National Oncologic PET Registry
Evolution of Clinical PET

- PET well established as a research tool since its development in mid 1970s
- Research applications evolved into clinical applications
- Improvements in PET scanners made clinical studies practical
- However, acceptance into clinical practice occurred very slowly
Factors Facilitating US Growth of Clinical PET

- Gamma camera coincidence imaging
- Commercial distribution of FDG by regional cyclotron/production facilities
- Mobile PET services
- FDA Modernization Act of 1997 (FDAMA)
- Coverage decisions by Medicare and other carriers
- PET/CT
PET Reimbursement

- Complex, slowly evolving process
- Dependent on FDA approval of PET drugs
- Facilitated by FDAMA (1997)
- Reimbursable clinical indications
  - Determined by technology assessment panels of third-party payers
  - Process dominated by Centers for Medicare and Medicaid Services (CMS)
Medicare Coverage of PET

- Centers for Medicare and Medicaid Services (CMS)
  - Formerly Healthcare Financing Administration (HCFA)
- Standard for reimbursement is “reasonable and necessary”
- In 1990s, CMS adopted a new evidence-based approach for making coverage determinations
  - Requires peer-reviewed scientific evidence to document that new technology leads to changes in patient management and to improved health outcomes for Medicare beneficiaries
Medicare Coverage of PET

- CMS elected not to consider oncologic indications for PET broadly
- Rather evaluated the evidence on a cancer-specific and indication-specific basis
- Problematic because the specific evidence typically has not been very robust

“Catch 22”
Medicare Coverage of Oncologic PET

1998  Evaluation of solitary pulmonary nodules and initial staging of NSCLC

1999  Suspected recurrent colorectal cancer, lymphoma, melanoma (covered after public meeting, with considerable restrictions)

2001  Further expanded coverage for six prevalent cancers after new request for broad coverage and public meeting (PET must either resolve inconclusive results of standard test or replace standard test)
Medicare Coverage of Oncologic PET

2002 Individual requests submitted for several other cancers

2004 Proposed mechanism for expanded coverage
Medicare Reimbursement for Oncologic PET (2005)

- Diagnosis, staging, and restaging of:
  - Non-small cell lung cancer
  - Esophageal cancer
  - Colorectal cancer
  - Lymphoma
  - Malignant melanoma
  - Head and neck cancer

- Staging, restaging, and Rx monitoring of breast cancer
- Detection of TG+/RAI– thyroid cancer
- Staging of cervical cancer (– CT/MRI outside pelvis)
- **All other cancers/indications**
  - National registry
NOPR

- Is a CMS-approved
  - “Coverage with Evidence Development” Program
- Developed for the November 2004 expansion by CMS
  - All other cancers and indications except:
    - Breast cancer diagnosis and axillary staging
    - Melanoma regional nodal staging
- All Medicare-eligible PET facilities can participate (for a fee)
- Requires timely Pre-PET and Post-PET information
- All data will be submitted to CMS
- Cases with patient and physician consent will be used by the NOPR to assess change in intended management
Objectives & Goals

• Objectives
  – Assess the effect of PET on referring physicians’ plans of intended patient management
    • across a wide spectrum of cancer indications for PET that are currently not covered by the Medicare program, and
    • in relation to cancer-type, indication, performance status, physician’s role in management, and type of PET.

• Goal
  – Acquire data that can be used to evaluate PET in a manner that does not interfere with patient clinical care and minimizes the burden to the patient, PET center, and referring physician.
Prototype for NOPR Design

• “Clinical decisions associated with positron emission tomography in a prospective cohort of patients with suspected or known cancer at one United States center.”

• Referring physicians’ intended management plans assessed by questionnaires before and after PET

• Change in intended management occurred in:
  – 61% of patients overall
  – 79% of patients where original plan was more testing or biopsy
  – 32% of patients, from a non-treatment to a treatment strategy
Prototype for NOPR Design

- No Change: 39.1%
- Tests/Biopsy to Treat: 25.4%
- Treat to Watch: 10.9%
- Change Treatment Goal: 6.5%
- Tests/Biopsy to Watch: 2.8%
- Watch to Treat: 6.5%
- Watch to Test/Biopsy: 3.9%

