with timely implementation and integration of new cancer therapies into Canadian cancer care systems. A key learning was that earlier timing of implementation planning activities (in juxtaposition to the HTA and pricing negation process) is associated with earlier final funding decisions and patient access to new cancer innovations (Figure 4).

Figure 4. Timing of launch of implementation activities



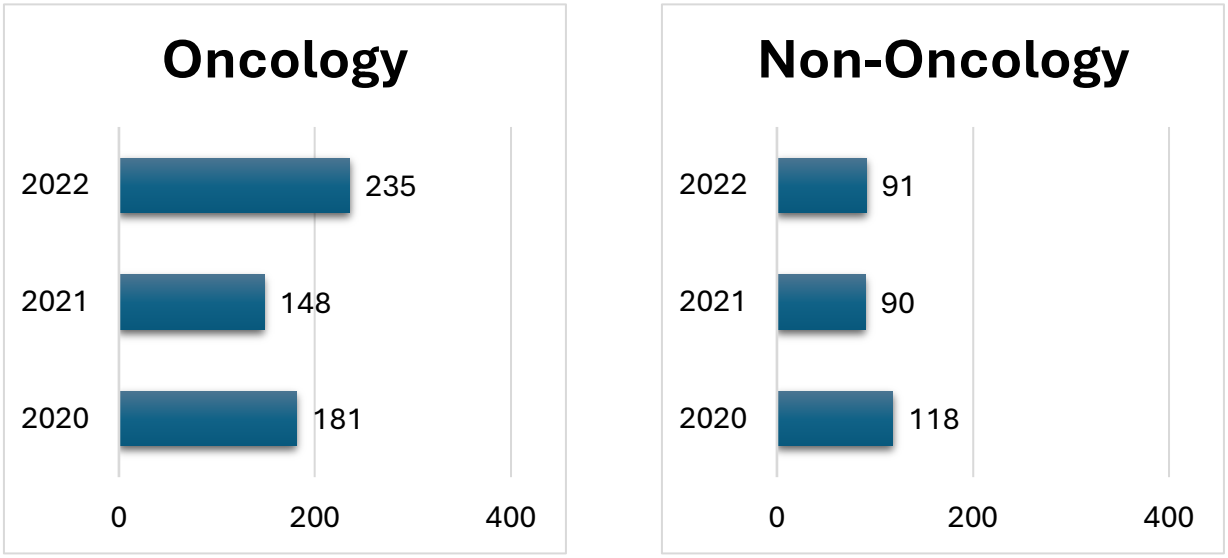
The Conference Board of Canada (CBoC) carried out a more recent evaluation of the timeframes associated with provincial listing of new medications.[5] As part of a report published in January 2024, they

[4] Glennie J, Gesy K, Nguyen Y (2023). Canadian public payer best practices for providing timely patient access to cancer therapies. Canadian Health Policy, NOV 2023. https://doi.org/10.54194/VIEL2883 | canadianhealthpolicy.com
[5] Conference Board of Canada (January 4, 2024). Access and Time to Patient: Prescriptions Drugs in Canada. https://www.conferenceboard.ca/product/access-and-time-to-patient-jan2024/

analyzed the average time it took for both oncology and non-oncology drugs to be listed (i.e., funded) on provincial public drug plans.

Specific to Ontario, the most recent data (i.e., 2020-2022) reveal that it took almost 2 months longer for oncology drugs to be listed than non-oncology drugs on average (i.e., 279 versus [vs.] 222 days; difference of 56.9 days). In 2022, the difference in time to listing in Ontario between oncology and non-oncology drugs had increased to 144 days (see Figure 5).

Figure 5. Oncology Drugs vs. Non-Oncology Drugs in Ontario, 2020-22 (adapted from Reference 5)



It should be noted that both OH's PDRP and Ontario's public drug program within the Ministry of Health have recently undertaken a range of initiatives to address the issue of timely patient access to medications.

