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Pharmaceutical Reviews Program Renewal

What We Heard: Improvements to Drug Reimbursement Reviews

March 6, 2025

Introductions and Format

- **Host**
  - Sam Sutherland, Engagement Officer
- **Speakers**
  - Sudha Kutty, Executive Vice President, Evidence, Products & Services
  - Peter Dyrda, Director, Pharmaceutical Reviews
  - Michelle Gibbens, Director, Engagement
- **Format**

Agenda

- Presentation
  - Overview of Pharmaceuticals Reviews (PR) Renewal Initiative
  - Post-Consultation Conclusions
  - Evolving Patient & Clinician Group Input

- Q&A

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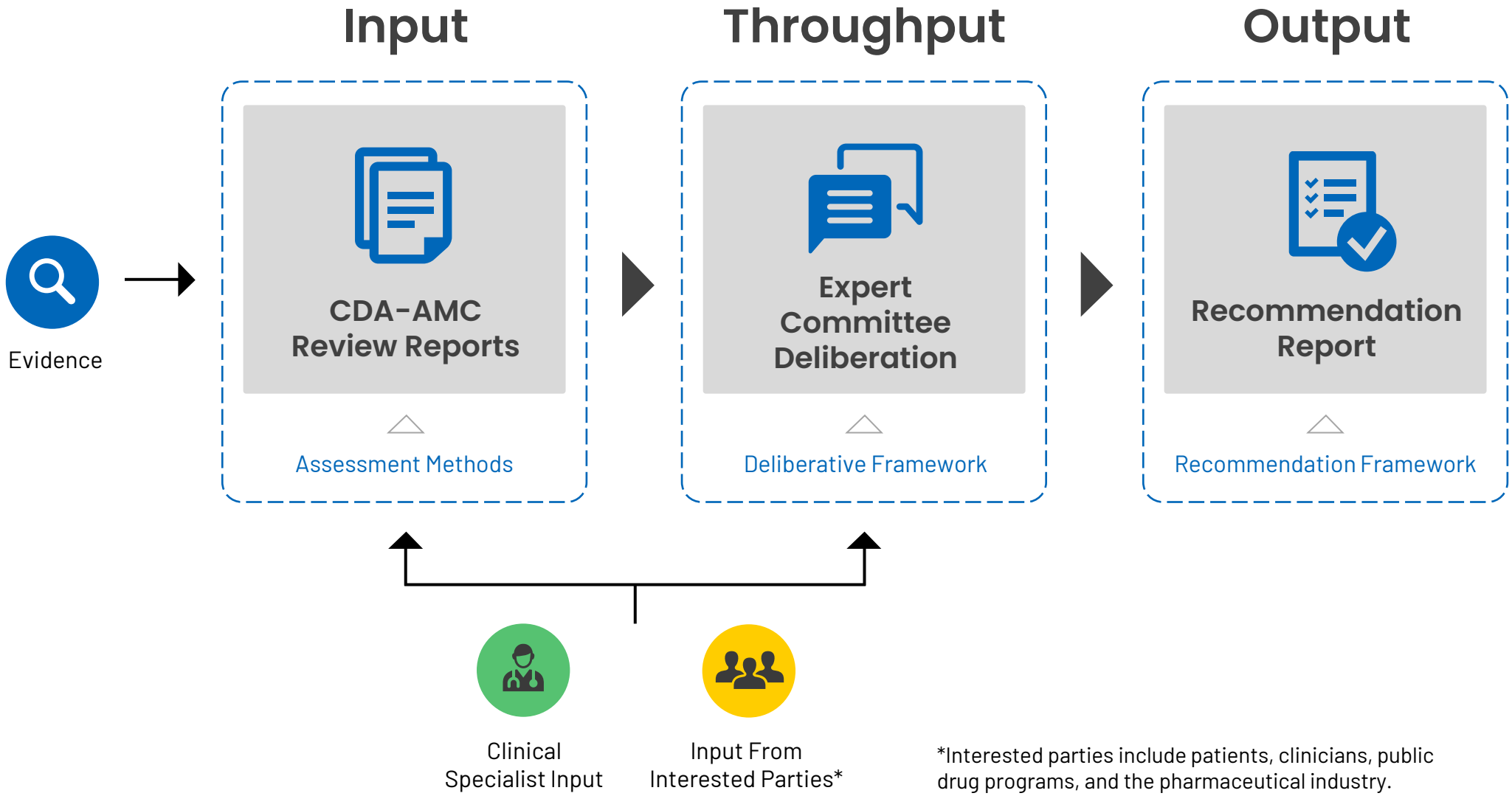
Overview of Pharmaceutical Reviews Renewal Initiative