Data Analysis and Expected Results

- Data analyzed by cancer type and indication (reason for PET).
- For the most frequent cancer indications, interim analysis will be performed at N=200 to refine sample size estimates.
- If the frequency of change in intended management for a particular cancer indication is sufficient to suggest benefit, data (along with summary of published literature) will be provided to CMS with request for coverage.
- Results also to be published in peer-reviewed literature.
- Eventual goal is to achieve broad coverage through analysis of data across all cancers and indications.
Another Expected Benefit

- Reimbursement for PET under NOPR overcomes “Catch 22”

- Now possible to develop more rigorous evidence concerning accuracy and utility of PET for previously non-covered cancers
Institutional Review Board (IRB) Approval and Subject Informed Consent

- Is this research? Yes, but only for the NOPR. Individual PET facilities and referring physicians are not engaged in research.

- Is IRB approval needed? Yes. ACR IRB has approved the NOPR. Individual PET facilities and referring physicians do not need to obtain IRB approval to participate.
  - All data will be sent to CMS. CMS is not engaged in research.
  - Patients and referring physicians will be given an IRB-approved information sheet and asked for consent to have their data included for NOPR research.
  - Only cases where both patient and physician give consent will be included in the NOPR research dataset.
Consent Procedure

• Patient
  – Patient Information Sheet provided to patient by PET facility
  – Patient gives oral consent

• Referring Physician
  – Physician Information Sheet included with Post-PET Form
  – Consent noted on that form
HIPAA Requirements

- HIPAA requirements met through execution of a Business Associates Agreement with the American College of Radiology as an agent for the Academy of Molecular Imaging and CMS.
- There are no additional HIPAA-related requirements for referring physicians.
How is the NOPR funded?

- Start-up funding provided by AMI.
- NOPR is expected to be self-sufficient by collection of registration fees from participating PET facilities
  - $50 per facility
  - $50 per patient
Participation Requirements - PET Facilities

- Any PET facility that is approved to bill CMS for either technical or global charges can participate in the NOPR.
- Facilities are not required to have or obtain ACR or ICANL accreditation.

Participation Requirements - Patients

- Medicare beneficiaries, including those with Medicare HMO coverage, who are referred for FDG-PET for essentially all oncologic indications that are not currently reimbursable under Medicare.
- **Oral consent** is necessary for inclusion in the NOPR research dataset; however, no consent is necessary to submit data to NOPR that **must** be sent to CMS.
PET Facility Responsibilities

- Collect and enter all required data via the NOPR Web site.
  - Patient must be registered within 14 days of PET scan date
  - Pre-PET Form must be entered by midnight of PET scan date
  - The PET Report & Post-PET forms must be entered within 30 days of scan

- PET facility is eligible to bill CMS when all required data are received at NOPR Operations Office.
Referring Physician Responsibilities

- Complete Pre-PET Form (5 questions) and return it to PET Facility prior to PET scan.
- Complete Post-PET Form (4 - 7 questions) and return it to PET Facility within 30 days of PET scan.
- Pre- and Post-PET forms can be returned to the PET facility via FAX, mail, or hand delivery.
- No Medicare payment to referring physicians for completing the Pre- and Post-PET Forms.
- Referring MD cooperation is essential to achieve success of this CED project!
## Ineligible Indications

Not Eligible for Entry into NOPR

<table>
<thead>
<tr>
<th>Indications</th>
<th>Diagnosis</th>
<th>Initial Staging</th>
<th>Treatment Monitoring</th>
<th>Restaging/Suspected Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nationally Covered Oncology Indications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cervical</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Esophagus</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Head &amp; Neck</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Lung, non-small cell</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Melanoma of skin</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Solitary Pulmonary Nodule</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Thyroid</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Nationally NON-Covered Oncology Indications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Melanoma</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

* = Does not cover initial staging for axillary lymph nodes for breast cancer patients and regional lymph nodes for melanoma patients.