For instance, PDRP undertakes pipeline meetings with manufacturers which provide the opportunity to discuss issues with particular relevance to health system planning (e.g., potential implementation considerations/concerns). While these meetings often include representatives from other parts of OH, there may be an opportuniy to develop more systematic approaches that include other oncology system stakeholders in this process. PDRP also places an emphasis on working closely with the Ministry to ensure coordinated implementation of cancer products funded by both the New Drug Funding Program (NDFP) and the High Cost Therapy Funding Program (HCTFP), as well as determining eligibility criteria and the separate listing agreements needed for each program.

The provincial drug program undertook a Lean Six Sigma process in 2022 to identify opportunities for efficiencies in their processes (see Figure 6). Unfortunately, there is limited transparency regarding the specific changes that have been implemented by the drug program. Further analysis to determine the impact of these changes would be valuable.

A key "timely access" success story was shared with meeting participants to demonstrate the value of recent policy changes at the HTA and pCPA level – namely, CDA's time-limited reimbursement

recommendation (TLR) pathway[6] and pCPA Temporary Access Process (pTAP).[7] The manufacturer of EPKINLY™ (epcoritamab), an innovative treatment for relapsed or refractory diffuse large B-cell lymphoma, pursued the opportunity for accelerated access offered by the TLR and pTAP processes. Figure 7 provides an outline of the HTA, pCPA, and Ontario funding timelines for this product.

It is clear these new processes have introduced more flexibility into the timing of pCPA negotiation vs. HTA processes. Ontario's listing of this product within a month after issuance of the pCPA LOI also demonstrates a commitment to more timely patient access. It is hoped that the accelerated approach used to list this product in Ontario will be applied to a broader range of products outside of these specialized CDA/pCPA processes, in order to address the opportunity for improved patient outcomes and system capacity demands.

Figure 6. Summary of Ontario drug program efficiency initiatives (per Invest Ontario)

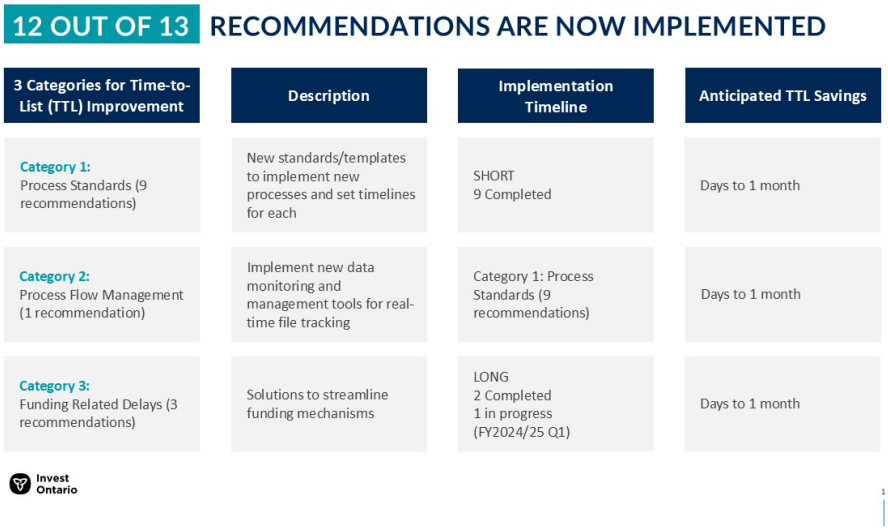
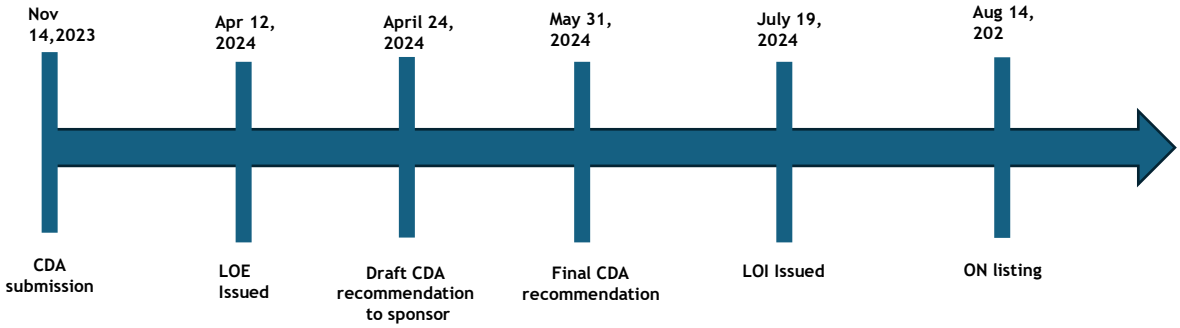