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

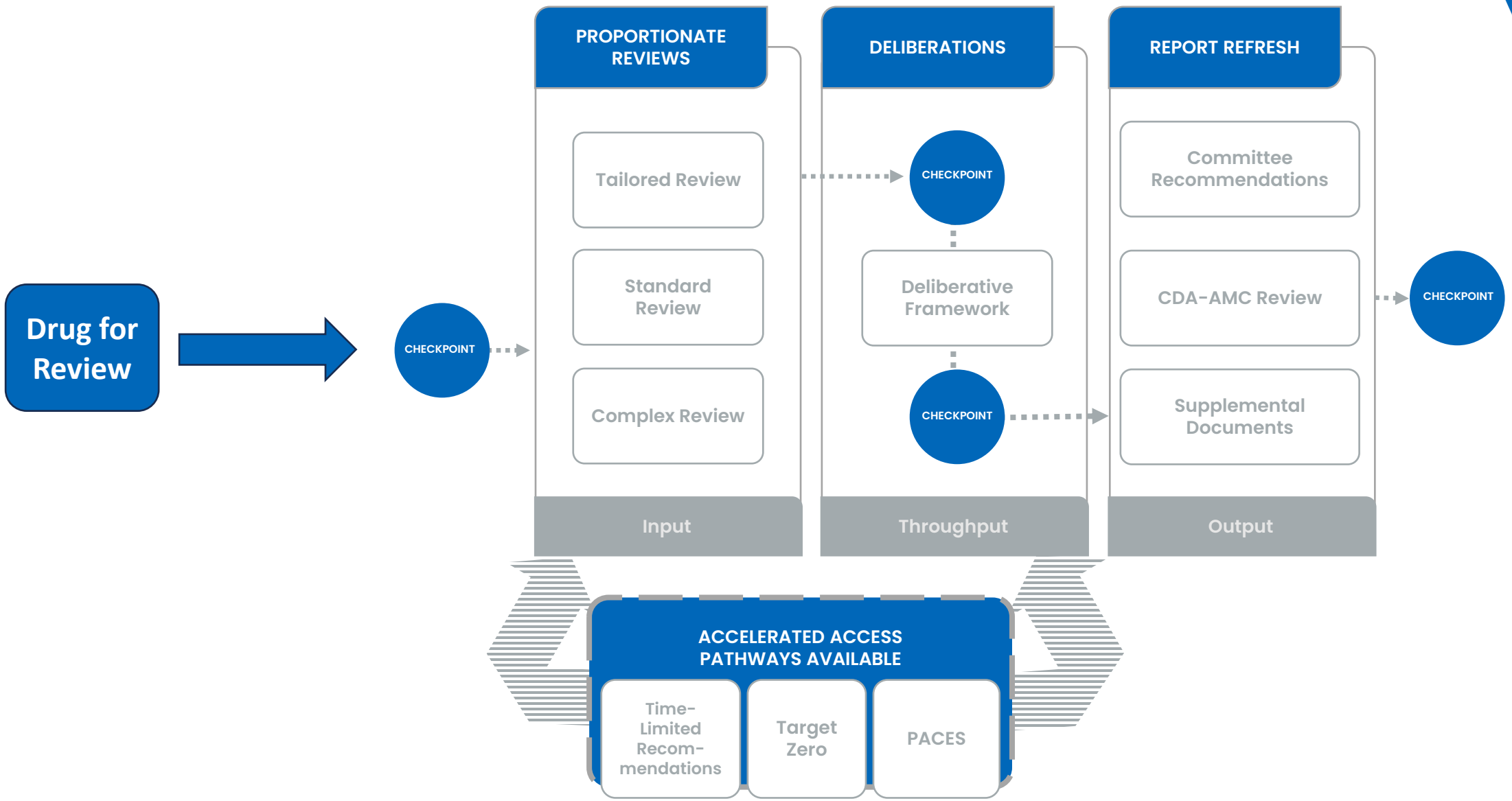
Accelerated Access Pathways

Expansion of existing initiatives and creation of PACES

Checkpoints

Increased cadence of meetings with clear scope

Process Flow of Drug Reviews



Timeline Reminders

Changes applied to files targeting October 2025 committee meetings

- Changes apply to files submitted on or after April 28 (oncology) and May 12 (non-oncology)
- Current procedures and processes apply to files submitted before these dates
- Corresponding deadlines for Advance Notification: April 8 (oncology) and April 23 (non-oncology)