** = Patient must have prior CT or MRI negative for extrapelvic metastatic disease

*** = Thyroid cancer must be of follicular cell origin and been previously treated by thyroidectomy and radiiodine ablation and have a serum thyroglobulin >10ng/ml and negative i-131 whole body scan.
<table>
<thead>
<tr>
<th>Indications</th>
<th>Diagnosis</th>
<th>Initial Staging</th>
<th>Treatment Monitoring</th>
<th>Restaging/Suspected Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lip, Oral Cavity, and Pharynx (140-149)</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
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<tr>
<td>Esophagus (150)</td>
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<td>Stomach (151)</td>
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<tr>
<td>Small Intestine (152)</td>
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<td></td>
</tr>
<tr>
<td>Colon (153) and Rectum (154)</td>
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<tr>
<td>Anus (154)</td>
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<td>✓¹</td>
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</tr>
<tr>
<td>Liver and intrahepatic bile ducts (155)</td>
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<td>✓</td>
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<tr>
<td>Gallbladder &amp; extrahepatic bile ducts (156)</td>
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<td>Pancreas (157)</td>
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<tr>
<td>Retroperitoneum and peritoneum (158)</td>
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<tr>
<td>Nasal cavity, ear, and sinuses (160)</td>
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<tr>
<td>Larynx (161)</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Lung, non-small cell (162)</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Lung, small cell (162)</td>
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<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Pleura (163)</td>
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<td>✓</td>
<td></td>
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<tr>
<td>Thymus, heart, mediastinum (164)</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td>Bone/cartilage (170)</td>
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<tr>
<td>Connective/other soft tissue (171)</td>
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<tr>
<td>Melanoma of skin (172)</td>
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<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Female breast (174)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male breast (175)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaposi’s sarcoma (176)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Uterus, unspecified (179)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Cervix (180)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

continued on next slide
Cancers & Indications Eligible for Entry in the NOPR

(continued)

<table>
<thead>
<tr>
<th>Indications</th>
<th>Diagnosis</th>
<th>Initial Staging</th>
<th>Treatment Monitoring</th>
<th>Restaging/ Suspected Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterus, body (182)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Ovary and uterine adnexa (183)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Prostate (185)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Testis (186)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Penis and other male genitalia (187)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Bladder (188)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Kidney and other urinary tract (189)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Eye (190)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Primary Brain (191)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Thyroid (193)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Lymphoma (200-202)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Myeloma (203)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Leukemia (204-208)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Other or not listed</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

✓ = Eligible for Entry in NOPR

☐ = Not Eligible for Entry in NOPR

* = Patients who do not qualify for covered indications (e.g. because CT or MRI not done or because either showed extrapelvic metastatic disease)

** = Patients who do not qualify for covered indication (e.g. because tumor of other than follicular cell origin or thyroglobulin not elevated)

¹ Some Medicare carriers include anal cancer in their coverage of "colorectal cancer"; for PET facilities served by those carriers, PET for these indications is a covered indication.
Clinical Applications of PET and PET/CT under NOPR Expanded Coverage

• Diagnosis
• Initial staging
• Treatment monitoring *during therapy*
• Restaging *after completion of therapy* and detection of suspected recurrence

• Surveillance **X**
Does NOPR Apply to Oncologic PET with Radiopharmaceuticals other than FDG?

Does NOPR Apply to FDG-PET for Imaging of Infection/Inflammation?

• No

• If NOPR is successful as one of the first “Coverage with Evidence Development” programs, it could presage similar programs for other indications or for PET with F-18 fluoride, F-18 flurothymidine, etc.
Facility and Patient Registration

- Register via the NOPR Web site www.cancerPETregistry.org
  - Complete Facility Registration Form
    - PET facility information including Medicare Provider Number
    - PET facility administrator (the individual responsible for managing registry activities at the facility)
    - Participating interpreting physician(s)
    - Equipment details
- Submit Executed Business Associates Agreement (BAA)
- $50 Facility Application Fee
- $50 Processing Fee for Each Patient
  - Advance payment held in escrow account
NOPR Web Site

- Information for
  - PET Facilities
  - Referring Physicians
  - Patients
- Blank Forms
- Register PET Facilities
- Register Patients
- PET Facility Tools
  - Case Status Reports
  - Account Balance
  - Fund Account by Credit Card

http://www.cancerPETregistry.org
Pre-PET Form – 5 Questions

• Reason for the PET Scan
• Cancer Site/Type
• Summary of Disease Stage
  – NED, Localized, Regional, Metastatic, Unknown
• Performance Status
  – Asymptomatic, Symptomatic, Bedridden
• Intended Patient Management Plan
Pre-PET Form: Specific Reason For PET

