Canada's Drug and Health Technology Agency | L'Agence des médicaments et des technologies de la santé au Canada

Consultation: Proposal for Reform to Provisional Funding Algorithm

Provisional Funding Algorithm Reform Overview

The Provisional Funding Algorithm (PFA) process is used to provide advice when drug programs have indicated that there is a need to harmonize the place in therapy for the funding of the drug under review, relative to alternative treatments that are currently reimbursed by the public drug programs. PFAs provide a summary of reimbursed drug options (in a sequence) for a tumour type and are requested by the Provincial Advisory Group (PAG) following a reimbursement recommendation. PFAs can be done in a rapid (i.e., no external expert input required) or panel (i.e., panel of experts required) approach.

Over the past year we have heard from various stakeholders that there were opportunities to improve the transparency and timeliness of the current PFA process. As a result, the following changes to the PFA process are being proposed. The objectives of these PFA reforms are to provide greater opportunities for stakeholder input, enhance transparency in the process, and to provide public drug programs with timely evidence to inform their decision making.

Table 1: Proposed changes to the PFA Process

Proposed Change	Current Process	New Process	Rationale
Publish final reports faster by initiating the process earlier.	Initiated at the time of a draft Reimbursement Recommendation.	Initiated during the open call for input stage of the Reimbursement Review process (at the request of the public drug programs).	Earlier initiation of the algorithm process will expedite the delivery of final reports ~ 30 to 40 business days sooner than the current process.
Provide more opportunities and time for stakeholders to provide input on the rapid and panel PFAs.	No opportunity for stakeholder input on Rapid PFAs. Open call for stakeholder input on a Panel PFA is 10 business days.	Both Rapid and Panel PFAs will have an opportunity for stakeholder input for 35 business days.	Patient and clinician groups have expressed that 10 days is not enough time to mobilize and provide meaningful input. Note: We have lengthened the time for stakeholder input, but

			we have kept constant the time for stakeholder feedback.
Summarize how stakeholder input and feedback is considered in the final report.	Not addressed in the current process.	The PFA final report will include a dedicated section to address important and relevant stakeholder engagement. All stakeholder input and feedback will be published online, similarly to Reimbursement Recommendations.	Transparency of the process will be improved by addressing how stakeholder engagement was considered in the report and by publishing input/feedback online,
Improve readability and ease of use of templates and reports.	Existing templates and reports have been described as too lengthy.	Templates for stakeholder input and feedback will incorporate more descriptive and open-ended questions to better capture insights. PFA final reports will have improved readability by leveraging learnings from other pilots (e.g. FMEC reports).	The process will have greater impact if it becomes more user-friendly.
Increase efficiency by requesting materials from sponsors to greater support PFA reviews.	Sponsors may provide suggestions for PFAs (i.e., Proposed Place in Therapy Template).	Sponsors will be asked to provide a draft PFA diagram in an AODA compliant format and summarize previous evidence described by reimbursement reviews in CADTH Place in Therapy Template.	Sponsors will have more opportunity to shape discussions by providing more submission materials to facilitate the process.
Delineate the perspectives of the HTA review versus the final PFA as accepted by payers.	Two organizations of payers participate in the PFA process: CAPCA and PAG. CAPCA proposes expert panellists for Panel PFAs and provides	CAPCA will continue to assist in identifying expert panel members. CAPCA will no longer provide an 'endorsement' of a PFA but are eligible to provide stakeholder input or feedback (which will be published online).	To enhance transparency of CAPCA's role in the development of a PFA and the difference between the clinical expert consensus compared to the accepted PAG PFA.

	'endorsement' for all Panel PFAs. PAG requests PFAs and agree to funding criteria based on a treatment sequence.	Where there is deviation from the HTA review and the final PFA desired by PAG, the nature of the disparity will be described in the report.	

Preamble

These draft procedures are to replace the current Section 13 of Procedures for CADTH Reimbursement Reviews (pages 113 to 120). These procedures will be finalized upon consideration of stakeholder feedback.

13. Provisional Funding Algorithm for Oncology Drugs

13.1 Purpose and Eligibility

The provisional funding algorithm (PFA) process is used to provide advice when the drug programs have indicated that there is a need to harmonize the place in therapy for the funding of the drug under review, relative to alternative treatments that are currently reimbursed by the public drug programs. A PFA may impact the sequencing of treatments for the purposes of reimbursement (e.g., should reimbursing the drug under review result in a shift or a displacement of other available treatments). This process is distinct from the Reimbursement Review process and is offered for the purposes of assisting jurisdictions in implementing recommendations and/or making reimbursement policy decisions.