PACES Reviews

- We will begin accepting Advance Notifications for PACES reviews with the same timelines
- Updated Fee Schedule to include Schedule B in March PRU (i.e., 90% of Schedule A fee)

PACES Reviews

- Overview
  - Tailored reviews for pharmaceuticals with anticipated comparable efficacy & safety (PACES)
  - For simple, low risk files where a claim of clinical benefit is not made

- Timelines
  - Review completed in 100 to 120 days (versus 180 days)

- Post-Recommendation
  - pCPA to communicate their corresponding process for PACES reviews

A word from pCPA on PACES Reviews

- The pCPA has been actively involved in the PACES discussions/development with our partner, the CDA-AMC.
- Similar to the TLR-pTAP continuum, we will have a negotiation pathway for this (PACES).
- We understand the need for a negotiation pathway that is aligned with PACES and for the process to be smooth and seamless for manufacturers, the CDA-AMC, and the pCPA.
- We're looking forward to sharing more on this shortly, and in the meantime, manufacturers can reach out directly to the pCPA if they have any questions.

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Post-Consultation Conclusions

Consultation Process

- We received 56 submissions of written feedback during the one-month consultation period from:
    - Pharmaceutical companies (17)
    - Industry associations or working groups (4)
    - Consulting companies (3)
    - Patient groups (26)
    - Clinician group (1)
    - Public drug programs (4)
    - Academic (1)

- We held several roundtables of patient groups and industry associations from November 2024 through January 2025

Themes for Discussion

What We Proposed → What We Heard → Where We Landed

- Submission Components
- PACES Reviews
- Accelerated Access Pathways
- Checkpoint Meetings
- Deliberations
- Complex Reviews
- Persons with Lived Experience

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Submission Components

Peter Dyrda

Submission Components

Streamlining Application Requirements

What we Proposed

- A list of discontinued application requirements were proposed (e.g., cover letter, CTD 2.7.1, editorials, copy of NOC/c, disease prevalence).

What we Heard

- Consider removing CTD 5.2, Table of Clarifaxes, Place in Therapy, Cover Letter, Comparator Reimbursement Status, Validity of Outcome Measures

Where we Landed

- No additional items were added to the discontinued application requirements as they were all deemed important for the review team

Submission Components

Clinical Expert Suggestions

What we Proposed

- We would request that sponsors provide a list of clinical experts to be considered for contracting by CDA-AMC for each review, where we would aim to include 1 expert from this list

What we Heard

- Requests for clarity on what would be considered conflicts of interest for potential clinical experts, transparency of names, and role of patient groups should be explored

Where we Landed

- Conflict of Interest forms will be shared broadly so potential candidates can see questions, specialty and province of practice will be published (not names), and will be limited to sponsor submissions

Submission Components

Proposed Reimbursement Criteria/Conditions

What we Proposed

- Sponsors will have an opportunity to suggest more detailed criteria and conditions for the expert committee to consider as part of their application (vs status quo)

What we Heard

- Clarity requested on the level of details and participation from sponsors

Where we Landed

- Participation is voluntary and criteria/conditions that we are looking for are initiation, renewal, discontinuation, and prescribing information

Submission Components

Indirect Comparisons

What we Proposed

- By default, we would typically allow sponsors to submit 1 type of indirect comparison for a given combination of patient population, comparator, and endpoint

What we Heard

- Allowing for multiple comparisons with different methodologies may mitigate uncertainty

Where we Landed

- Multiple comparisons will be accepted as a form of Complex Review; an anchored matching-adjusted indirect comparison (MAIC) may be accepted in addition to another indirect comparison for PACES reviews

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PACES

Peter Dyrda

PACES Reviews

Screening

What we Proposed

- Sponsors will be required to submit for 1 of the 3 drug review types, where CDA-AMC will only assess eligibility based on listed criteria at screening

What we Heard

- Questions were raised on how to demonstrate comparability and whether acceptance of a file through PACES implies comparability

Where we Landed

- We will not conduct a detailed appraisal of the evidence beforehand, but will guide sponsors in the pre-submission phase if there are questions

PACES Reviews

Eligibility Criteria

What we Proposed

- Sponsor is not making a claim of clinical benefit versus relevant comparators that have the same indication

What we Heard

- Reluctance to use the process may be driven by the language around ‘clinical claim’