1. Check the **single best** match for the reason for the PET.
   - Diagnosis: To determine if a suspicious lesion is cancer
   - Diagnosis
     - Unknown primary tumor: To detect a primary tumor site in a patient with a confirmed metastatic lesion
     - Paraneoplastic: To detect a primary tumor site in a patient with a presumed paraneoplastic syndrome
   - Initial staging of histologically confirmed, newly diagnosed cancer
   - Monitoring treatment response: during chemotherapy, radiotherapy, or combined modality therapy
   - Restaging after completion of therapy
   - Suspected recurrence of a previously treated cancer
Pre-PET Form: Intended Patient Management Plan

5. If PET were not available, your current management strategy would be (select one)?
   - Observation (with close follow-up)
   - Additional imaging (CT, MRI) or other non-invasive diagnostic tests
   - Tissue biopsy (surgical, percutaneous, or endoscopic).
   - Treatment (if treatment is selected, then also complete the following)
     - Treatment Goal: (check one)  Curative   Palliative
     - Type(s): (check all that apply)
       - Surgical   Chemotherapy (including biologic modifiers)
       - Radiation   Other   Supportive care
1. **SPECIFIC REASON FOR PET STUDY**

   a. Check the single best match for the reason for the PET (you must check only one of the following and then answer the section(s) indicated for question 2)

   - **Diagnosis**: To determine if a suspicious lesion is cancer (answer 2a and 2b)
   - **Diagnosis/Unknown Primary Tumor**: To detect a primary tumor site in a patient with a confirmed metastatic lesion (answer 2c)
   - **Diagnosis/Paraneoplastic**: To detect a primary tumor site in a patient with a presumed paraneoplastic syndrome (answer 2a and 2b)
   - **Initial Staging**: Staging of histologically confirmed, newly diagnosed cancer (answer 2a and 2b)
   - **Monitoring Treatment Response**: during chemotherapy (answer 2a and 2b)
   - **Monitoring Treatment Response**: during radiation therapy (answer 2a and 2b)
   - **Monitoring Treatment Response**: during combined modality therapy (e.g., chemo + radiation + surgery + biologic therapy) (answer 2a and 2b)
   - **Restaging**: after completion of therapy (answer 2a and 2b)
   - **Suspected Recurrence**: of a previously treated cancer (answer 2a and 2b)

2. **Cancer Type (ICD-9 Code)** - check the one cancer that most closely relates to the specific reason for the PET study indicated in response to Question 1. (Check only one)

   - Lip, Oral Cavity, and Pharynx (140-149)
   - Esophagus (150)
   - Stomach (151)
   - Small Intestine (152)
   - Colon (153) and Rectum (154)

3. **Your working summary stage for the patient before the PET scan is? (you must check only one)**

   - No evidence of disease / In remission
   - Localized only
   - Regional by direct extension or lymph node involvement or both
   - Metastatic (distant) with a single suspected site
   - Metastatic (distant) with multiple suspected sites
   - Unknown or uncertain

---

**42 Primary and Metastatic Sites Listed**
4. PATIENT PERFORMANCE STATUS

a. Check the box best describing your patient's global functional status (ECOG Performance Score)

☐ (0) Asymptomatic: fully active, able to carry on all activities without restriction.
☐ (1) Symptomatic, fully ambulatory: restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.
☐ (2) Symptomatic in bed <50% of the day: ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.
☐ (3) Symptomatic in bed >50% of the day, but not bedridden: capable of only limited self-care, confined to bed or chair 50% or more of waking hours.
☐ (4) Bedridden: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

5. MANAGEMENT PLAN

If PET were not available, your current management strategy would be? (you must check only one)

☐ Observation (with close follow-up)
☐ Additional Imaging (CT, MRI) or other non-invasive diagnostic tests
☐ Tissue Biopsy (surgical, percutaneous, or endoscopic). Note: If concurrent biopsy and total surgical resection are planned, then mark "surgical" treatment below.
☐ Treatment (if treatment is selected, then also complete the following)

☐ Curative  ☐ Palliative

Type(s): (check all that apply)

☐ Surgical
☐ Chemotherapy (including biologic modifiers)
☐ Radiation
☐ Other
☐ Supportive care

Will treatment be directly provided by you? (check one)

☐ Yes  ☐ No
Post-PET Form – 4 to 7 Questions

- Questions Customized by Specific Reason for PET (Indication)
- 3 - 6 Questions per Indication
- Most Require a Yes or No Answer
- 2 Questions are Repeated from the Pre-PET Form
  - Intended Patient Management Plan
  - Planned Cancer Care Provider
- Referring Physician Consent
1. Has a tissue biopsy been performed of a suspicious site?
   - Yes
   - No

