Reimbursement Review

Provisional Funding Algorithm: Proposed Scope

Indication: HR-positive, HER2-negative breast cancer

Background

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 a drug under reimbursement review relative to the alternative treatments that are currently reimbursed by the public drug programs. This document outlines a draft scope for a PFA should the drug under review result in a reimburse recommendation. The development of a PFA initiates before a reimbursement recommendation is finalized to provide public drug plans with more timely evidence to inform their decision-making and to allow for more meaningful engagement. Two types of provisional funding algorithms are available:

Rapid provisional funding algorithm

 A rapid algorithm is undertaken when an expert committee (e.g., pan-Canadian Oncology Drug Review Expert Review Committee [pERC] or Formulary Management Expert Committee [FMEC]) recommendation can be directly incorporated into an existing PFA without supplemental advice from clinical specialists. The rapid algorithm process will typically be initiated in situations in which 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).

Panel provisional funding algorithm

 A panel algorithm is undertaken when the advice of clinical specialists is required to establish a new PFA or to adapt an existing PFA. Panel algorithms will typically be initiated when 1 or more drug(s) may be impacted by the implementation of a new drug (e.g., shifting existing drugs to different lines of therapy).

At the request of the drug programs that participate in the Canada's Drug Agency (CDA-AMC) drug reimbursement review processes, we are initiating a rapid provisional funding algorithm per the <u>provisional funding algorithm procedures</u>.

Objective

To provide advice on the place in therapy of drugs for the treatment of HR-positive, HER2-negative breast cancer. The drug(s) currently under review that triggered a possible new or updated PFA can be found in Table 1 (note that the list is not exhaustive).

Table 1: List of Drugs Under Consideration and Related CDA-AMC Recommendations

Generic name	Expert committee meeting date		
(brand name)	Manufacturer	(project number)	CDA-AMC recommendation

Ribociclib (Kisqali)	Novartis Pharmaceuticals Canada Inc.	June 11, 2025 (<u>PC0395-000)</u>	To be determined based on upcoming expert committee decision
Pertuzumab	N/A	July 17, 2025 (<u>PX0379-000)</u>	To be determined based on upcoming expert committee decision

CDA-AMC = Canada's Drug Agency.

Past reimbursement recommendations of impacted drugs which may be impacted can be found within the latest version of the PFA for this therapeutic area: <u>HR-positive-HER2-negative-breast-cancer (December 2024)</u>

Refer to <u>Provisional Funding Algorithms</u> for current and previous relevant reports. For this project, CDA-AMC will be updating previously completed related work.

If a panel PFA is initiated, the implementation advice panel will comprise clinical specialists with expertise in the diagnosis and management of patients with non-small cell lung cancer without actionable oncogenic alterations in Canada. The objective of the panel will be to provide advice to the participating drug programs regarding the funding algorithm and any related implementation questions identified by public drug programs or through input received during the open call on the proposed scope. In addition to the clinical panellists and CDA-AMC staff, representatives from public drug programs, the pan-Canadian Pharmaceutical Alliance, and the Canadian Association of Provincial Cancer Agencies (CAPCA) may participate in the discussion and provide input in advance of the meeting on the topics for discussion. For more information on the implementation advice process, please refer to provisional funding algorithm procedures.

Consultation Process and Input and Feedback Opportunities

Eligible patient, clinician, and industry groups are invited to provide input on the proposed scope for a PFA. Input is sought before the project is initiated to help shape the direction and/or the scope of the funding algorithm, whereas feedback is collected when the funding algorithm is near completion for revision.

Interested parties are invited to provide comments and/or complementary information, including published evidence on treatment sequencing, if available, in support of algorithm development. Note that for panel PFAs, clinician panellists will be primarily identified by CAPCA. Interested parties may suggest clinicians with relevant expertise and knowledge practising in Canada to be the panellists if a panel PFA is requested. These details will be forwarded to CAPCA for consideration and will be redacted before posting publicly. All input will be considered in the finalization of the PFA.

As described in <u>Procedures for Reimbursement Reviews</u>, the proposed scope document is posted for input for 35 business days. Following the expert committee recommendation for the drug that triggered the PFA process, a draft provisional funding algorithm report will be posted for feedback for 7 business days. The final provisional funding algorithm report will be posted on the CDA-AMC website.

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