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Pharmaceutical Reviews Program Renewal

Pre-Consultation Webinar for Patient Organizations

December 17, 2024

Introductions and Format

- **Host**
  - Sam Sutherland, Engagement Officer
- **Speakers**
  - Peter Dyrda, Director, Pharmaceutical Reviews
  - Michelle Gibbens, Director, Engagement
- **Format**

Agenda

- Overview of proposed improvements to drug reimbursement reviews
- How will patients be impacted
- Summary and what comes next

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Overview of Pharmaceutical Reviews Renewal Initiative

Our Role

Health Canada:
Is it safe? Does it work?

Patented Medicine Prices Review Board:
Is the price excessive compared with some other developed countries?

Canada's Drug Agency:
How does it compare with existing treatment options? Is it good value?

Federal, provincial, and territorial public drug plans and the pan-Canadian Pharmaceutical Alliance:
Is it needed? Is it affordable?

Clinical Analysis

Economic Analysis

External Engagement

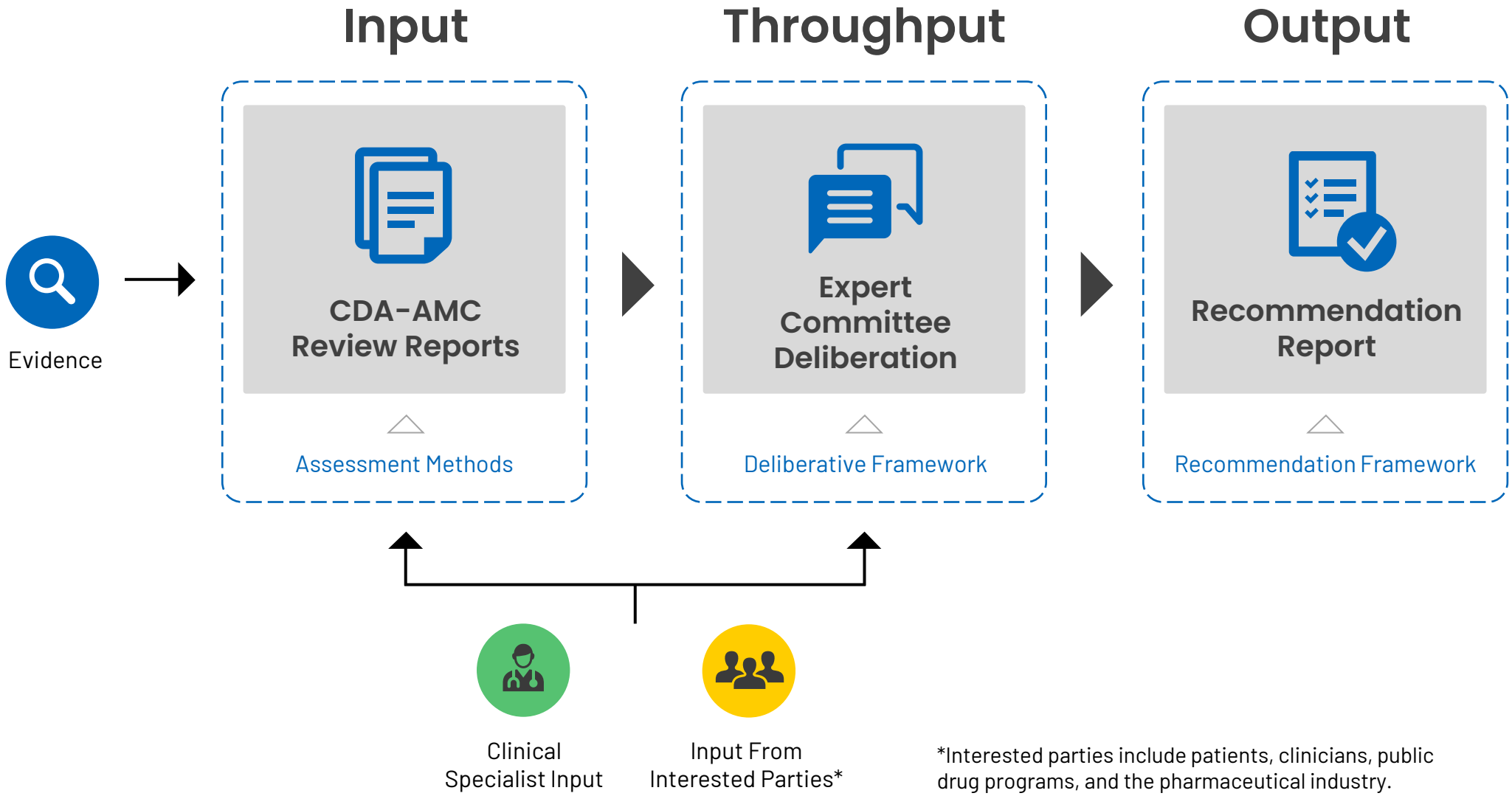
Funding Recommendations

Reimbursement Reviews: Objectives and Review Types

- Reimbursement Reviews provide recommendations to publicly funded drug plans and provincial cancer agencies
- Aims to reduce duplication across jurisdictions and increase efficiency

Sponsored reviews	Non-sponsored reviews
Sponsor-initiated	Initiated upon drug program request
Typically conducted in parallel with or just after regulatory approval	Conducted for drugs later in their life cycle
Canadian Drug Expert Committee (CDEC) & pCODR Expert Review Committee (pERC)	Formulary Management Expert Committee (FMEC)

Reimbursement Reviews: Process Overview



*Interested parties include patients, clinicians, public drug programs, and the pharmaceutical industry.