The PFA can be requested by public drug programs during the Review Phase of Drug Program Input (Section 6.4.2b).

If the final Reimbursement Recommendation for a drug under review is "Do not Reimburse", an initiated PFA process will be suspended indefinitely.

The PFA process initiates before a reimbursement recommendation is finalized to provide public drug programs with more timely evidence to inform their decision making. In addition, early initiation of the PFA also provides more time for meaningful stakeholder engagement.

Note that PFAs are updated only when new evidence has been reviewed by an expert committee (e.g., pERC, FMEC). For new evidence to be considered in a PFA, sponsors or tumour groups must submit an application for a reimbursement review and recommendation (e.g., re-submission) or a public drug plan must request a non-sponsored review. Late-breaking abstracts from a recent congress or updated clinical practice guidelines are not in scope for a PFA review unless previously reviewed by an expert committee.

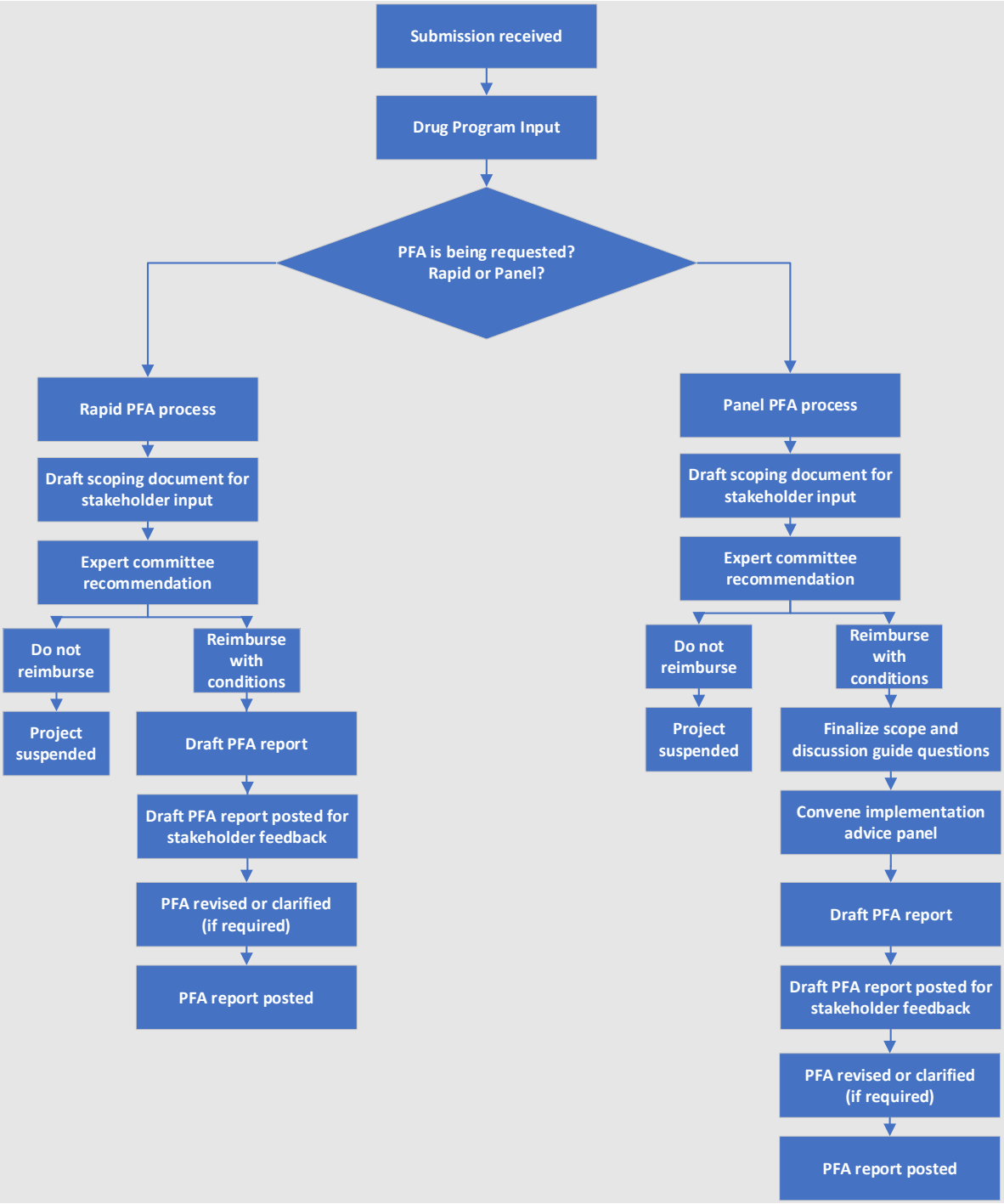
13.2 Algorithm Process

We aim to conduct our reviews in the most efficient manner and the following processes are applied depending on the complexity of the algorithm:

- A panel algorithm is undertaken when the advice of clinical specialists is required to adapt an existing PFA or establish a completely new PFA. Panel algorithms will typically be initiated when 1 or more drugs may be impacted by the implementation of a new drug (e.g., shifting existing drugs to different lines of therapy).
- A rapid algorithm is undertaken when an expert committee (e.g. pERC or FMEC) recommendations can be directly incorporated into an existing PFA without supplemental advice from clinical specialists. The rapid algorithm process will typically be initiated in situations where the new drug will not alter the current sequence of drugs within an existing funding algorithm (e.g., a follow-on drug within an existing line of therapy or a completely new line with no comparators).

Figure 1: Proposed Provisional Funding Algorithm Processes

Alt text: This figure depicts the proposed provisional funding algorithm processes.



13.3 Targeted Time Frames

The key targeted time frames and the status of all reviews are posted on our website. We attempt to align the timelines closely with the final recommendation report(s) of the new drug(s). The actual timelines may vary depending on the scheduling of PAG meetings as well as the complexity of the treatment space that may require additional discussions. For example, it is possible that some panel algorithm may require multiple panels, which would impact timelines.

13.4 Stakeholder Engagement

a) Industry Engagement

The sponsor whose drug is under review (which initiated the PFA) is required to submit a template with a suggested PFA and a summary of relevant previous expert committee recommendations.