Where we Landed

- To ensure plain language, the wording is unchanged, but it should be noted that not making a clinical claim does not imply that the sponsor does not support the drug satisfying an unmet need

PACES Reviews

Subcommittee Process

What we Proposed

- After the subcommittee writes their recommendation, they will validate it with the corresponding broader expert committee at the next available agenda

What we Heard

- Having the broader committee validate the subcommittee could be redundant and an inefficient use of time

Where we Landed

- The subcommittee's recommendation will move forward in a 'consent agenda' format by the broader committee and only require validation if consensus is not reached

PACES Reviews

Additional Data

What we Proposed

- PACES reviews will be limited in the types of evidence that will be in scope for review, since there is no claim for clinical benefit

What we Heard

- If files have supplementary evidence, it should be heard by the expert committee

Where we Landed

- If sponsors feel strongly about the supplementary evidence, it can be submitted via a Standard or Complex Review process

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Accelerated Access Pathways

Peter Dyrda

Accelerated Access Pathways

Expansion of TLR Pathway

What we Proposed

- Expanding it to resubmissions for files that previously received a ‘do not reimburse’ recommendation for a Ph2 study with a NOC/c and Ph3 study in progress

What we Heard

- TLR should be expanded beyond the current scope to other types of drugs with NOC/c and drugs for rare diseases

Where we Landed

- We will need to assess the TLR pilot with the initial scope to determine expansion, but are open to proposals

Accelerated Access Pathways

Expansion of Rolling Reviews

What we Proposed

- Rolling reviews now have guidance for sponsors in terms of their eligibility, generally looking at a 20 business day difference between clinical and economic components

What we Heard

- Sponsors would like flexibility to submit new evidence up to the day before the expert committee meeting

Where we Landed

- We will need to assess the benefit of the current scope of rolling reviews prior to considering any expansion

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Checkpoint Meetings & Deliberations

Peter Dyrda

Checkpoint Meetings

Pre-Submission & Evidence Presentation Meetings

What we Proposed

- Limiting the attendance of clinical experts only to Evidence Presentation Meetings

What we Heard

- There may be instances where place in therapy and deviations for relevant comparators could use a clinician's voice during pre-submission meetings

Where we Landed

- Clinical experts may be invited to pre-submission meetings if there is a request provided to CDA-AMC based on need

Deliberations

Recommendation Pathway

What we Proposed

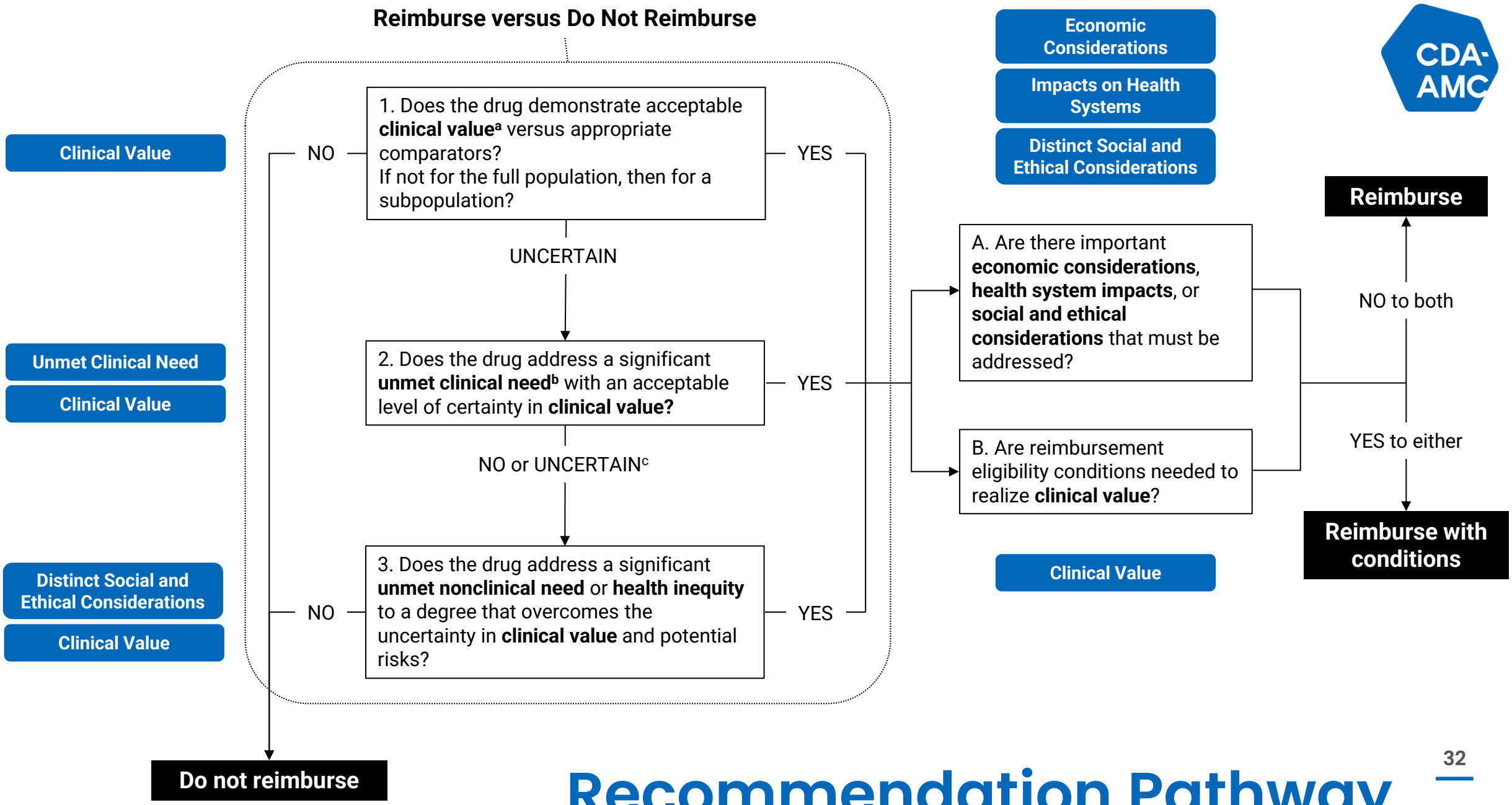
- The 5 domains of the deliberative framework will be published and used by all drug expert committees to ensure consistency and transparency