Our Goals

- **Modernize program to adapt with changing needs of the health system**
  - Committing to dialogue, engagement and transparency during the review process
  - Improving the usefulness of our outputs
- **Enable a proportionate approach to drug reviews**
  - Applying streamlined approaches to simpler low-risk assessments
  - Addressing needs for reviews with increasing complexity
- **Catalyst for accelerated access pathways across the health system**
  - Increasing scope of existing accelerated access pathway initiatives

Areas of Focus

Proportionate Reviews

3 streams for reviews that are fit for purpose

Reports

Succinct reporting in 3 categories

Deliberations

Transparency and consistency through novel framework

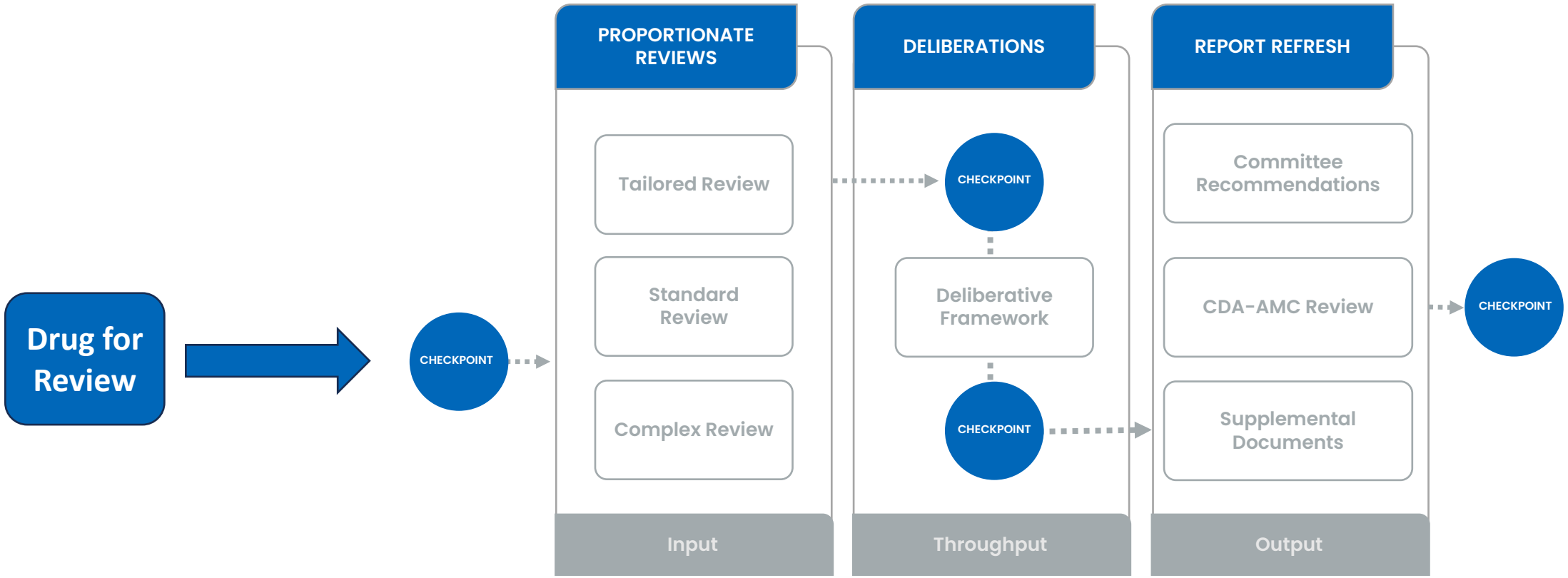
