

Bulletin



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4464	February 1, 2008	Ministry of Health and Long-Term Care Processing Sites
Distribution		(address below)
Physicians, Hospitals, Clinics and Laboratories		

Subject: Accessing Positron Emission Tomography (PET) Studies/Program Funded by the Ministry of Health and Long-Term Care, Ontario, Canada

This Bulletin is an update to Bulletin #4452 distributed July 12, 2007.

Positron emission tomography is a nuclear medicine diagnostic imaging procedure using positron emitting radiopharmaceuticals, often F18 fluorodeoxyglucose (FDG). Evidence supports a role for PET in the assessment of certain cancers and myocardial viability. The FDG produced by most Ontario PET centres is currently not approved by Health Canada for routine clinical use, but may be used for research purposes.

At present, PET scanning is not an insured health service in Ontario. The Ministry of Health and Long-Term Care (MOHLTC) has adopted an evidence-based approach to the introduction of PET imaging in the province. To ascertain the effectiveness of FDG-PET in the clinical management of patients, the MOHLTC is funding FDG-PET evaluative studies for specific indications.

This Bulletin provides a brief description of the ministry-funded PET studies/programs. Please read each section to determine which study or program may best meet the needs of your patient and **refer to the appropriate attachment for details and referral process**. Should you have any questions relating to the referral of patients to any of the ministry funded PET evaluation studies or the Ontario PET Access Program, please call, **1-877-4PET-411 (1-877-473-8411)**.

PET Clinical Trials (Attachment 1)

- Five PET clinical trials were funded by the MOHLTC. **Three** of these trials are still recruiting patients while two have completed patient accrual and are now closed.

Eligibility for the three active trials:

- Patients with locally advanced head and neck cancer
- Stage III non-small cell lung cancer
- Liver metastases from colorectal cancer being considered for surgical resection

Cancer PET Registry Study (Attachment 2)

- The Cancer PET Registry study covers six types of cancer.

Processing Sites			
Hamilton 119 King Street West, 10 th Floor P.O. Box 2280, Stn A L8P 4Y7	Kingston 1055 Princess Street, Suite 401 P.O. Box 9000 K7L 5A9	London 217 York Street, 5 th Floor Station A N6A 5P9	Mississauga 201 City Centre Drive Suite 300 L5B 2T4
Oshawa Executive Tower, Oshawa Centre 419 King Street West P.O. Box 635 L1J 7J2	Ottawa Fuller Building 75 Albert Street K1P 5Y9	Sudbury 199 Larch Street Suite 801 P3E 5R1	Toronto 47 Sheppard Avenue East Suite 505 M2N 7E7

Indications:

- o **New Indication Added** - Potentially resectable non-small cell lung cancer
- o A solitary pulmonary nodule which may be cancer and suitable for surgical resection
- o Suspected recurrent thyroid, colorectal, or germ cell cancer with elevated biomarker but negative MRI or CT findings

Cardiac PET Registry study (CADRE) (Attachment 3)

Indication:

- o Pre-revascularization myocardial viability assessment for patients with severe left ventricular dysfunction

Ontario PET Access Program (Attachment 4)

- A review process established by the MOHLTC to assess applications for PET scans for patients **not** eligible for the clinical trials or registry studies.

Physicians may make a referral to one of the active clinical trials, or a registry study that matches the patient's condition. Eligible patients can receive a PET scan at participating health sciences centres in Toronto, Hamilton, London, or Ottawa. There will be no charge to the patient.

Please Note: Before requesting a PET scan under the Ontario PET Access Program, it is advisable for physicians to first review the information on the clinical trials (Attachment 1) and registries (Attachment 2 & 3). If eligible, the patient should be offered enrolment to one of the clinical studies or registry studies. The Ontario PET Access Program should only be considered for patients who do **not** meet the criteria for any of the clinical trials or registry studies.

NEW – Northern Health Travel Grant Program

Effective October 1, 2007, patients residing in Northern Ontario who travel to Southern Ontario for a PET scan as a result of enrolment in the Ontario-funded PET evaluation/program are eligible for the Northern Health Travel Grant.