What we Heard

- The relationship between the domains, the inputs for the domains, and how the domains are used in the deliberations was not clear

Where we Landed

- We have published the recommendation pathway as an Appendix to the deliberative framework document to address what we heard



Recommendation Pathway

Deliberations

Transparency

What we Proposed

- We will publish vote counts, summarize dissenting opinions, and provide the recommendation pathway for each review

What we Heard

- Desire from external parties to standardize questions provided to committee members and have access to discussions (e.g., transcripts of deliberations)

Where we Landed

- Publication of the ‘recommendation pathway’ which will be included in recommendation reports for each file

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Complex Reviews

Peter Dyrda

Complex Reviews

Scenario 1 Reviews

What we Proposed

- Scenario 1 Complex Reviews would be generally limited to the first in class drugs in a therapeutic area

What we Heard

- Clarity of what is meant by therapeutic area was requested

Where we Landed

- Where there are multiple lines of therapy, the first drug indicated for the target type (e.g., cancer) would be considered first in class, but not for subsequent submissions that follow for different lines of therapy

Complex Reviews

Scenario 2 Reviews

What we Proposed

- Priority Reviews from Health Canada would be the signal for eligibility for Scenario 2 Complex Reviews

What we Heard

- For some therapeutic spaces, namely rare diseases, priority reviews may not be possible, but instead regulatory may provide a NOC/c designation

Where we Landed

- We added a NOC/c designation as an additional signal of priority review in the eligible of Scenario 2 Complex Reviews

Complex Reviews

Process Enhancement – Societal Perspective

What we Proposed

- Societal Perspective would be applied as a second base case in Scenario 1 Complex Reviews

What we Heard

- Desire by external parties to apply the Societal Perspective more broadly

Where we Landed

- Instead of applying the Societal Perspective under the new eligibility definition of Complex Reviews, a decision will be made upon pilot completion (July 2025)

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Questions and Answers

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Person with Lived Experience Presentations

Michelle Gibbens

Persons with Lived Experience Presentations (PWLE)

Type of Reimbursement Reviews for PWLE Presentations

What we Proposed

- Starting with applicable complex review scenarios.

What we Heard

- Consider including PWLEs in all standard reviews, as well as for specific conditions.

Where we Landed

- CDA-AMC will proceed with introducing the PWLE for the subset of files identified in the consultation document.

Persons with Lived Experience Presentations (PWLE)

Number of PWLEs presenting per Review

What we Proposed

- CDA-AMC will seek to engage a person with experience with the condition under review (i.e., a patient, caregiver, or family member)

What we Heard

- Consider including multiple PWLEs for a review to ensure a range of experiences and perspectives.

