



PET Access Program Policy

Version 2.0.

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A. Purpose

The purpose of the Positron Emission Tomography (PET) Access Program Policy is to:

- I. Describe the requirements for a PET scan to be funded by the PET Access Program.
- II. Outline the application and review process.

B. Scope

The PET Access program's intent is to provide access to PET scans that do not meet eligibility for indications funded under other programs as outlined below. Individual patient requests are assessed on a case-by-case basis.

The PET Access Program considers funding requests that are:

- I. For PET scans that are not currently funded through insured services, other public programs (e.g., PET registry) or via clinical trials (<u>here</u>); and
- II. For PET scans with radiopharmaceuticals that are available in Canada.

The PET Access Program is not intended to:

- I. Fund PET scans that are provided as part of a clinical trial; or
- II. Fund PET scans that are required to determine patient suitability for a therapy (e.g., drugs, radionuclide therapy, etc.) that is not publicly funded and/or has not received regulatory approval in Canada.

C. Eligible Patients

The PET Access Program will consider applications for:

I. Adults and pediatric patients who have a valid Ontario Health Insurance Number.

D. Eligible Applicants

The PET Access Program applicant must be:

- I. A physician who is treating the patient's disease or is requesting a PET scan on behalf of and with the support of the intended treating physician; and
- II. A physician who is licensed to practice:
- a) In Ontario (holds a valid license from the College of Physicians and Surgeons of Ontario); or
- b) In other jurisdictions within Canada.



E. Applicant's Responsibilities

- I. Before applying to the Ontario PET Access Program:
- a) You must have the patient's expressed consent.
- b) Review the PET Access policy for eligibility.
- c) Review the <u>PET Scans Ontario website</u> to ensure the patient is not eligible for any currently funded indications.
- d) Submit a complete <u>Ontario PET Access Program request form</u> with the required clinical documentation and any supporting published literature (if available). Application for funding **should** be completed prior to scanning the patient, please see *Evaluation of Funding Criteria* in **Section G** for exceptions.
- II. Be the liaison between the PET Access Program and the patient. The program does not have the authority to provide information regarding requests to the patient (e.g., status, funding decision). All correspondence regarding the request will be through the applicant.

F. Funding Criteria

The request will be evaluated against the following funding criteria to determine if it aligns with the program's intent.

I. General

- a) The indication requested for a PET scan is not currently publicly funded through insured services, or other public programs (e.g., PET registry) (see the <u>PET Scans Ontario website</u> for the current list of funded indications).
- b) The requested PET imaging product (e.g., FDG) must be available in Canada.
- c) The PET scan must be intended for active clinical management. Funding requests for diagnostic purposes and/or routine surveillance when there is no clinical, biochemical, or conventional imaging suspicion of disease are not eligible.
- d) If the PET scan is solely to determine patient suitability for a therapy (e.g., drugs, radionuclide therapy, etc.), the therapy must be publicly funded and/or has received regulatory approval in Canada. For adult patients, if a PET is a requirement of a clinical trial, it is expected that the costs will be covered by the clinical trial sponsors.

Note: Funding criteria **I., d)** is not applicable to pediatric patients, as most treatments are provided through clinical trials.

II. Evidence

a) Based on the best available evidence, there is sufficient evidence that supports the use of a PET scan, over conventional imaging, for the requested indication/ clinical circumstances.

III. Diagnostic Alternatives

- a) There is demonstration of improved test performance (i.e., greater sensitivity and specificity) over standard diagnostic work-up;
- b) Identification of disease beyond the extent defined by conventional imaging;



- c) There is rationale that deems the test is safer than standard diagnostic work-up; or
- d) There are inconclusive results from standard diagnostic tests.

IV. **Clinical Impact**

- a) The PET scan results are expected to contribute to clinical management decision-making.
- b) The patient may avoid unnecessary invasive interventions (e.g., exploratory surgery) or treatment due to the use of a PET scan.

G. Review Process

The review process for new requests is comprised of the following components:

- 1. Screening for completeness: The PET Access Program will screen each request for completeness. The PET Access Program will contact the applicant when the application is deemed incomplete if any of the following are unclear or missing:
- a) Mandatory questions on the request form
- b) Required clinical documents

Requests that are incomplete will not be assessed further for funding until the applicant provides the requested information. Incomplete applications will be "closed" after 60 days from the last communication received by the applicant. If an applicant responds after 60 days, the applicant must submit a new request with updated supporting documentation.