Patients wishing to apply for the Northern Health Travel Grant for a PET scan must:

- Have possession of a valid Ontario Health Card on the date of the scheduled PET scan and meet all other eligibility criteria;
- Be enrolled within one of the ministry-funded FDG-PET evaluation studies or registry that require travel from Northern Ontario to one of the ministry-funded PET imaging centres to receive a PET scan;
- Have a signed form letter from the coordinator of the PET study or PET registry at the enrolment hospital, verifying enrolment to a ministry-funded study.
- Complete the Northern Health Travel Grant application form and submit with it the above signed verification letter to one of the Ministry of Health & Long-Term Care offices listed on the application form.

To obtain additional details on the Northern Health Travel Grant program for PET and access a copy of the application form, please visit: <http://www.health.gov.on.ca/english/public/pub/ohip/northern.html>

NEW - Toll Free Ontario PET Information Line

Should referring physicians have any questions relating to the referral of patients to any of the ministry-funded PET evaluation studies or the Ontario PET Access program, please call the toll free Ontario PET Info Line:

1-877-4PET-411 (1-877-473-8411)

Attachment 1 - PET Clinical Trials

Three of the five Ontario ministry-funded clinical trials are still recruiting patients. These trials are summarized in Table 1.

Patient Referral Procedure: Physicians may refer patients to these clinical trials by contacting a principal investigator listed in Table 1 for the appropriate clinical trial.

Table 1: Summary of MOHLTC-Funded PET Clinical Trials

Clinical trial	Purpose	Eligible Cancer Types	Target Sample Size	Contacts for Principal Investigators
PET PREVENT	Prospective cohort study to determine the ability of FDG-PET to detect metastatic cancer in neck lymph nodes in patients with head and neck cancer and to determine whether the cancer has responded to treatment. All enrolled patients will receive a PET scan before & after treatment	Squamous cell carcinoma of the head and neck arising in either the oral cavity, larynx and pharynx (except non-nasopharyngeal cancer) with N ₂ or N ₃ lymph nodes being considered for neck dissection following primary curative radiation therapy.	400	Hamilton- Juravinski Cancer Centre: Dr. Ian Hodson (905) 387-9711 ext. 64702 London Regional Cancer Centre: Dr. Alex Hammond (519) 685-8650 Ottawa Regional Cancer Centre: Dr. Libni Eapen (613) 737-7700 ext. 70199 Toronto- Princess Margaret Hospital Dr. John Waldron (416) 946-6522
PET START	A prospective randomized controlled trial to determine (1) whether PET will help detect how far the lung cancer has spread beyond the chest after the patient has undergone all the usual standard diagnostic tests for lung cancer and (2) determine whether PET results will change how much of the chest will need radiation. Half of the enrolled patients will receive a PET scan.	Stage III non-small cell lung cancer suitable for combined modality therapy, radical radiation therapy, or trimodality therapy	400	Hamilton – Juravinski Cancer Centre Dr. Jim Wright (905) 387-9495 ext. 64417 London Regional Cancer Centre Dr. Edward Yu (519) 685-8500 ext. 53347 Ottawa Regional Cancer Centre Dr. Rob MacRae (613) 737-7700 ext. 70205 Toronto -Princess Margaret Hospital Dr. Alex Sun (416) 946-6522 Toronto – Odette Cancer Centre Cindy Foden (416) 480-5846
PET CAM	A prospective randomized controlled trial to determine the impact of pre-operative FDG-PET on patients who have been assessed as having resectable colorectal cancer liver metastases by conventional imaging, by determining the proportion of patients who have a change in management resulting from PET imaging. Half of the enrolled patients (randomised to the PET arm) will receive a PET scan.	Colorectal adenocarcinoma (excluding carcinoid, squamous cell cancer, gastrointestinal stromal tumour, or lymphoma) with resectable metastasis isolated to the liver.	400	Toronto: Princess Margaret Hospital Dr. Steven Gallinger (416) 586-8550 Toronto- Odette Cancer Centre Linda Last (416) 480-5000 ext. 3885 London: St. Joseph's Health Centre Dr. Richard Hart (416) 530-6841 Hamilton: St. Joseph's Healthcare & Hamilton Health Sciences Centre Dr. Ved Taqndan (905) 521-6148
PET PREDICT	Patient accrual completed	Study closed.		
ELPET	Patient accrual completed	Study closed; patients should be referred to the Cancer PET Registry. Please see Attachment 2.		