Accelerated Access Pathways

Expansion of existing initiatives and creation of PACES

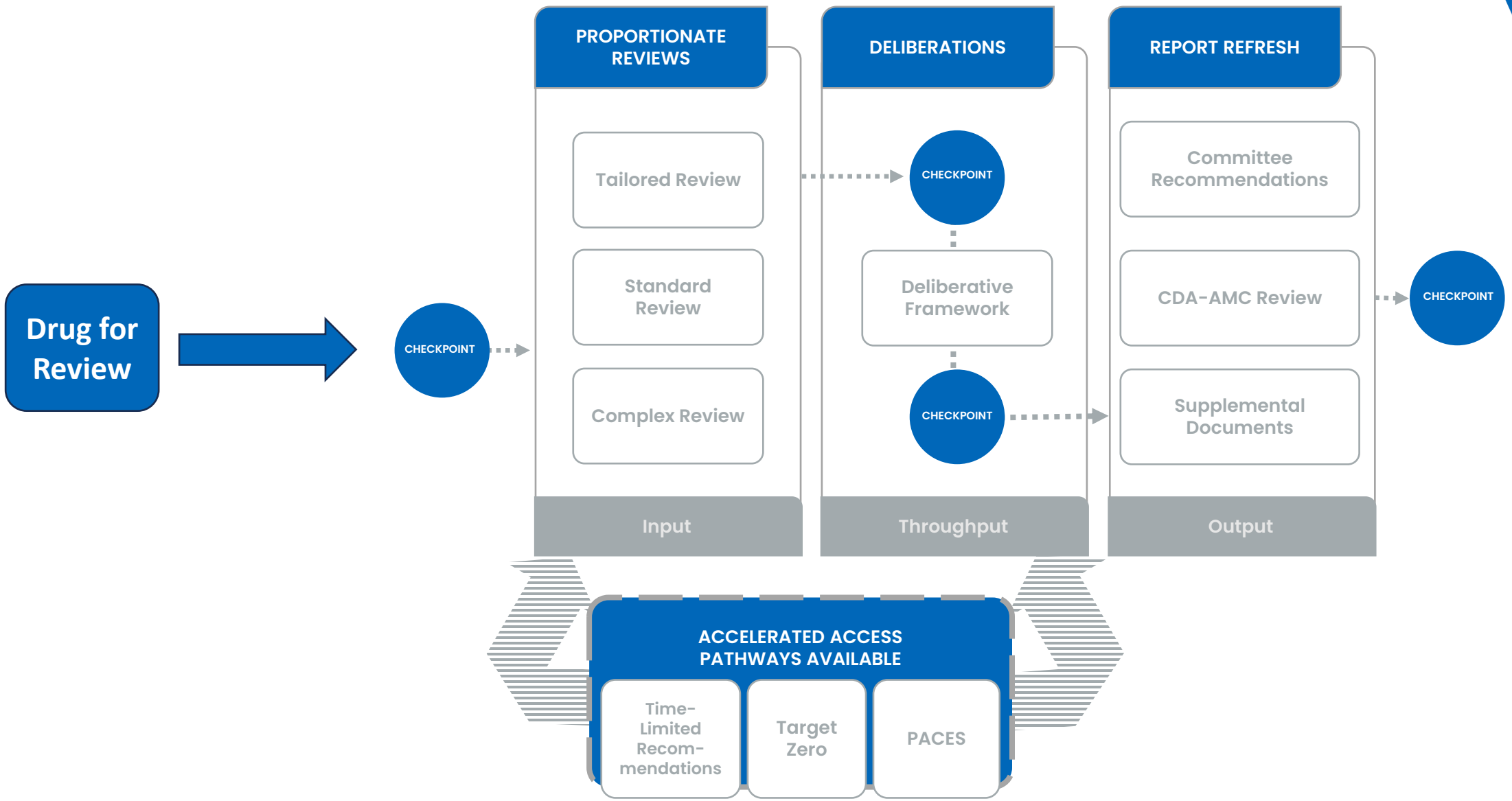
Checkpoints

Increased cadence of meetings with clear scope

Process Flow of Drug Reviews



Process Flow of Drug Reviews



Proportionate Reviews

Expand Tailored Reviews

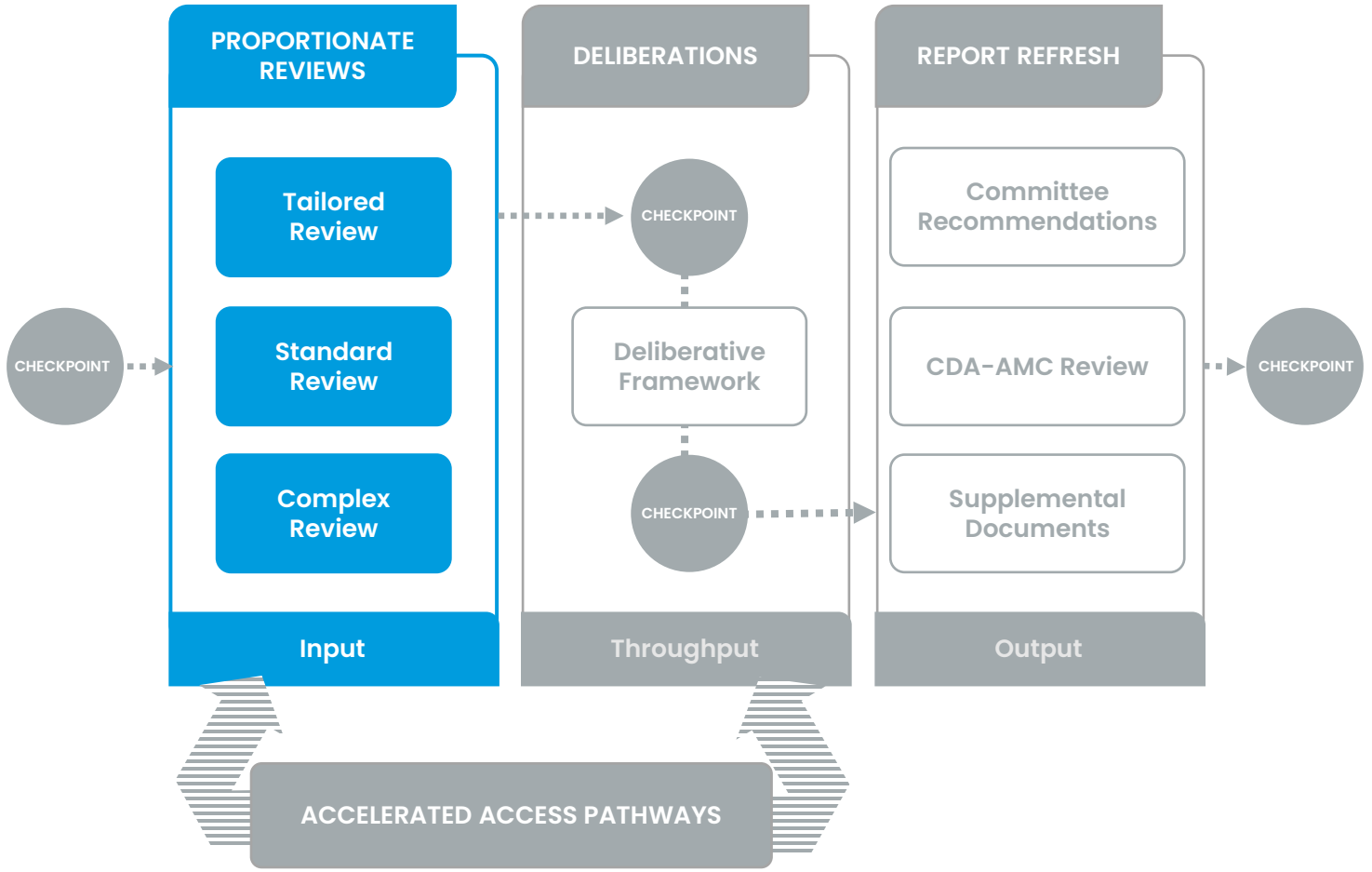
Expand 'Tailored Review' stream to include simpler low-risk assessments (e.g., pharmaceutical with anticipated comparable efficacy/safety [PACES]) that can be conducted within 100-120 days

Simplify Standard Reviews

Simplify requirements within Standard Review stream to improve efficiency and streamlined new additions (e.g., ethics)

Refine Complex Review Stream

Incorporate best practices from FMEC and formalize eligibility of Complex Review Stream.



