



## RESUBMISSIONS AND APPEALS POLICY

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### New Drug Funding Program and Evidence-Building Program

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Policy Owner: Provincial Drug Reimbursement Programs

## A. OVERVIEW

There are two options available to an Applicant who has received a negative funding decision from the New Drug Funding Program or Evidence Building Program with respect to: (a) an Enrolment Request; or (b) a Treatment Claim:

- I. **Resubmission:** The Applicant may request a Resubmission if he/she has new pertinent medical documentation that he/she believes may change the decision.
- II. **Appeal:** The Applicant may appeal a negative funding decision if he/she believes that the applicable Drug Funding Policy was wrongfully applied but he/she does not have new pertinent medical documentation that may change the decision.

## B. PURPOSE

The purpose of the *New Drug Funding Program/Evidence Building Program (NDFP/EBP) Resubmission and Appeals Policy (Policy)* is to:

- I. ensure that the programs clearly define the application criteria for a Resubmission or Appeal; and
- II. outline the adjudication process for an eligible Resubmission or Appeal.

## C. DEFINITIONS

For the purposes of this Policy, the following terms are defined as:

**Appeal:** An Enrolment Request or Treatment Claim has been denied funding and the Applicant requests a review of the decision because he/she believes the applicable Drug Funding Policy was wrongfully applied.

**Applicant:** The Applicant is the patient's most responsible physician who is licensed to practice in Ontario (i.e., holds a valid license from the College of Physicians and Surgeons of Ontario). A staff member (e.g., a pharmacist, pharmacy technician, or claims administrator) from the pharmacy at the patient's treating hospital or cancer centre may be designated by the patient's most responsible physician for the purposes of submitting a Resubmission or Appeal on the Applicant's behalf.

**Clinical Expert Reviewer:** A physician specialist in an area relevant to the Enrolment Request or Treatment Claim (e.g., medical oncologist or hematologist with expertise in the relevant disease site) who is asked to review the Enrolment Request or Treatment Claim, Resubmission, and/or Appeal. The Clinical Expert Reviewer is asked to provide an opinion on the evidence or the clinical aspects of a case (e.g., diagnosis, disease progression, standard of care). The Clinical Expert Reviewer may also be asked to provide an opinion on whether the Enrolment Request or Treatment Claim, Resubmission, and/or Appeal meets the eligibility criteria of the applicable Drug Funding Policy based on the information provided by the Applicant.

**Drug Funding Policy:** Eligibility criteria listed for a specific cancer drug or combination of cancer drugs for a given indication (i.e., reason for use). The criteria of each Drug Funding Policy is approved by the Executive Officer of the Ministry of Health and Long-Term Care's Ontario Public Drug Programs.

**eClaims:** A web-based adjudication system used by Cancer Care Ontario to review and adjudicate enrolment requests and treatment claims submitted by hospitals and cancer centres.

**Enrolment:** An enrolment form specifies the eligibility criteria for reimbursement of cancer drugs and drug combinations for indications covered under the NDFP/EBP. Completed enrolment forms and supporting clinical documents (when required) must be submitted to NDFP/EBP via eClaims before treatments begin. In this Policy, a submitted enrolment form is referred to as an “**Enrolment Request**”.

**Evidence-Building Program (EBP):** A publicly funded drug program under the Ministry of Health and Long-Term Care’s Ontario Public Drug Programs that seeks to resolve uncertainty around clinical and cost-effectiveness data when drugs have evolving, but incomplete evidence of benefit. The EBP complements and strengthens the NDFP and the process for making drug funding decisions related to the expansion of cancer drug coverage within Ontario.

**Funding decision:** The decision as to whether an Enrolment or Treatment Claim met the criteria of the applicable Drug Funding Policy.

**New Drug Funding Program (NDFP):** A publicly funded drug program under the Ministry of Health and Long-Term Care’s Ontario Public Drug Programs that directly covers the cost of many newer, and often very expensive, injectable cancer drugs administered in hospitals and cancer centres.

**Patient:** A resident of Ontario with a valid Ontario Health Insurance Plan (OHIP) card.

**Resubmission:** An Enrolment or Treatment Claim has been denied funding and the Applicant requests a review of the decision because he/she has new pertinent medical documentation that the Applicant believes may change the decision.

**Treatment Claims:** Treatment Claims are submitted to the NDFP/EBP for a patient once the applicable Enrolment Request for such patient has been submitted to the NDFP/EBP. Treatment Claims specify the treatment date, treatment location, drug, and dose administered to the patient. Treatment Claims and supporting documentation, if applicable, must be submitted to the NDFP/EBP via eClaims according to the monthly submission schedule.

## **D. ELIGIBLE APPLICANTS**

In order to be eligible to request a Resubmission or Appeal on a negative funding decision by NDFP/EBP, the Applicant must be the patient's most responsible physician as indicated on the NDFP/EBP Enrolment Request form or Treatment Claim form. A pharmacy staff member who is an eClaims user at the treating hospital or cancer centre can be designated by the patient's most responsible physician to act on their behalf as a delegate. Patients cannot directly request a Resubmission or Appeal on a negative funding decision by NDFP/EBP.

## **E. FILING PROCESS**

- I. The Applicant must file a request for a Resubmission or Appeal electronically using the "Appeal" button on the Enrolment Request or Treatment Claim in eClaims.
- II. The Applicant must identify whether the request is for a Resubmission or Appeal.
- III. Upon receipt, NDFP/EBP will screen the request against the Application Criteria (**see Sections F and G**).