Where we Landed

- CDA-AMC will proceed with 1 PWLE for each identified complex review.

Persons with Lived Experience Presentations (PWLE)

PWLE Presentation Recruitment Criteria in Reimbursement Reviews

What we Proposed

- Selection Criteria included that PWLE ideally have Experience with Drug under review

What we Heard

- Feedback varied from suggesting PWLE should and should not have experience with the drug under review

Where we Landed

- Removed criteria around experience with the drug under review and only focuses on the indication/ condition under review.

Persons with Lived Experience Presentations (PWLE)

Engagement Efforts Clarification

What we Proposed

- CDA-AMC will endeavor to engage a person with relevant lived experience to present for every complex review meeting the criteria for applying this process, but this may not always be possible.

What we Heard

- Feedback suggested to ensure that the procedures highlight what happens if a PWLE is not found, as well as ensuring that CDA-AMC will attempt to engage PWLE and not may engage.

Where we Landed

- If a PWLE is not found for the review or if they are not able to attend due to unforeseen circumstances, the committee meeting will proceed as scheduled

Persons with Lived Experience Presentations (PWLE)

Role of PWLE and Patient Group Input

What we Proposed

- Supplementary to Patient group input: The goal of including lived experience presentations at committee meetings is to supplement the written patient group input by…

What we Heard

- Feedback highlighted the need to clarify the roles of patient group input and PWLE presentations.

Where we Landed

- Clarity added on their distinct roles and supplementary nature of patient group input and PWLE Presentations.

Persons with Lived Experience Presentations (PWLE)

Recruitment Criteria & Selection

What we Proposed

- Transparency on Selection Criteria: Our initial proposal did not include specific selection criteria related to selecting a PWLE when multiple individuals are interested.

What we Heard

- Feedback highlighted the question on how CDA-AMC would select between multiple groups or individuals interested in participating.
- Emphasized the need to ensure diverse perspectives.

Where we Landed

- Criteria Added: In instances where there are multiple individuals interested in participating, CDA-AMC will prioritize the inclusion of underrepresented and underserved populations in our selection process.

Persons with Lived Experience Presentations (PWLE)

Definition of a PWLE

What we Proposed

- CDA-AMC will engage a person with lived experience, such as a patient, caregiver, or family member.

What we Heard

- Some feedback suggested to focus on patients only, while others highlighted the need for caregiver involvement where applicable, and to have flexibility in who a PWLE is.

Where we Landed

- Expanded definition to explicitly include patients, caregivers, close support, or family members to ensure inclusivity.

Persons with Lived Experience Presentations (PWLE)

Support, Accommodations & Preparation

What we Proposed

- CDA-AMC staff will support and guide persons with lived experience throughout the process by providing:
- guidance leading up to the presentation and;
- an emotional support debrief following the presentation.

What we Heard

- Need for standardized resources for PWLE preparation, dedicated support and standard guidance provided for presentations

Where we Landed

- Clarity added on the preparatory meeting and its goal, support available for PWLEs, Forms to complete and described the preparation process in depth.

What we Heard

- Need for support and accommodations for PWLEs when needed.

Where we Landed

- Clarity added: CDA-AMC will endeavor to accommodate the participant's needs to ensure meaningful participation.

Persons with Lived Experience Presentations (PWLE)

Honoraria

What we Proposed

- Honorarium: They will be offered an optional honorarium for their involvement

What we Heard

- Feedback highlighted the need to ensure appropriate compensation is provided to PWLEs for their efforts.

Where we Landed

- The time commitment and honorarium practice is currently under review for PWLE presentations and will be updated accordingly.

Persons with Lived Experience Presentations (PWLE)

Engagement Evaluation

What we Proposed

- Current practice was to obtain qualitative feedback informally at two touchpoints during the engagement

What we Heard

- Implement a formal Feedback mechanism to improve and define the process and ensure it remains patient centric

Where we Landed

- A formal feedback mechanism is under development to obtain further clarity on areas of improvement for the engagement approach.

Evolving Patient & Clinician Group Input

Reduce effort and resources required

Patient & clinician groups have informed us that they expend considerable time, effort and resources to prepare written input submissions

Increase transparency

Patient & clinician groups who submit input are unclear about how their input is used and considered in deliberation

Align and focus input on what is needed

Patients & clinicians have expressed uncertain about what is needed/useful. Opportunities to better align with what is needed to inform review reports and support deliberations

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