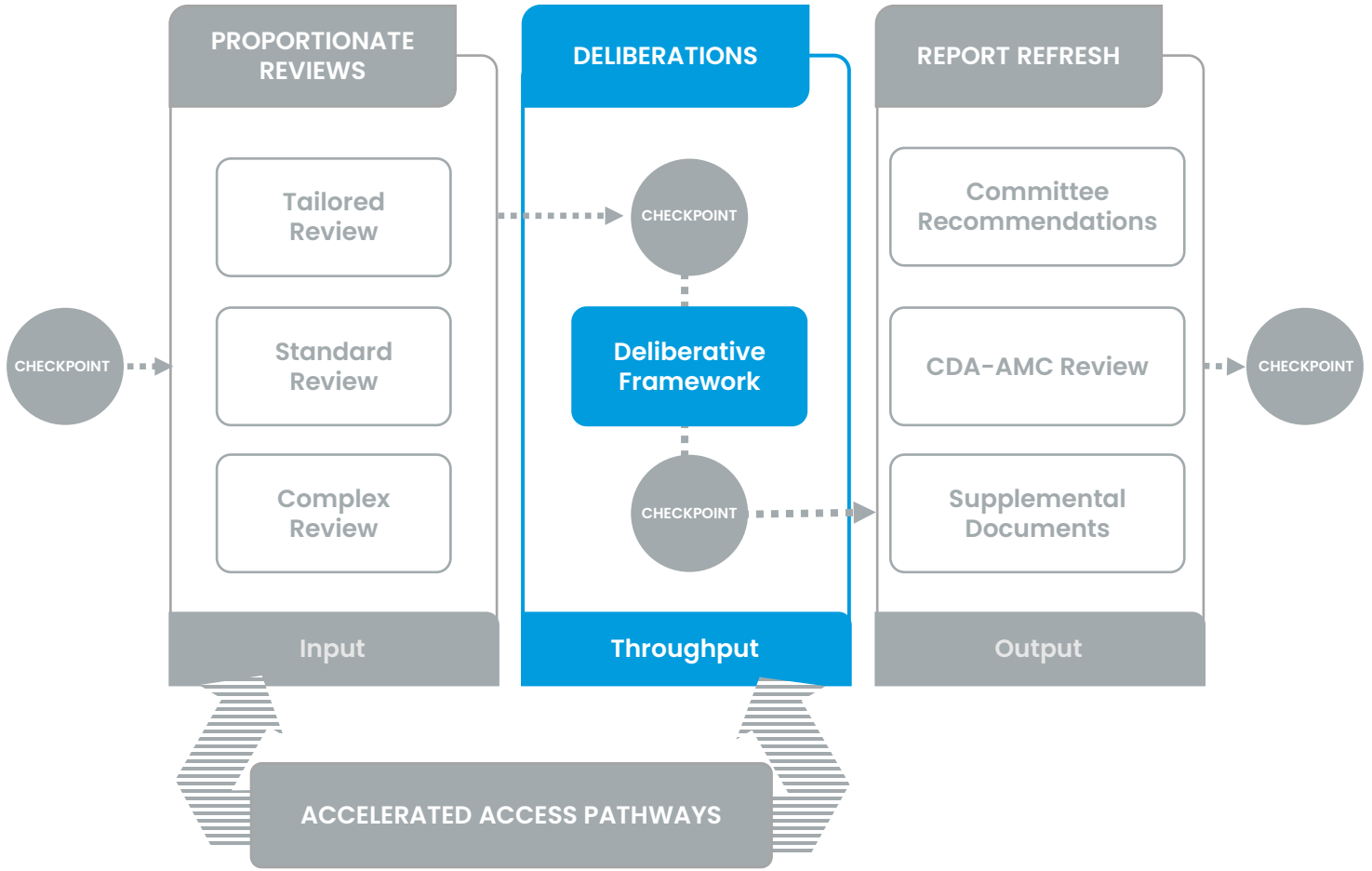
Deliberations

Deliberative Framework

Publish a deliberative framework used by our expert committees which will provide transparency to readers with how recommendations were formed

Incorporate New Approaches

Incorporate some of the innovative approaches trialed at FMEC (i.e., increase opportunities for the involvement of persons with lived experience [PWLE] and guest clinical specialists with our expert committees)



Report Refresh

Improve Readability

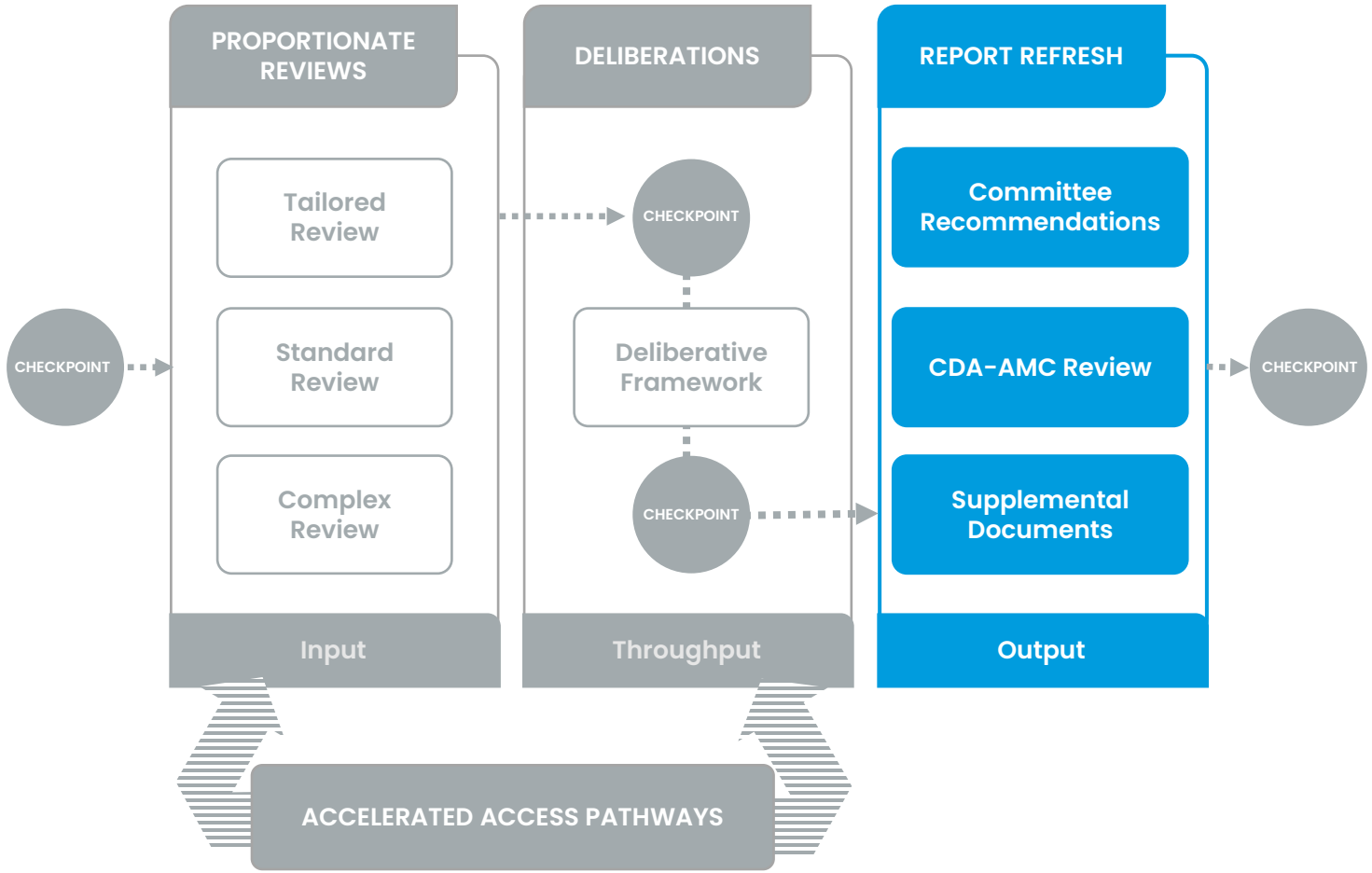
Improve the readability of our reports by limiting the page counts to focus on the value -add of our assessments