All sponsors (i.e., DIN holders) whose products may be directly impacted by PFA may provide input. We will post a scoping document with the following information:

- Indication of interest
- List of drugs that may be impacted.

Notifications of PFAs and related timelines will be communicated via Weekly Summary Newsletters only (i.e., sponsors will not be contacted directly). All sponsors will have 35 business days to provide written input regarding their perspectives on the treatment paradigm and the place in therapy for their product(s). This input must be shared using the template posted online and must not contain any confidential information (as all information included in the template will be considered disclosable).

Once we have drafted the PFA report, sponsors can also provide comments during the open call for stakeholder feedback period (5 business days).

All input/feedback provided by sponsors will be considered in the PFA process and be posted on our website for transparency.

b) Drug Program Engagement

The participating drug programs will be engaged throughout all phases of the PFA process. Once the PFA report is drafted, drug programs will be provided with an opportunity to review and provide comments during the open call for stakeholder feedback period.

The CAPCA Board of Directors offers important input and guidance in the development of PFAs. Input and feedback received by CAPCA will be considered in PFA process and be posted on our website for transparency.

c) Patient and Clinician Group Engagement

Upon notification via Weekly Summary Newsletter that a PFA is being developed, relevant patient and clinician groups will have 35 business days to provide written input regarding their perspectives on the PFA. This input must be provided using our template and must not contain any confidential information (as all information included in the template will be considered disclosable).

Once we have drafted the PFA report, patient and clinician groups will be provided with an opportunity to review and provide comments during the open call for stakeholder feedback period (5 business days).

All stakeholder input/feedback made by patient and clinician groups will be considered in the PFA process and be posted on our website for transparency.

13.5 Development of Panel Algorithms

We will convene clinical panels to advise on panel algorithms. The panellists will be comprised of clinical specialists with expertise in the diagnosis and management of the condition for which the PFA is required. The clinicians may be identified by CAPCA (e.g., clinical leads affiliated with provincial cancer agencies) or through other sources, and will join a panel chair. A representative for PAG may attend the panel to provide any jurisdictional perspective for the meeting. All panellists will be required to comply with our Conflict-of-Interest Policy.

