Ontario Health

High Cost Therapy Funding Program (HCTFP)

Program Policy

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Ontario Health

Acronyms

CADTH	Canadian Agency for Drugs and Technologies in Health
HCTFP	High Cost Therapy Funding Program
pCODR	pan-Canadian Oncology Drug Review
pCPA	pan-Canadian Pharmaceutical Alliance

Definitions

Enrolment request: Refers to the initial request submitted by the Applicant for coverage of a High Cost Therapy Funding Program (HCTFP)-funded drug and indication. To enrol a patient, the applicant must complete the specific eligibility form.

Treatment claim: Refers to a claim submitted by the hospital that specifies the name of the drug product, treatment date, treatment location, and dose administered to the patient.

A. INTRODUCTION

The High Cost Therapy Funding Program (HCTFP) is administered by Ontario Health on behalf of the Ministry of Health. The HCTFP was established by Ontario Health in collaboration with the Ministry of Health to provide funding for cancer drugs that require specialized administration or delivery in a hospital setting.

The Provincial Drug Reimbursement Programs (PDRP) at Ontario Health administers the HCTFP on behalf of the Ministry of Health.

B. PURPOSE

The purpose of the HCTFP Program policy is to:

I. Outline the process to determine which drug products and indications (reason for use) are eligible for public funding in Ontario; and

II. Describe the application, adjudication, and reimbursement processes for HCTFP-funded drug products in Ontario.

C. SCOPE

I. The intent of the HCTFP is to provide Ontario patients with access to clinical and cost-effective drug products that are approved for funding by the Ministry of Health.

II. The HCTFP is intended to fund cancer drugs primarily administered in an inpatient hospital setting (e.g., ICU, inpatient oncology unit). Upon approval from the Ministry of Health, the HCTFP may also fund other specialized non-oncology therapies.

III. In cases where reimbursement is requested for continued treatment for a drug product previously funded through a clinical trial or paid for by other means (such as a third-party payer), the patient must meet all HCTFP funding criteria at the time treatment was initiated and during the course of the treatment.

IV. The program is not intended:
   a. to provide interim funding for new drug products or indications that are currently being reviewed or expected to be reviewed for public funding in Ontario; or
   b. to fund new drug products or new indications that are being investigated as part of a clinical trial; or
   c. to provide funding for special, exceptional, unique/rare, or compassionate requests that do not meet the intent of the established HCTFP funding criteria for a given therapy.

D. LISTING PROCESS

Ontario has a rigorous process for evaluating new drug products (e.g., cancer medicines) or new indications for existing drug products that are funded through the HCTFP. It includes an explicit consideration of the therapy's effectiveness, safety, and value for money. Throughout this process, Ontario considers advice from provincial and/or pan-Canadian clinician experts on the relevant drug product. Additionally, Ontario typically considers the outputs from the following organizations to

inform funding decisions and criteria:

Health Canada: Health Canada provides federal market authorization to sell drug products, including biological products, under the Food and Drugs Act. Health Canada will evaluate the safety, efficacy, and quality of a drug product for a given indication.

Canadian Agency for Drugs and Technologies in Health (CADTH): CADTH evaluates the clinical- and cost-effectiveness of new drug products and provides a reimbursement recommendation to provinces and territories.

Pan-Canadian Pharmaceutical Alliance (pCPA): The pCPA uses a pan-Canadian pricing negotiation process with pharmaceutical manufacturers to obtain consistent and lower drug costs (including biological products). Ontario is a participant in this process.

Ministry of Health: The Ministry of Health is responsible for authorizing funding for drug products and indications listed under the HCTFP. Ontario Health is subsequently responsible for administering the program, adjudicating individual patient applications, and reimbursing hospitals for the cost of the drug product and associated clinical care costs (as applicable).

E. APPROVED PRODUCTS AND INDICATIONS

I. The HCTFP will only fund drug products and indications that are approved by the Ministry of Health (see **section D** for Ontario's listing process).

II. Each approved drug product and indication has an eligibility form that specifies the funding criteria. Patients must meet the current funding criteria at the time of approval and over the course of the treatment.

F. PATIENT ELIGIBILITY

I. The HCTFP will consider applications for adult and pediatric patients living in Ontario who have a valid Ontario Health Insurance Number.