Please Note: Two trials have completed patient accrual and are now closed. The results of these trials are being analyzed, and will be reported to the Ontario PET Steering Committee shortly. In addition to the current clinical trials, the Ontario PET Steering Committee provides advice to MOHLTC regarding new indications and the need for additional trials based on ongoing international research.

Attachment 2 – Ontario Cancer PET Registry Study

Ontario Cancer PET Registry

The Cancer PET Registry study provides a PET scan and tracks the outcomes of patients who meet the eligibility criteria for specific indications. This registry study is coordinated by Hamilton Health Sciences and registry data is being maintained by the Institute for Clinical Evaluative Sciences.

NOTE: NEW INDICATION ADDED

A new indication has been added to the Ontario Cancer PET Registry. As of December 15, 2007 FDG-PET imaging will be funded for the evaluation of patients with potentially resectable non-small cell lung cancer (NSCLC), based upon conventional physical exam, blood work and imaging, and histological or cytologic proof of NSCLC. The addition of NSCLC to the Registry is an interim decision based on preliminary findings in the ELPET (Early Lung Cancer) Study. The final recommendation regarding funding for this indication will occur when the analysis of ELPET is complete and results reported.

With the above addition, the Ministry of Health and Long-Term Care will fund PET imaging through the Ontario PET Registry for the following indications:

- Solitary pulmonary nodule (SPN) for which a diagnosis has not been established by fine needle aspiration (FNA), is inaccessible to FNA or there is a contra-indication to the use of FNA to obtain cytology;
- Thyroid cancer where recurrent or persistent disease is suspected on the basis of an elevated and/or rising thyroglobulin but standard imaging studies are negative;
- Germ cell tumours where recurrent disease is suspected on the basis of elevated tumour markers (beta HCG and/ or alpha fetoprotein) and standard imaging tests are negative, or a mass persists after primary treatment and surgical resection is being considered; or
- Colorectal cancer where recurrent disease is suspected on the basis of elevated or rising carcinoembryonic antigen (CEA) during follow-up after surgical resection, but standard imaging studies are negative.
- Patients with potentially resectable non-small cell lung cancer (NSCLC)

Repeat PET Scans

- For solitary pulmonary Nodule
If the prior PET scan was negative but follow-up radiologic evidence shows progressive increase in the size of the SPN, a repeat PET scan may be performed at least 3 months after the previous PET scan.
- For Biomarker Positive and Anatomical Imaging Negative Tumours
If the prior PET scan of a patient with colorectal cancer or germ cell tumour was negative and repeat radiologic imaging remains negative, but the biomarkers continue to rise over a 3 month period, a repeat PET scan may be performed

Patient Referral Procedure: To refer patients to the Ontario Cancer PET Registry, physicians will need to complete the *Ontario Cancer PET Registry Physician Fax Back Form (following page)*. This will ensure that you are enrolled with the trial office at Hamilton Health Sciences for the Ontario Cancer PET Registry Study. Once your registration is received, you will be provided with a package explaining the registry process, along with the necessary consent forms. To contact the Ontario PET Registry Coordinating Centre at Hamilton Health Sciences, please call: **905- 521-2100 ext. 74445**.

Ontario Cancer PET Registry

PHYSICIAN FAX BACK FORM

Please fax this form to Ontario Cancer PET Registry - Angela Bonin at (905) 521-2356.

Physician's Name: _____
Office Address: _____

Postal Code: _____
Phone: _____ Ext. _____
Fax: _____ Email: _____

Please indicate below which patients you see in your practice who may require a PET scan. (Indicate all that apply)

- ☐ Solitary Pulmonary Nodule
- ☐ Recurrent Thyroid Cancer
- ☐ Recurrent Germ Cell Tumours
- ☐ Recurrent Colorectal Cancer
- ☐ Potentially Resectable Lung Cancer

Please indicate to which PET Centre you would normally refer your patients for a PET scan.