Publish Simultaneously

Publish the recommendation report and CDA-AMC review reports simultaneously to allow for more succinct recommendation reports

Increase Transparency

Align recommendation reporting with the delib erative framework for greater transparency in how the committee deliberated.



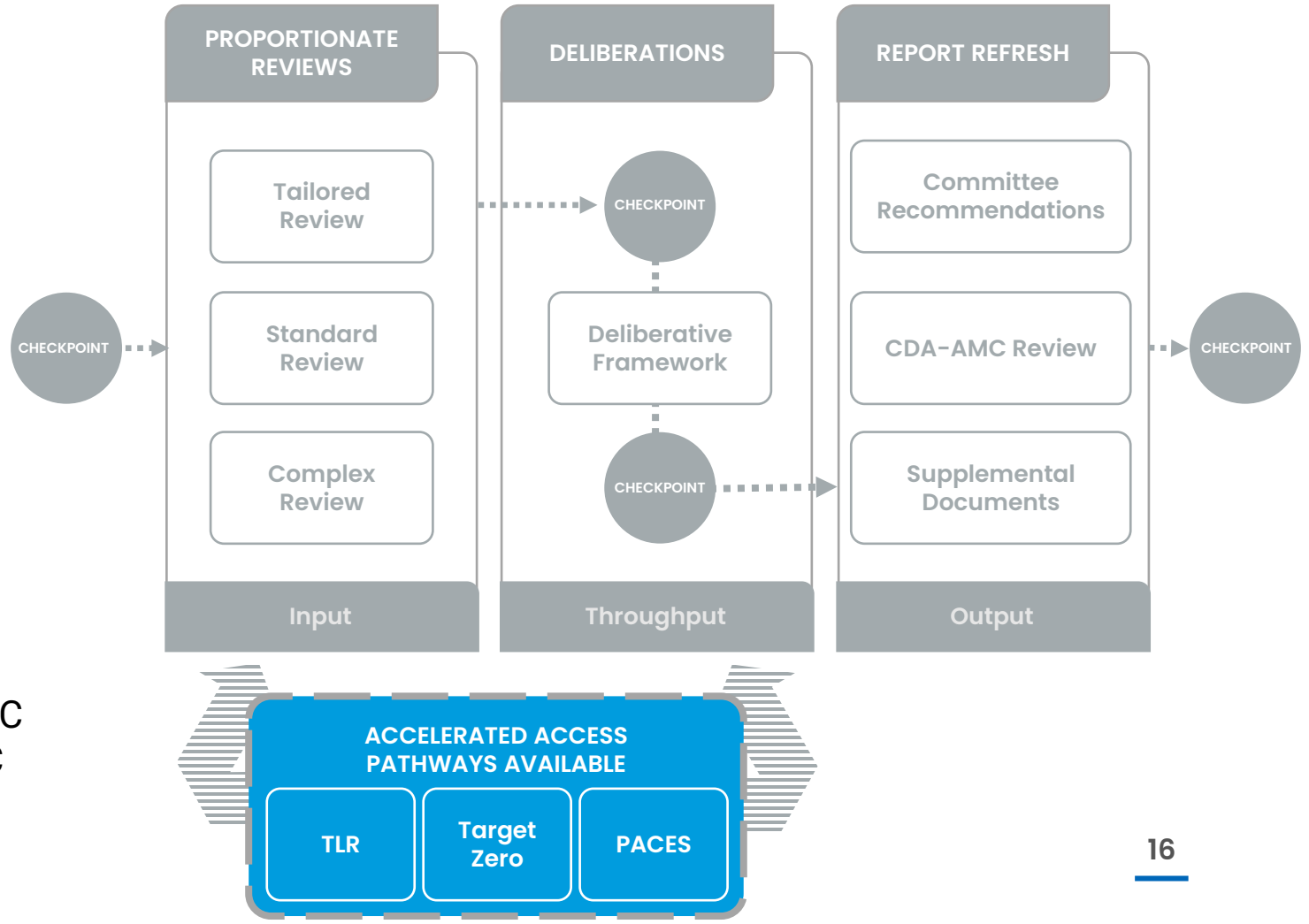
Accelerated Access Pathways

Expand Existing Initiatives

- Formalize ‘rolling reviews’ pilot to help facilitate the ‘Target Zero’ initiative
- Minor expansion of time-limited recommendation (TLR) pathway