G. APPLYING FOR FUNDING

I. Patients cannot directly apply for funding. The Applicant must be:
   a. The patient's physician or surgeon who is prescribing and/or administering the drug product; and
   b. A physician who is licensed to practice either in Ontario (holds a valid license from the College of Physicians and Surgeons of Ontario) or other provinces/territories; and
   c. A specialist with the relevant therapeutic expertise (e.g., cancer drugs must be prescribed by a medical oncologist or hematologist).

II. The Applicant must complete a patient-specific application ("**enrolment request"**) and confirm that the patient meets all the funding criteria. The Applicant or their delegate can submit the enrolment request via the online adjudication system (**"eClaims"**). The enrolment request should be completed before the first dose is administered.

III. For drug products offered in a specialized setting (e.g., operating room, ICU), the treating facility has confirmed that they have the capacity to administer the requested drug product in a clinically appropriate timeframe.

H. ELIGIBLE ONTARIO HOSPITALS

I. Only hospitals that have established a funding agreement with Ontario Health can be reimbursed. For patients approved for a HCTFP funded drug product, hospitals will be

reimbursed according to specific conditions (see **section M**).

II. For drug products with specialized prescribing, ordering, and administration requirements (e.g., systemic chemotherapy, immunotherapy), hospitals are expected to adhere to recommended best practices, protocols, and standards for care delivery.

I. FUNDING EXCLUSIONS

Not all clinical circumstances and drug products are eligible for funding. For example, the HCTFP does not fund any of the following situations:

I. The requested drug product and indication are currently being reviewed or expected to be reviewed for funding in Ontario (e.g., under review by Health Canada or CADTH).

II. Pricing negotiations for the requested drug product and indication have yet to be finalized.

III. For the requested drug product and indication, provincial funding has not yet been implemented.

IV. The requested drug product and indication have previously been reviewed and rejected for public funding in Ontario.

V. Delivery of the drug product is inconsistent with the funding criteria and/or the Funding Agreement established between Ontario Health and the participating hospital.

VI. Special, exceptional, unique/rare, or compassionate requests that do not meet the intent of the established funding criteria for a given drug product. As evidence evolves, funding criteria and new indications are expected to be formally evaluated or re-evaluated through the regular listing process (see **section D**)**.**

J. ADJUDICATION PROCESS

The HCTFP will adjudicate each **enrolment request and treatment claim** to verify that the patient meets the funding criteria for the listed drug product and indication as follows:

I. Enrolment requests and/or treatment claims will be either adjudicated by eClaims ("**system adjudicated"**) or adjudicated by a Reimbursement Specialist ("**manually adjudicated**"):
   a. It is at the discretion of HCTFP whether an enrolment request or a treatment claim is manually or system adjudicated. Factors considered include the complexity of the patient's case, level of uncertainty in meeting eligibility criteria, and need for supporting clinical documents.
   b. For enrolment requests or treatment claims that are system adjudicated, hospitals must ensure that they retain the appropriate supporting clinical documents. These documents may be requested by Ontario Health for audit purposes or if Ontario Health is made aware of clinical circumstances which may affect a patient's continued eligibility for funding.

II. The HCTFP will notify the Applicant (or designate) via eClaims if more information is needed to adjudicate the case (e.g., copies of pathology reports, imaging results, bone marrow studies, genetic testing results).

III. Where there is uncertainty based on clinical grounds (e.g., diagnostic uncertainty, issues regarding patient's performance status) that the patient meets all the funding criteria, the HCTFP will consult external clinical experts. For clarity, the HCTFP is not bound by the advice given by clinical expert reviewers and will make a funding decision based on the totality of the information gathered.

IV. The HCTFP will notify the Applicant (or their delegate) in writing, via eClaims, whether an enrolment or treatment claim has been approved or denied.

V. It is the Applicant's responsibility to ensure the patient meets the funding criteria at the time of enrolment and throughout the course of the treatment. In cases of uncertainty, the Applicant can submit a **prior approval** request (see **section K**).