- | | | |
|-----------------|---|--------------------------|
| Hamilton | – McMaster University Medical Centre | ☐ |
| | – St. Joseph's Healthcare Hamilton | ☐ |
| Ottawa | – Ottawa Hospital, General Campus | ☐ |
| Toronto | – Princess Margaret Hospital | ☐ |
| | – Sunnybrook Hospital | ☐ |
| London | – St. Joseph's Healthcare London | ☐ |

By completing this form, your practice will be enrolled into the Ontario Cancer PET Registry and you will be informed of the protocol and information regarding access and consent procedures for your patients who may be eligible.

Thank you for your participation.

Dr. W.K (Bill) Evans
Chair, Provincial PET Steering Committee
Sr. Medical Officer, Ontario PET Registry

Attachment 3 – Ontario Cardiac PET Registry Study

MOHLTC is funding a province wide Cardiac FDG-ET Registry (CADRE). The objective of this study is to evaluate, in the clinical setting, the role of FDG-PET viability imaging in providing additional diagnostic information in patients with coronary artery disease and severe left ventricular dysfunction that are being considered for revascularization or a heart transplant. This registry will be conducted at 4 PET centres in Ontario: the University of Ottawa Heart Institute (Coordinating Centre), Hamilton Health Sciences Centre, London Health Sciences Centre and the University Health Network, Toronto.

The CADRE registry will facilitate FDG PET imaging in Ontario. Through this registry a PET scan will be provided to patients who meet all of the following criteria.

- Severe ischemic left ventricular dysfunction (Left ventricular ejection fraction < 35%), and
- Symptomatic (New York Heart Association or Canadian Cardiovascular Society Class II-IV) despite maximal medical therapy, and
- Suitable candidates for revascularization if there was viable myocardium OR who would be considered for heart transplantation if there is no viable myocardium, and
- For patients referred from centres without direct access to PET, have undergone myocardial viability assessment using other modalities (i.e. SPECT using Thallium or MIBI or dobutamine echocardiography) and the results of those tests are equivocal or negative in terms of the existence of viable myocardium.

Through data collection and telephone follow-up, the registry will characterize the patient population, referral patterns upstream, clinical outcomes, and downstream resource utilization of those eligible patients that participate in the study.

Patient Referral Procedure

To refer a patient to the CADRE Registry a referring physician will:

- **Complete** the patient registration form available online at <http://www.ottawaheart.ca/UOHI/doc/CADRE.pdf>
- **Append** to the registration form, all relevant reports of previous diagnostic imaging tests
- **Send** the completed registration form and all appended reports to the University of Ottawa Heart Institute Coordinating Centre by Fax (613)-761-4344 or via e-mail to cadre@ottawaheart.ca

Following receipt of the registration form by the Coordinating Centre:

- The CADRE coordinator will review the form and accompanying documentation to confirm that the patient meets eligibility criteria. Registration forms that meet the above criteria will be forwarded (within 24 hours of receipt) to the closest PET facility for booking. (In the rare circumstance that there is a question regarding eligibility, the case will be reviewed by the Principal Investigator, Dr. Rob Beanlands and one other participating CADRE investigator. Rare exceptions to the eligibility as outlined above may be considered on a case-by-case basis.)

- The Coordinating Centre will fax a letter to the referring physician to confirm whether the patient is eligible for CADRE, and if so, the location of the PET facility performing the scan.
- If eligible, the PET facility will contact the patient directly with the date, time, and location of the FDG-PET scan.
- Standard reports will be forwarded by the PET facility to referring physicians in a timely fashion following the PET scan procedure.

To refer your patient to CADRE, fax a completed registration form to 613-761-4344.

Registration forms are available online

<http://www.ottawaheart.ca/UOHI/doc/CADRE.pdf>

Contact the CADRE coordinator at 613-798-5555 ext 18817 or via email

cadre@ottawaheart.ca

Information and contacts visit our web link at

http://www.ottawaheart.ca/UOHI/doc/CADRE_intro.pdf

Attachment 4 – Ontario PET Access Program

If a patient is **not** a candidate for any of the clinical trials or registry studies, the patient might still be able to receive a funded PET scan in Ontario through the Ontario PET Access Program.

The Ontario PET Access Program is a review process established by the MOHLTC to assess requests for PET scans in cases where conventional diagnostic tests have not answered the clinical question (referring physicians will need to provide evidence of this within the application). Through the review process, applications for a funded PET scan are assessed on a case-by-case basis by an expert panel consisting of a radiologist, a nuclear medicine physician, and an oncologist. If on review it is determined that a PET scan would be appropriate, the PET Access Program Office located at Hamilton Health Sciences is notified and arrangements will be made for the patient's referral to an appropriate Ontario PET Centre.