Applicants and/or delegates will not be allowed to have direct contact with the Clinical Expert Reviewer(s) involved.

## **F. RESUBMISSION**

### **Resubmission Application Criteria**

- I. The Applicant may request to resubmit an Enrolment Request or Treatment Claim with a negative funding decision rendered by the NDFP/EBP if he/she has new pertinent medical documentation that he/she believes may change the decision.
- II. The Applicant must submit the request for a Resubmission, together with the new pertinent medical documentation, to the NDFP/EBP within 30 days of notification of the negative funding decision by the NDFP/EBP. After 30 days, the patient's clinical circumstance may have changed. A new request and/or updated clinical information may be required.
- III. In the request for Resubmission, the Applicant must clearly describe how the new pertinent medical documentation should change the decision with reference to the applicable Drug Funding Policy criteria that the Enrolment Request or Treatment Claim originally failed to satisfy.

### **Assessment Process**

- I. The NDFP/EBP will review the Enrolment Request or Treatment Claim with the new pertinent medical documentation to determine if it meets the Resubmission Application Criteria. If it fails to meet such criteria, no further review will take place and the NDFP/EBP will inform the Applicant, in writing via eClaims. If it meets such criteria, NDFP/EBP will proceed to the next step.

- II. The NDFP/EBP will review the Enrolment Request or Treatment Claim with the new pertinent medical documentation against the applicable Drug Funding Policy.
- III. If there is clinical uncertainty as to whether the Resubmission meets the eligibility criteria of the applicable Drug Funding Policy, the NDFP/EBP program may forward the application to Clinical Expert Reviewer(s) for advice. For clarity, the NDFP/EBP program is not bound by the advice given by Clinical Expert Reviewer(s) and will make a funding decision based on the totality of information.
- IV. The NDFP/EBP will make a decision to approve or reject funding based on new medical documentation.
- V. The NDFP/EBP will inform the Applicant, in writing via eClaims, of the funding decision. If the initial negative funding decision is maintained, the NDFP/EBP will provide the rationale for rejection and provide standard options to the Applicant as follows: (a) if the Applicant has additional new pertinent medical documentation, he/she may make another Resubmission within 30 days of notification of the negative funding decision by the NDFP/EBP; or (b) if the Applicant does not have additional new pertinent medical documentation, the NDFP/EBP will outline how to submit an Appeal.

## **G. APPEAL**

### **Appeal Application Criteria**

- I. The Applicant may appeal a negative funding decision rendered by NDFP/EBP if he/she believes that the applicable Drug Funding Policy was wrongfully applied to the applicable Enrolment Request or Treatment Claim but does not have new pertinent medical documentation that may change the decision.
- II. The Applicant must submit an Appeal within 30 days from notification of the negative funding decision. After 30 days, the patient's clinical circumstance may have changed. A new request and/or updated clinical information may be required.
- III. In the Appeal, the Applicant must clearly:
  - i. describe how the applicable Drug Funding Policy was incorrectly applied or interpreted with reference to the Drug Funding Policy criteria that the Enrolment Request or Treatment Claim failed to satisfy; and
  - ii. comprehensively refute the grounds for rejection.

### **Assessment Process**

- I. Upon receipt of an Appeal, the NDFP/EBP will review the justification to determine if it meets the Appeal Application Criteria. If it fails to meet such criteria, no further review will take place and the NDFP/EBP will inform the Applicant, in writing via eClaims. If it meets such criteria, NDFP/EBP will proceed to the next step.
- II. The NDFP/EBP will review the Enrolment Request or Treatment Claim, the Drug Funding Policy criteria, prior decisions and justification for Appeal. If required, the Reimbursement Analyst may escalate the appeal to the Pharmacist, Manager, and/or Director of the program for review.

- III. If there is clinical uncertainty as to whether the Appeal meets the eligibility criteria of the applicable Drug Funding Policy, the NDFP/EBP program may forward the application (including the rationale for the prior funding decision(s) and the justification for the Appeal) to Clinical Expert Reviewer(s) for advice. For clarity, the NDFP/EBP program is not bound by the advice given by Clinical Expert Reviewer(s) and will make a funding decision based on the totality of information.
- IV. The assessment by NDFP/EBP will include:
  - i. a review of the request and previous decision(s) against the applicable Drug Funding Policy;
  - ii. a determination of whether the grounds for Appeal are substantiated, given the applicable Drug Funding Policy criteria; and
  - iii. a review of the Clinical Expert Reviewer(s)' opinions (when sought).
- V. The NDFP/EBP will make a decision to approve or reject funding.
- VI. The NDFP/EBP will inform the Applicant, in writing via eClaims, of the final funding decision. If the initial negative funding decision is upheld, the NDFP/EBP will inform the Applicant, in writing in eClaims, of the rationale for rejection. The rationale will include a summary of the appeal assessment process that occurred for the Appeal.
- VII. No further Appeals will be eligible.

#### **H. TIMELINES FOR FUNDING DECISION**

- I. The NDFP/EBP will aim to assess a Resubmission or Appeal as quickly as possible. Due to the complexity of these cases and the possibility of a clinical external review, an assessment may take up to two weeks to complete. An incomplete Resubmission request or Appeal may result in longer turnaround times. The decision to treat a patient before a final funding decision is made is the responsibility of the hospital or cancer centre and clinicians involved in the treatment of the patient. The hospital or cancer centre assumes the cost of any unfunded treatments.