Figure 7. Epcoritamab – A case study in accelerated patient access



[6] Canada's Drug Agency. News – Our Time-Limited Recommendation Category Aims to Support Earlier Access to Promising Drugs (September 28, 2023). https://www.cda-amc.ca/news/our-time-limited-recommendation-category-aims-support-earlier-access-promising-drugs
[7] pCPA. pCPA Temporary Access Process (pTAP). https://www.pcpacanada.ca/pTAP

Panel Session

Panel members were asked to identify, from their individual perspectives, how stakeholders can work together to improve health system readiness to implement and provide access to important new cancer therapies.

The key issues and/or solutions identified by the panel included the following:

- **Timely patient access is contingent upon effective and proactive implementation at the local level, beyond the product funding decision.**
    - When new oncology products are funded, cancer centres are often given very little lead time and/or support to address implementation issues (e.g., development of side effect management protocols, securing and allocating incremental human and physical resources, creation of new systems and/or processes to enable patient management, legal agreements for each new complex therapy [e.g., cell therapies], etc.) that may need to be tackled to enable actual administration of a new product to patients.
        - It was noted that some new therapies are more impactful than others, and that individual health systems will make choices about which products they will adopt based on their scope of specialization, experience with current therapies, etc.
    - Time to use of a new product at the local level is an operational construct. Hospitals have little to no flexibility in the funds they have available to deliver care.
    - Implementation of new technologies is left up to teams at the local level, creating new workload for which cancer centres that do not have the funding and/or other resources (e.g., staff) to do so and, thus, introducing new sources of inequity into an already fragmented system.
    - There is also significant duplication of effort across Ontario cancer centres, with each one going through the process of developing and executing their own individual implementation plans.
- **Early communication, planning, and coordination is key.**
    - Early communication between different stakeholders and parts of the cancer system needs to become the norm in Ontario, to ensure that all sectors are prepared to move quickly once a new cancer treatment is funded.
    - Communication with centres throughout the reimbursement process would facilitate their ability to prepare for new products to ensure their timely utilization in the patients who need them patient once funding is confirmed.
- **The expertise and experience of major/academic health centres (e.g., via clinical trials, etc.) could be leveraged more effectively.**
    - Major centres are taking on the burden of developing new systems, etc. to enable the introduction of new complex cancer therapies in their own centres as well as the province as a whole.
    - Centres without such experience may be at a disadvantage and, thus, slower to develop their implementation plans.
    - There is an opportunity for major centres to “step up” and to more effectively leverage their expertise to create partnerships and/or networks that will support translation and adoption of practices to treatment sites across the province and, thus, enable access to new therapies more broadly.
    - However, taking on such a role would require allocation of incremental resources to these centres.