Panellists will be provided with details regarding the PFA, including the deliberative framework, the existing PFA, and the proposed place in therapy for the drug(s) reviewed through the reimbursement review process. In addition, all input from stakeholders will be reviewed.

Deliberations will be focused on addressing specific policy questions raised by the jurisdictions. This will typically be related to understanding the implications of one or more new therapies on the existing sequence of treatments that are funded by the jurisdictions. The following items will be considered by the expert panellists when advising the jurisdictions on the PFA:

- Unmet therapeutic need for patients (particularly those in understudied populations)
- Evidence supporting a particular sequence of therapies (if available)
- Clinical experience and opinion that support a particular sequence of therapies

- Clinical practice guidelines
- Variability across jurisdictions regarding the reimbursement status of existing treatment options
- Affordability and sustainability of the health care system
- Implementation considerations at the jurisdictional level.

Clinical and economic evidence to inform an optimal treatment sequence is typically limited; therefore, the clinical experience and knowledge of specialists will often form the basis of the advice offered by panel. The rationale for the panel's proposed PFA will be documented. Stakeholders will be consulted and provided with an opportunity to comment on the proposed PFA before it is finalized.

In the final PFA report, the details related to the deliberative framework (e.g., discussion guide questions), the source(s) of evidence, any potential limitations and the panel's guidance will be published for transparency. A discussion of whether the panel advice was supported by PAG for implementation will be included in the PFA report.

The final report will provide both a pictorial and descriptive representation of the algorithm.

13.6 Development of Rapid Algorithms

We, in consultation with PAG and starting from the materials submitted by a sponsor, will draft a PFA using the following sources of information:

- Prior pERC recommendations on all drugs that are to be considered in the PFA
- Prior implementation advice and PFAs in the same therapeutic area
- Drug reimbursement criteria implemented by jurisdictions at the pan-Canadian level following decisions made by consensus

Evidence not previously reviewed by an expert committee will not be considered in the development of rapid algorithms.

In situations when new evidence may be available after we have completed a review, sponsors and/or tumour groups are encouraged to prepare an application (e.g. re-submission) for review of drug(s) through the drug reimbursement process.

The final report will provide both a pictorial and descriptive representation of the algorithm.

13.7 Provisional Funding Algorithm Reports

a) Scoping Document and Call for Input

We will notify all stakeholders via weekly summary newsletters that a panel or rapid algorithm is being initiated to discuss the sequencing of treatments for a particular indication. We will post a document detailing the scope and will communicate that the call for stakeholder input is open. All stakeholders will have 35 business days to provide written input regarding their perspectives on a treatment algorithm. No requests for extensions will be granted. This input must be provided using our template and must not contain any confidential information (all information included in the template will be considered disclosable).

All stakeholders who have provided stakeholder input will be acknowledged in the final PFA report. In addition, the stakeholder input will be published for transparency.

b) Draft Provisional Algorithm Report

We will post the draft PFA report for stakeholder feedback. The call for feedback will be open for 5 business days. No requests for extensions will be granted. Comments must be provided using our template and must not contain any confidential information (all information included will be considered disclosable). For a panel algorithm, we will review and discuss the stakeholder feedback with the chair of the implementation advice panel, who will determine if there is a need for additional discussion(s). For both panel and rapid algorithms, stakeholder feedback will be reviewed and discussed during monthly PAG meetings and draft reports will be finalized accordingly.

All stakeholders who have provided stakeholder feedback will be acknowledged in the final algorithm report. In addition, the stakeholder feedback will be published for transparency.

c) Final Provisional Algorithm Report

The final report from this process will be posted on the website. In the final PFA report of a panel algorithm, the details related to the deliberative framework (e.g., discussion guide questions), the source(s) of evidence, any potential limitations and the panel's guidance will be published for transparency. A discussion of whether the panel advice was supported by PAG for implementation will be included in the PFA report.

For both panel or rapid algorithm, the final report will provide both a pictorial and descriptive representation of the algorithm.

There will be no confidential information included in the PFA report; as such, sponsors and other stakeholders will not have the opportunity to request any redactions.

13.8 Comments on Provisional Funding Algorithms

Occasionally, stakeholders may want to reach out to provide comments related to PFAs outside the open call period for input or feedback. These comments can be sent to requests@cadth.ca with the following information:

- Therapeutic Area and Publication Date
- Project Number
- Specific Comments

If deemed relevant, these comments will be reviewed at upcoming PAG monthly meetings.