- II. **Evaluation of Application Criteria**: Upon receipt of a complete application, the PET Access Program will assess the request against Sections C-E of this policy. Requests that do not meet any one of the requirements will be deemed ineligible for funding and will not be assessed further. The applicant will be notified.
- III. Evaluation of Funding Criteria: All requests that satisfy Sections C-E of this policy will be sent for external review by a panel of clinical experts to assess eligibility based on the Funding Criteria (Section F):
- a) Prior to sending the request for expert review, the PET Access Program will remove all patient and physician/institution identifiers to support an unbiased adjudication process.
- b) The request will be sent to an expert review panel. Each review panel must consist of three members, representing experts in PET imaging and in treatment. If necessary, the expert review panel may request Ontario Health (Cancer Care Ontario) to engage reviewers with disease specific expertise.
- c) The panel performs their review consultatively, in correspondence with one-another to support interdisciplinary discussion.
- d) The primary review panel will assess the request against the Funding Criteria (Section F) and provide a recommendation to the PET Access Program. In the evaluation, the panel will consider the clinical information and justification for a PET scan submitted by the applicant, best available evidence, and expert opinion.

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e) If the primary panel cannot provide a recommendation, the request will automatically be sent to the secondary review panel for consideration. The secondary review panel is comprised of 3 clinical experts who have not previously reviewed the request.

Note: An application to the PET Access Program **should** be submitted prior to the PET scan being performed. We will consider post-scan evaluation for scans already performed when the applicant, in consultation with the PET Centre's Nuclear Medicine physician and other relevant healthcare providers from various disciplines (e.g., Multidisciplinary Cancer Conference), deems the PET scan is **urgently** required (e.g., in-patient) and all supporting documentation is provided.

IV. Funding Decision:

For each request, the PET Access Program will make the final decision to approve or deny a request for funding. The PET Access Program will notify the applicant, in writing, of the funding decision.

For a positive funding decision, each of the following must be met:

- a) The request satisfies Sections C-E of this policy.
- b) Upon evaluation against the *Funding Criteria* (Section F), the request meets the intent of the policy.
- c) The majority of clinical experts on the review panel support the use of the PET scan for the requested indication in this patient.
- V. For approved requests, the PET Access Program will notify the preferred PET Centre by sending the unmasked application and approval letter. This automatically initiates the booking process for the PET scan.

H. Conditions of Payment

The PET Access Program will directly reimburse PET centres for approved requests as per the funding agreement between Ontario Health (Cancer Care Ontario) and the PET centre.

The PET scan must be performed within 6 months of approval for PET centres to be reimbursed. After 6 months, additional clinical information may be requested to confirm that the PET scan is still eligible for funding under this program.

I. Options in the Event of a Negative Funding Decision

If a request for a PET scan is not approved, the applicant can submit a request for resubmission, a reassessment, or an appeal. For information on the eligibility criteria, and filing and review processes, download the <u>PET Access Program Resubmission, Reassessment and Appeals Policy</u>.



J. Request for Repeat Scan

- I. Requests for repeat PET scans must satisfy all application and funding criteria to be approved for funding.
- II. Requests for repeat scans will be assessed as per the *Funding Criteria*, **Section F.** of this policy.
- III. If requests for repeat scans are denied, Applicants can submit a resubmission, appeal, or request a reassessment as per **Section I.** of this policy.

K. Post-Scan Data

PET Scans Ontario requires PET centres to submit data for approved PET scans as per the Funding Agreement between Ontario Health (Cancer Care Ontario) and the PET centre. Ontario Health (Cancer Care Ontario) will collect and assess this data for program planning and management purposes.

See the **<u>Privacy</u>** section on the website for information about our authority to collect personal health information for health system management and planning.

L. Timelines for Review

The PET Access Program aims to provide a funding decision within 5 business days of receiving the completed application with all supporting documentation. If additional information is required, the review process may take longer.

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, <u>info@ontariohealth.ca</u>. Document disponible en français en contactant <u>info@ontariohealth.ca</u>.