    - While there is a role for OH and/or the Ministry in the context of implementation discussions and/or activities, cancer centres ultimately run operations - thus, centres have to do the work and set up the systems within their own institutions to achieve the final step in patient access.
- **There are significant barriers to enabling innovation in implementation processes.**
    - Creation of additional capacity and resources to support implementation (locally and/or via the network noted above) that does not pull away from existing patient care resources is key.
    - There is a need to proactively identify and then remove barriers (e.g., legal, logistical, bureaucratic) to implementation.
- **Political will is a key success factor.**
    - Establishing political will is a key factor in achieving action on the issue of time to patient and bringing attention to challenges in proactively addressing implementation issues.
    - Credible evidence generated externally can help enable bureaucratic action, allowing it to respond to political pressure from above.
    - The Premier's comments regarding delays in access to medications were a result of advocacy and present an important opportunity for bringing focus to this issue within Ontario.
    - Superior performance levels in other jurisdictions (e.g., Quebec [QC] listings within 44 days, per CBoC data) need to be used as levers to show what Ontario should do with the resources it has.[8]
    - Patient groups have an important role in advocacy and demanding that Ontario government do better to meet urgent patient needs – both at a provincial level and through their influence as a lead jurisdiction at pCPA.
- **The role of private drug plans/payers also needs to be considered as part of this discussion.**
    - Delays in timely access are also happening at the private payer level, starting to mirror those delays seen in the public payer space.
    - Strategies are needed to ensure that private insurance industry reverses this trend and does not become yet another impediment to timely access to new therapies.
- **The differences in funding approaches for intravenous vs. oral (i.e., "take-home") cancer drugs in Ontario needs to be resolved.**
    - The current system introduces inequities in patient care (e.g., out-of-pocket patient costs for oral therapies) within Ontario, let alone inequities compared with patients in other parts of the country.
    - CanCertainty is spearheading a national patient group advocacy effort related to time to patient issues across the country.

Workshop/Plenary Discussion

Discussion was opened up to all participants, with the goal of identifying ideas for improving the timeliness of patient access to innovative cancer therapies in Ontario. Suggestions for how to improve coordination between different parts of the system and/or how stakeholders can work together to improve health system readiness were also discussed. The following summarizes some of the issues and potential solutions identified, over and above those cited in earlier discussions.

Issues

- Challenges in the pathology laboratory sector are important to address within the scope of issues that need to be tackled in optimizing implementation process and timely patient access to new treatments.

[8] Binder L and Bick R. Premier Ford wants to speed up drug approvals – patient groups have some advice. Canada HealthWatch (August 19, 2024). https://canadahealthwatch.ca/2024/08/19/premier-ford-wants-to-speed-up-drug-approvals-patient-groups-have-advice

- One of the gaps Ontario needs to address is having a more precise understanding of the "true" timeline to patient access (i.e., timing of funding vs. actual utilization in patients in different regions of Ontario) and the linkage of this metric to equity of access across the province.
    - Delays in access to biomarker testing results in the northern vs. southern parts of the province were cited as an example of implementation issues that impede patient access and optimal health outcomes.
- Individual cancer centres started their own implementation planning activities for bi-specifics, because the OH working group started their activities too late.
    - As noted in the epcoritimab case study above (see Figure 7), the HTA package was submitted in November 2023, pricing negotiations launched in April 2024, and Ontario announced funding in August 2024.
    - OH launched its bi-specifics working group in March 2024 and its report is not expected until March 2025. While establishing this group is an important step for this category of products, there is little transparency regarding the terms of reference for the working group and/or the expected output.
    - It is important that any centralized implementation activities carried out are executed in a timely manner and are coordinated with cancer centres, so that duplication of effort is minimized.
- Cancer centres are not privy to the timelines associated with provincial funding agreements after the LOI is issued by pCPA. As a result, they cannot anticipate the timing of funding announcements and coordinate those with implementation activities at the cancer centre level.
- Discussion of challenges associated with implementation and patient access to new radioligand therapies are similar to those seen with other complex cancer treatments.
- The limitations related to quality-adjusted-life-year (QALY) thresholds for cancer products at CDA were discussed.
- Opportunities to include more community-based centres for clinician trials to mitigate future implementation challenges were reviewed.
- The topic of outcomes-based agreements and real-world evidence generation as tools for dealing with uncertainty in the HTA process was discussed.
- It was noted that many patients are getting access to new medications during the various review and approval processes via compassionate programs, etc.
    - There is not a lot of transparency regarding these other access mechanisms.
    - Ultimately, there is a need for transparency from all parties involved in the system.