Launch ‘PACES’ Trial

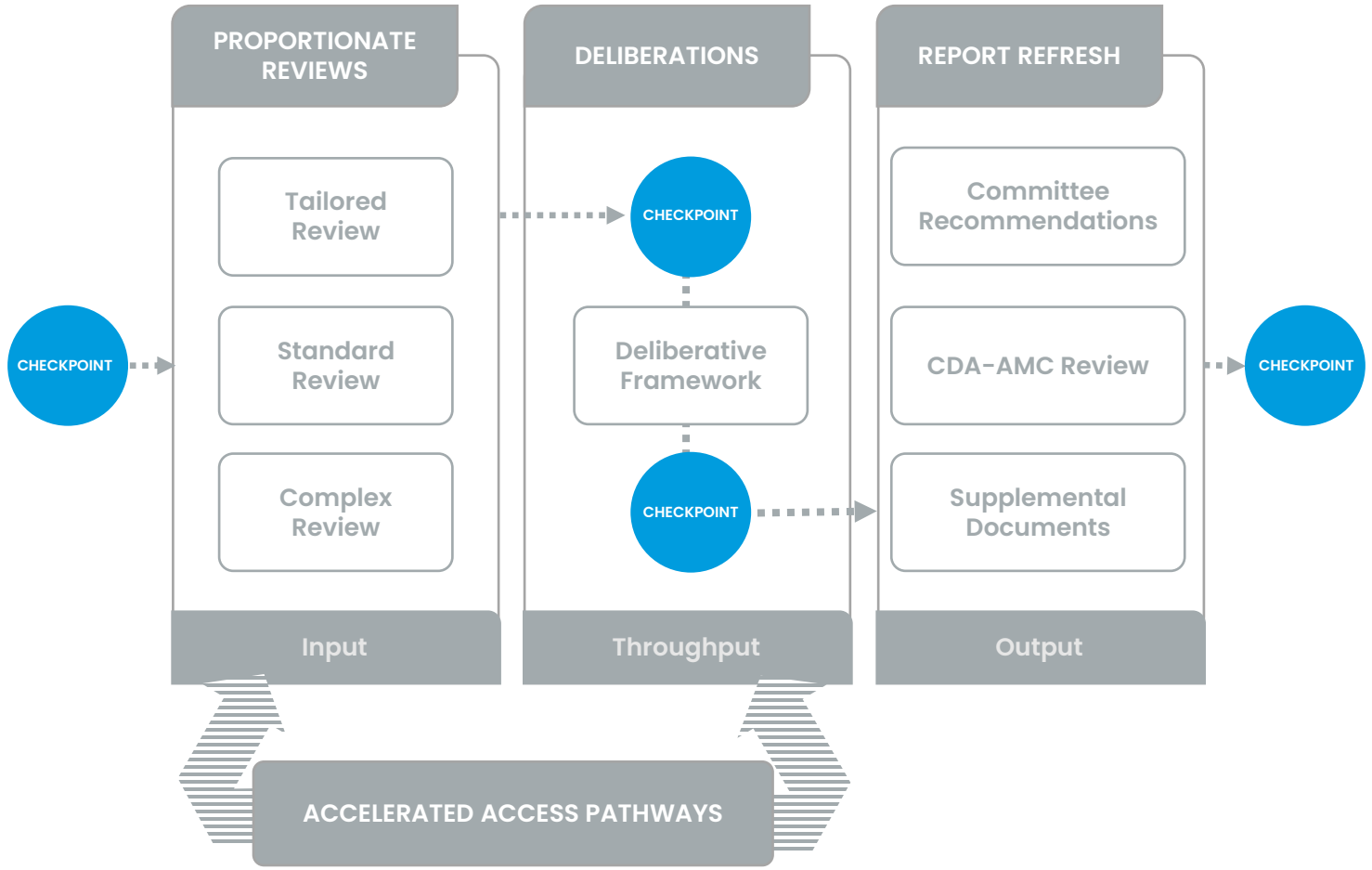
- Pharmaceuticals with Anticipated Comparable Efficacy and Safety (PACES)
- Initiative to focus on accelerating access for simpler low-risk files through an abbreviated review (i.e., PACES Tailored Review) at CDA-AMC
- Aligns with initiatives at INESSS, NICE, and SMC



Review Checkpoints

Increasing Dialogue

Increasing dialogue with sponsors by offering more checkpoints throughout the review process with clearly stated scope and suggested attendees.



When will these changes come into effect?

Changes applied to files at October 2025 committee meetings

- Cut-off dates for Advance Notifications: April 08 for oncology (pERC) and April 23 for non-oncology (CDEC)
- Any files submitted prior to the cut-off date will be subject to the current processes/procedures

Consultation of interested parties over next 3 months

- Written consultation period open from **January 6, 2025, to February 6, 2025**
- Virtual webinar on **March 6, 2025** (after updated procedures posted on February 27, 2025)

Upcoming Consultation Period

- Opens: January 6, 2025
- Closes: February 6, 2025 (feedback must be received by 5 pm ET on this date)
- Notes:
  - Individuals and organizations must be identified by name in the submitted feedback template
  - One response per organization will be considered
  - Send questions about the feedback process to feedback@cda-amc.ca

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How Will Patients Be Impacted?