K. PRIOR APPROVAL REQUESTS

I. Where there is uncertainty in the patient meeting the funding criteria, the Applicant can seek prior authorization or "**prior approval**" for funding. Examples of where a prior approval is appropriate include:
   a. When there is uncertainty in whether the patient meets the criteria for a given therapy and indication (reason for use)
   b. If the Applicant wishes to request modifications to the funded dose, frequency, route of administration, or duration for the given therapy
   c. When holding or substituting one of the drugs in the regimen (for drugs funded as part of a multi-drug regimen)

II. The Applicant (or their delegate) should submit a prior approval request in eClaims at the following times:
   a. For patients who have not initiated therapy, submit a prior approval request at the enrolment level.
   b. For patients currently on therapy and the Applicant needs to modify the treatment regimen (e.g., dose, frequency, duration, route of administration), submit a prior approval at the treatment level.

III. In the prior approval request, the Applicant (or their delegate) should:
   a. Clearly explain for which funding criterion there is uncertainty.
   b. Provide a robust and detailed clinical justification for the use of the requested therapy.
   c. Submit recent documentation (e.g., clinic notes, imaging, pathology reports, bone marrow studies) relevant to the prior approval request.

d. Describe the patient's treatment history, and response to prior therapies (e.g., if the clinic note says the patient is progressing, include the relevant imaging or bone marrow studies).

IV. Upon receipt of a complete prior approval request, the HCTFP will assess whether the patient meets the intent of the funding criteria.

V. External clinical experts will be consulted where there is uncertainty based on clinical grounds (e.g., diagnostic uncertainty, issues regarding patient's performance status) to verify that the patient meets all of the funding criteria. For clarity, the HCTFP is not bound by the advice given by clinical expert reviewers and will make a funding decision based on the totality of the information gathered.

VI. The HCTFP will notify the Applicant (or their delegate) in writing, via eClaims, whether an enrolment or treatment claim has been approved or denied.

L. TIMELINES FOR REVIEW

For enrolment and treatments that require prior approval, HCTFP aims to provide a decision within **five business days** after receiving a complete application. If additional information and/or clinical expert review is required, the review process may take longer.

M. REIMBURSEMENT CONDITIONS

I. To be reimbursed:
   a. Hospitals must be registered on eClaims.
   b. Hospitals must submit treatment claims and any supporting clinical documents (if required) via eClaims in accordance with the PDRP claims submissions schedule.

II. For approved treatment claims, HCTFP will cover drug product costs and clinical care costs (if applicable) as per the Provincial Drug Reimbursement Programs Agreement between Ontario Health and participating hospital.

III. As applicable the HCTFP will reimburse hospitals for the cost of the drug administered at a rate equal to the best available price in Ontario (if applicable).

IV. HCTFP will not pay for:
   a. Doses administered to patients who do not continue to meet the funding criteria for the requested therapy.
   b. Doses administered in a private infusion clinic.
   c. Doses dispensed from a community or retail pharmacy.

N. OPTIONS FOR A DENIED REQUEST

I. Where an enrolment request or treatment claim is denied, the Applicant has the following options:
   a. Resubmit the application with additional information (e.g., published literature, new pertinent clinical documentation) that is responsive to the rationale for rejection (**resubmission**), or
   b. Appeal the funding decision where there is no new additional evidence, but the Applicant believes the funding criteria for a given enrolment/treatment claim has been improperly applied or interpreted (**appeal**).

II. For an enrolment request, the Applicant has 30 days from the date of the HCTFP decision to file an appeal or resubmission. After this date, a new enrolment request and/or updated clinical information may be required.

III. For treatment claims, appeals submitted in the post-discrepancy period will not be permitted (See the PDRP eClaims Submission Policy for further details).

IV. A **resubmission** will be assessed according to the usual adjudication process for prior approvals (see **section K**).

V. For an **appeal**, the HCTFP will:
   a. Reassess the enrolment request and/or treatment claim against the funding criteria considering the Applicant's justification for the appeal, clinical evidence, and prior decisions.
   b. External clinical experts will be consulted where there is uncertainty based on clinical grounds (e.g., diagnostic uncertainty, issues regarding patient's performance status) to verify that the patient meets all of the funding criteria. For clarity, the HCTFP is not bound by the advice given by clinical expert reviewers and will make a funding decision based on the totality of the information gathered.

VI. The HCTFP will decide to uphold or overturn the initial funding decision.
   a. The HCTFP will inform the Applicant (or their delegate), in writing, via eClaims, of the decision on the appeal.
   b. If the initial negative funding decision is upheld, the HCTFP will inform the Applicant (or their delegate), in writing in eClaims, of the rationale for rejection.

VII. Once a decision on an appeal has been issued, subsequent appeals are not permitted.