<u>Potential solutions</u>

- Improve system capacity planning, with improved and earlier information sharing practices within and/or between OH, the Ministry of Health, and cancer centres.
    - PDRP's ***Industry Guidance for OH(CCO) Pipeline Meetings*** document[9] provides important guidance on key information to share regarding new products. While intended for use by pharmaceutical manufacturers, it could be adapted to meet the broader cancer system planning needs.
    - Recently, the I2U group developed a System Readiness Tool designed to strengthen health systems by identifying - and addressing - barriers preventing the successful implementation of complex new therapies.[10] This tool could be used proactively by stakeholders to guide discussions related to implementation challenges for new oncology therapies.
- Examine opportunities for centralization of some aspects of implementation planning at the OH and/or Ministry level, to minimize duplication of effort by individual cancer centres when planning for adoption of new therapies.

[9] PDRP. Industry Guidance for OH(CCO) Pipeline Meetings (May 31, 2021).
[10] I2U. I2U System Readiness Tool. https://i2u.ca/tool/

        - This centralized approach would be over and above existing activities that support implementation planning (e.g., PDRP pipeline meetings, provincial input into HTA processes, implementation discussions at pCPA, etc.).
        - Opportunities to improve these existing processes should also be examined (e.g., integrating jurisdictional implementation discussions and solution development into pricing negotiations, to ensure consistent approaches across the country).
- Examine opportunities for policy change to enable new models for access to treatments (e.g., in appropriate alternative settings, homecare, etc.).
- Expand scope of industry engagement and education with cancer system stakeholders regarding new therapies, to help cancer centres prepare their implementation plans.
    - For example, the introduction of pipeline and implementation planning meetings with Regional Vice-Presidents responsible for cancer system planning may be helpful.
    - Creation and/or adoption of tools (e.g., I2U System Readiness Tool) to support planning would also be helpful.
- CDA should be including pathology experts on their review teams to speak to implementation issues related to testing requirements, etc. as part of the HTA process.
- The CDA PAG members need to ensure that on-going implementation outreach within the cancer system of each individual jurisdiction is the norm across all provinces.
    - This would help address some of the early communication and planning issues identified at the jurisdictional level, as well as ensure that more fully informed implementation planning occurs during the HTA process.
    - Industry is willing to work with PAG members (as a group or individually) and other stakeholders to create processes, etc. (e.g., workshops, expended pipeline meetings, etc.) to facilitate these enhanced approaches.
- Examine the potential role of integrating additional quality/clinical indicators related to implementation and timely patient access to new treatments into the existing Ontario cancer quality program.
    - See Europe and the United Kingdom (e.g., Cancer Scotland) for examples of metrics.
- There are potential learnings from QC in terms of their best practices in timely patient access to new therapies.
    - It should be noted that there are gaps and challenges in QC as well.
- It is important that all stakeholders and decision makers are at the table for discussions around improving implementation processes in Ontario, and that their deliberations are transparent.
    - There are many examples of best practices in stakeholder engagement and transparency in Europe.
    - Discussions to develop solutions need to include balanced viewpoints from all sectors. There is a need to create safe spaces to have these discussions.
- There should be an opportunity for further discussions on the topic of timely patient access in the context of Phase 2 of Ontario's Life Sciences Strategy.[11]
    - These discussions need to go beyond Ontario's processes for product listing agreements, etc. and should focus on resolving health system issues related to the ability to utilize new products in the patients who need them.
    - Timely product reimbursement can only positively impact patient outcomes if health system uptake and utilization also occur in a timely manner.

Closing Remarks

In her closing remarks, Dr. Christine Williams – OICR noted that, while the focus of discussion was on drugs, the issues and potential solutions generated during the day's discussions apply more generally to other innovations (e.g., genomic testing, biomarkers, etc.) and the challenges of integrating them into the

[11] Government of Ontario. Driving growth in life sciences and biomanufacturing: Ontario's strategy (October 15, 2024). https://www.ontario.ca/page/driving-growth-life-sciences-and-biomanufacturing-ontarios-strategy?utm_campaign=%2Fen%2Frelease%2F1005175%2Fontario-launches-next-phase-of-life-sciences-strategy&utm_medium=email&utm_source=newsroom&utm_term=public

health system. One of the greatest challenges that the health care system has is knowing what to do with innovation – i.e., what innovations to adopt (i.e., what is worth investing in) and how to shift/modify the system to allow for their adoption. The implementation issues identified today are part of this overall gap in the system.