Key Relevant Changes for Patients

1. Deliberative Framework

2. Potential for Accelerated Access via PACES Reviews

3. Persons with Lived Experience (PWLE) Presentations

1. Deliberative Framework: Overview

- The deliberative framework is a tool that guides the committees' discussions and makes the relevant considerations more explicit
- Deliberations are communicated through the recommendation report
- The committee's discussion of the patient group input will be highlighted across the domains in the report, allowing interested and affected parties to better understand how the committee deliberated and reached a recommendation

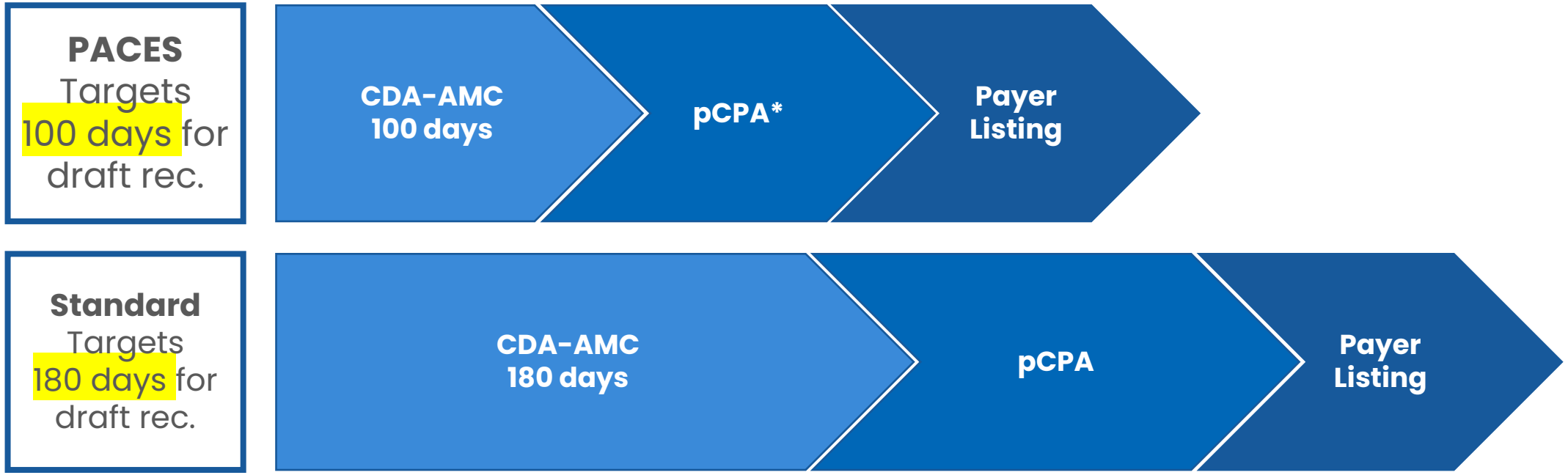
Recommendation Report

1. Deliberative Framework: Domains of Value

Clinical Value	Value that patients derive from a health technology in terms of its effect on their health and health-related quality of life.
Unmet Clinical Need	Morbidity and/or mortality arising from a condition or symptom that is not addressed effectively by available treatments.
Distinct Social and Ethical Considerations	The social and ethical implications of health technologies not already assessed in the other domains and how they affect patients, caregivers, populations, and the organization of health systems. It includes non-clinical needs, which are the social, psychological, and logistical factors that influence the appropriateness, accessibility, and acceptability of a health technology beyond its direct clinical outcomes.
Economic Considerations	Economic evidence to inform the financial, human or other resource implications associated with the technology under review, and whether it is worthwhile to allocate resources to the technology under review given its expected clinical benefits.
Impacts on Health Systems	Organizational feasibility of adoption—the ease with which the health technology can be implemented in the health system while realizing its clinical value—and economic feasibility of adoption—how the adoption of a health technology will economically impact the payer or budget holder.