Please Note: *Before requesting a PET scan under the Ontario PET Access Program, it is advisable for physicians to first review the information on the clinical trials (Section 1) and registries (Section 2). If eligible, the patient should be offered enrolment to one of the clinical studies or registry studies. The Ontario PET Access Program should only be considered for patients who do **not** meet the criteria for any of the clinical trials or the registry studies.*

Application Procedure for the Ontario PET Access Program

The procedure for requesting a PET scan under the Ontario PET Access Program is as follows:

- **Verify that the patient is not a candidate for any of the clinical trials or registry studies;**
- Complete the *Ontario PET Scan Access Program Request* and *Patient Consent Form* (see following pages). These application forms must be completed for a patient to be considered for a PET scan under the Ontario PET Access Program. The *Ontario PET Scan Access Program Request* must be signed by the referring physician and the patient must sign the *Patient Consent Form* so that his/her personal health information can be forwarded to the Ministry of Health and Long-Term Care and to Cancer Care Ontario for the purposes of the review process described above, and
- Include the following documents with the application (*the review cannot occur without these documents*):
 - Recent consult letters either to or from other physicians that describe the relevant medical circumstances of the patient or provide a brief written account of the patient's relevant medical history including the problem that PET is being asked to address, and
 - Recent diagnostic reports that are relevant to the application, and
 - Provide an opinion of what PET might demonstrate that cannot be proven by other means, and
 - Provide an opinion of what difference the information provided by PET may make to the management of the case,
- Fax the completed forms and all additional reports/documents in support of a PET scan to the Provider Services Branch at **(613) 536 -3184**.

Please note that failure to submit results of previous diagnostic tests may delay the review of the application.

If you have any questions about the Ontario PET Access Program, please call: 1-888-359-8807.

Ontario PET SCAN Access Program Request

Referring Physician's Name: _____

Referring Physician's Telephone: _____ **and Fax:** _____

Provider Number: _____

Patient Name: _____

OHIP Number - - -

Telephone: _____

Date of birth: ____/____/____ **Sex:** ☐ M ☐ F
 YYYY MM DD

Postal Code _____

Indications for the PET Scan:

Is your patient a candidate for one of the current PET clinical trials or registry study?

☐ Yes ☐ No If NO, you must attach reports and provide the dates :

☐ **Attach a copy of the reports from all relevant imaging studies**

Please note that failure to submit results of previous diagnostic tests may delay the review of the application.

List all relevant imaging studies

1. Date of:	____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MRI
2. Date of:	____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MRI
3. Date of:	____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MRI
4. Date of:	____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MRI
5. Date of:	____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MRI

Please fax this form, the patient consent form and any additional documents in support of a PET Scan to Provider Services Branch at (613) 536-3184.

Should you have any questions about this form or the program, please call 1-888-359-8807.

Ontario PET SCAN Access Program Request – Patient Consent

TO BE COMPLETED & SIGNED BY THE PATIENT or PARENT/GUARDIAN

Patient Consent

(To be completed and signed by the patient)

I, _____, consent to my physician disclosing personal health information to the Ministry of Health and Long-Term Care relevant to my medical condition that might qualify me for a diagnostic assessment using Positron Emission Tomography (PET). My medical information will be reviewed by an expert panel to determine whether I qualify for one of the current clinical studies or PET registry studies and if not, whether a PET scan would be potentially helpful in the management of my medical condition.

Signature of patient

Date

Patient Consent for minor child

(To be completed and signed by parent/legal guardian of patient)

I, _____, (name of parent/guardian) am the parent/ legal guardian of _____ (name of child). I consent to the above-named physician disclosing personal health information to the Ministry of Health and Long-Term Care relevant to the medical condition that might qualify my child for a diagnostic assessment using Positron Emission Tomography (PET). My child's medical information will be reviewed by an expert panel to determine whether he/she qualifies for one of the current clinical studies or PET registry studies and if not, whether a PET scan would be potentially helpful in the management of his/her medical condition.

Name of parent/guardian

Signature of parent/guardian or patient

Date