Dr. Williams noted that what is missing in our health system is a pathway for anticipating, prioritizing, evaluating, planning for, adopting, and evaluating the real-world effectiveness of innovations and new technologies. There is a need for a nimble, transparent, and structured system to assess and integrate innovations within the province.

It was emphasized that it is important for a broad range of perspectives to be in the room to facilitate discussions on how to address the gaps identified, in order to have a fulsome understanding of the issues and to move towards concrete, practical, and relevant solutions. It is hoped that one of the strategic objectives of the soon to be released Ontario Cancer Plan – that is, "to implement a streamlined approach for timely adoption of innovation and technologies" – will provide a key tool for achieving the goals discussed during today's session.

Conclusions

We know that delays in access to care and/or treatment can directly impact patients and their health outcomes.[12,13] We have a moral imperative to minimize delays in access to new cancer treatments to optimize patient outcomes. Proactive implementation planning and execution are key success factors in support of timely patient access to innovative therapies.

The increasing complexity of innovative oncology products and/or regimens requires a cross-Ministry and/or cross-sectoral approach to support effective planning and implementation. Learnings from efforts to improve time to access for oncology treatments will also be applicable to the pipeline of complex non-oncology products in the cell and gene therapy space. Investment of time and effort to address the issues identified in the cancer system will ultimately benefit the health system overall.

The recent announcement of Phase 2[14] of Ontario's Life Sciences Strategy[15] reinforces the government's commitment to building a strong, competitive, and resilient life sciences sector in the province. A key goal of Phase 2 of the strategy relates to adoption of innovations to improve health care.

Ontario Life Sciences Strategy (2022)

"Our **vision** is to establish Ontario as a global biomanufacturing and life sciences hub leading in the development, commercialization and early adoption of innovative health products and services."

[12] Hanna T P, King W D, Thibodeau S, Jalink M, Paulin G A, Harvey-Jones E et al. Mortality due to cancer treatment delay: systematic review and meta-analysis BMJ 2020; 371 :m4087 doi:10.1136/bmj.m4087 https://www.bmj.com/content/371/bmj.m4087

[13] Biagi JJ, Raphael MJ, Mackillop WJ, Kong W, King WD, Booth CM. Association Between Time to Initiation of Adjuvant Chemotherapy and Survival in Colorectal Cancer: A Systematic Review and Meta-analysis. JAMA. 2011;305(22):2335–2342. doi:10.1001/jama.2011.749

[14] Government of Ontario. Driving growth in life sciences and biomanufacturing: Ontario's strategy (October 15, 2024). https://www.ontario.ca/page/driving-growth-life-sciences-and-biomanufacturing-ontarios-strategy

[15] Government of Ontario. Taking Life Sciences to the Next Level: Ontario's Strategy (2022). https://www.ontario.ca/files/2022-04/medjct-taking-life-sciences-next-level-ontario-strategy-en-2022-04-07.pdf#:~:text=Our%20goal%20is%20to%20maintain%20and%20grow%20Ontario%E2%80%99s

There was also agreement that the Ontario innovation ecosystem would benefit from taking a systems approach to implementation planning for cancer and other innovative therapies. It is clear that individual groups understand their part of the system very well, but do not necessarily have a good understanding of other parts of the system and/or how they fit into the overall system. Today's discussion has pointed out that there is a lot to learn for everyone in the system.

Taking a holistic approach to building a vibrant life sciences sector will need to include a whole-of-government focus on ensuring that the products of this sector are integrated into the health system so that Ontarians can benefit from these advancements. The key to moving forward will be to create safe spaces to have cross-sectoral conversations about challenges and potential solutions.