2. Accelerated Access via PACES Reviews

2.5 months faster

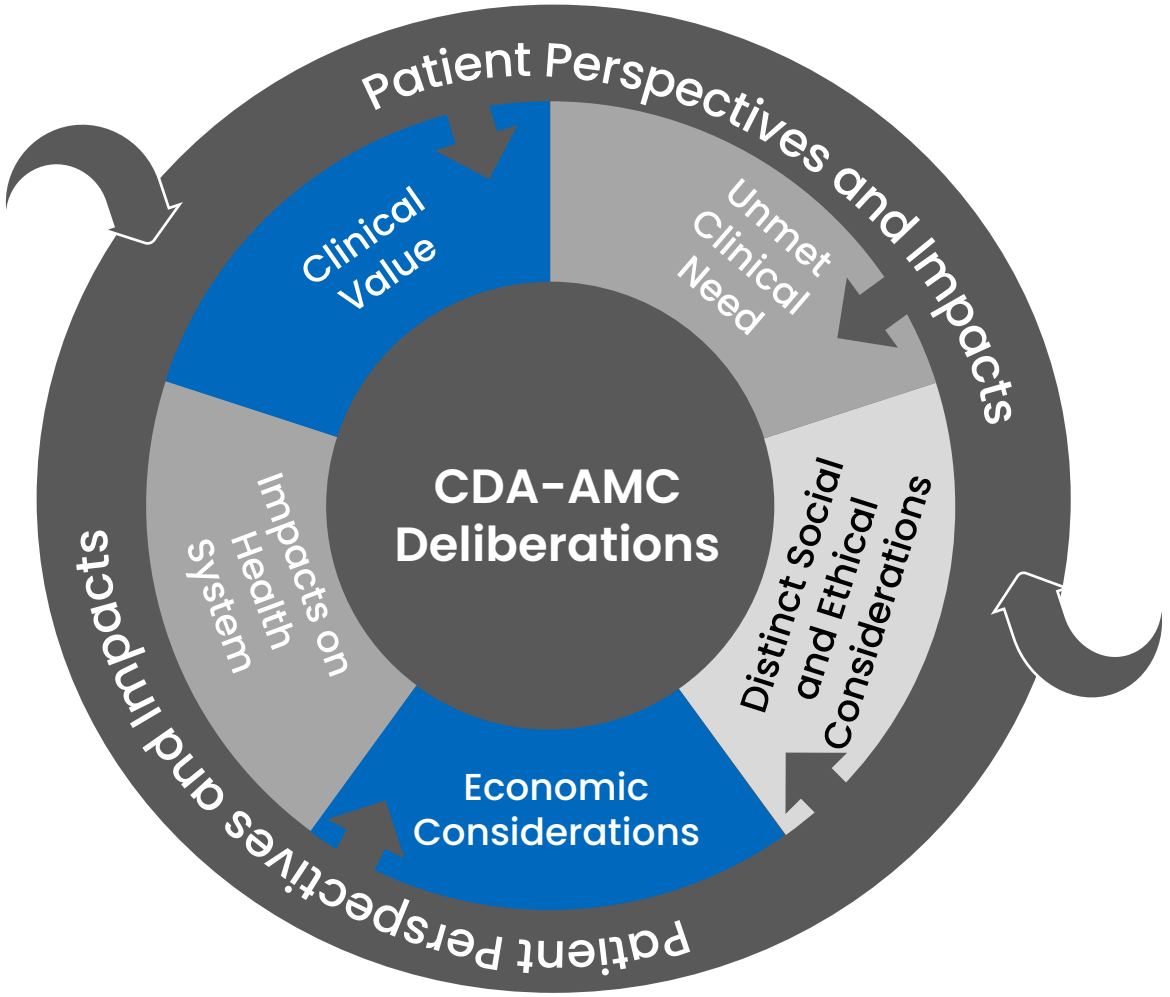


* Potential for accelerated pathway to reduce time to listing

3. How patient perspectives are incorporated into Reimbursement Reviews

Patient Group Input

- Received at the start of a Reimbursement Review through a 35-day written input period



Persons with Lived Experience Presentations

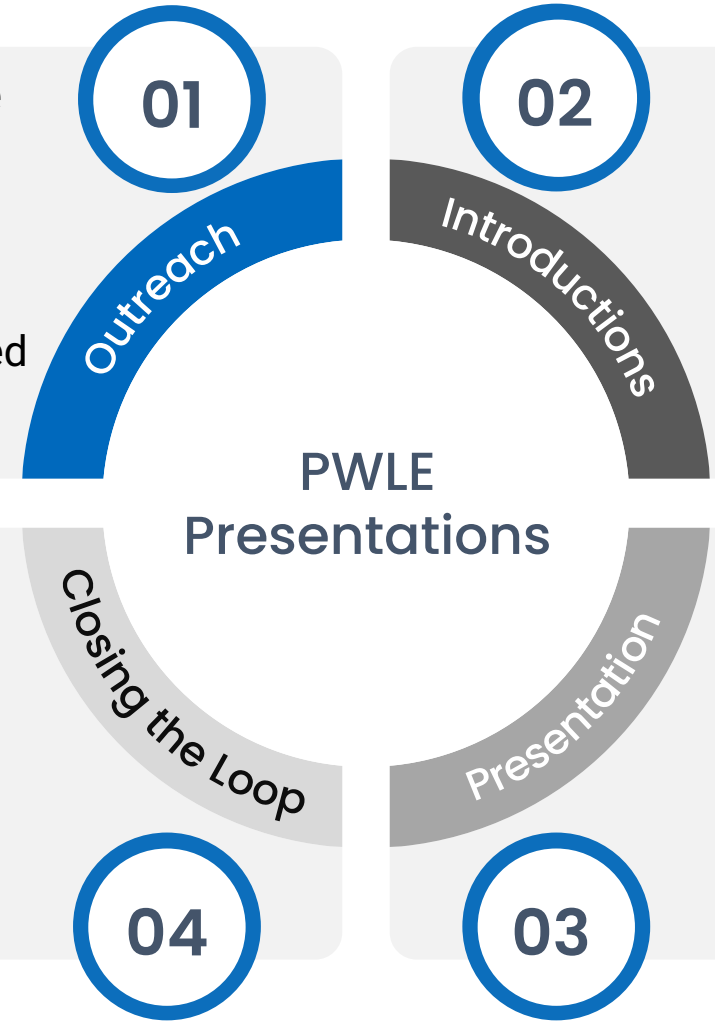
NEW

- Presentation and Q&A occurs during committee meeting, just prior to deliberations for complex reviews

3. Persons With Lived Experience Presentations to CDA-AMC Committees

Purpose	• Integrate voices of those directly impacted by treatments into Committee meeting to help better understand impacts on patients.
Impact	• Provide firsthand insights into real-world challenges, needs, and preferences of people with lived experience. • Highlight social, ethical, and practical implications.
Complementary Input	• Supplements input from patient groups in Reimbursement Reviews.

3. PWLE: Engagement Process Overview



- Outreach begins at the same time as the call for input.
- Outreach to relevant patient groups to collaborate on identification of PWLE
- Details of Engagement shared with interested parties

- Introductory meetings are held with identified PWLE to educate them on the CDA-AMC, Reimbursement Reviews, and their role
- Guidance provided to PWLE for presentation

- Summary of presentation & Q & A included in Rec. (reviewed by PWLE)
- Honorarium provided
- Acknowledged by name (optionally) in Rec.

- 5-minute presentation and 10-minute Q & A period
- CDA-AMC staff facilitate introduction of PWLE and Q & A period.
- Emotional Support De-brief offered to PWLE as needed

3. PWLE Presentations for Complex Reviews at CDEC & pERC

- CDA-AMC is now ready to expand this initiative to certain CDEC & pERC Reimbursement Reviews.
- Starting for files that are targeting the October 2025 committee meetings, CDA-AMC will undertake to include PWLE presentations for complex reviews that fit the following criteria:
  - Scenario 1: First drug indicated in a therapeutic area
  - Scenario 2: Priority review drugs

Why Complex Reviews?

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Summary and What Comes Next

Summary

- We are listening and committed to continuing to improve.
- Improving clarity and transparency of reimbursement review process, including how patient input is used and considered, is a priority.
- Patient group input remains a key element of the reimbursement review process for all types of reviews.

What Comes Next?

- Consultation period is open from January 6, 2025 to February 6, 2025, for those interested in contributing.

- Subscribe to eAlerts to be notified (cda-amc.ca/subscribe)

- After consultation on these changes, we will be engaging with patients to inform how we evolve the patient and clinician group input processes, including:
  - the information needed and requested from patients
  - how we obtain that information from patients

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Questions and Answers

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