2. Did the PET scan enable you to avoid any tests or procedures?
   - Yes
   - No

3. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (you must select only one)
   - Observation (with close follow-up)
   - Additional Imaging (CT, MRI) or other non-invasive diagnostic tests
   - Tissue Biopsy (surgical, percutaneous, or endoscopic).
     Note: If concurrent biopsy and total surgical resection are planned, then mark "surgical" treatment listed below.
   - Treatment (if treatment is selected, then also complete the following)
     Treatment Goal: (check one)
     - Curative
     - Palliative
   Type(s): (check all that apply)
   - Surgical
   - Chemotherapy (including biologic modifiers)
   - Radiobon
   - Supportive care
   - Other

Will treatment be directly provided by you? (check one)
   - Yes
   - No
NOPR Workflow

1. Referring MD Requests PET
2. Ask Patient For Consent
3. PET Done
4. PET Reviewed & Reported
5. Clinical Actions Ongoing
6. Pre-PET Questionnaire
7. Post-PET Questionnaire Sent
   - Includes Question for Referring Physician Consent
8. Questionnaire Completed $$
Timeline

- Pre- and Post-PET forms can be sent to and from the referring physician via FAX, mail, or hand delivery.
- All forms are entered into the database by the PET Facility. All forms must be entered within 30 days of the PET scan for the case to be eligible for CMS reimbursement.
  - E-mailed to PET Facility
    • Patient Information Sheet asks patient for oral consent to use data for research purposes. The Patient Information Sheet can be given to the patient at any time prior to the PET scan.
    • Referring physician is asked to provide consent for use of treatment management data in research.
  - All data sent to CMS. Data included in research dataset only if BOTH patient and referring MD information sheets are given.

PET must be done within 14 days of patient registration.

Post-PET Form must be entered within 30 days of PET.
Startup Problems

• Not all carriers prepared to accept claims on June 19, 2006
• Various billing issues (frequency limitations, non-cancer ICD-9 codes)
• Confusion about data entry deadlines
• Inclusion of covered cancers/indications under NOPR
Startup Problems

- Some problems with completion of case report forms by referring physicians (e.g., logically inconsistent responses to related questions)
- Confusion about the meaning of “Diagnosis”
- Payments to referring physicians for form completion
- Charging of NOPR fee to patients
NOPR Status (as of November 21, 2006)

- Opened for patient accrual on May 8, 2006
- 1,328 PET facilities nationwide participating
- 17,195 patients registered (882 ineligible)
- 14,663 patients - data entry completed
- Approximately 92% of patients and 96% of referring physicians are consenting to research use of data
NOPR Accrual (Cases Completed/Business Day)

*Through November 21, 2006
Location of Participants

*Bubble size increases with the number of participants enrolled from an area*
### NOPR Working Group Prioritization

<table>
<thead>
<tr>
<th>Priority and Relative Frequency</th>
<th>Diagnosis</th>
<th>Staging</th>
<th>Restaging/ Suspected Recurrence</th>
<th>Treatment Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pancreas Cancer</td>
<td>Pancreas Cancer</td>
<td>Ovarian Cancer</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>2</td>
<td>Cancer/ Unknown Primary</td>
<td>SCLC</td>
<td>Brain Tumors</td>
<td>NSCLC</td>
</tr>
<tr>
<td>3</td>
<td>Ovarian Cancer</td>
<td>Cervical Cancer</td>
<td>Metastatic Colorectal Cancer</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Multiple Myeloma</td>
<td></td>
<td></td>
<td>Head and Neck Cancer</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Esophageal Cancer</td>
</tr>
</tbody>
</table>
Top Ten NOPR Cancer Sites

- Prostate
- Ovary / Uterine Adenexa
- Pancreas
- Kidney / Other Urinary Tract
- Bladder
- Small-Cell Lung
- Stomach
- Liver / Intrahepatic Bile Ducts
- Uterus, body
- Myeloma
Top Ten NOPR Cancer Sites/Indications

- Prostate – Restaging / Recurrence
- Ovary / Uterine Adnexa – Restaging / Recurrence
- **Prostate – Initial Staging**
- Stomach – Restaging / Recurrence
- Bladder – Restaging / Recurrence
- Small Cell Lung Cancer – Restaging / Recurrence
- Stomach – Initial Staging
- Pancreas – Initial Staging
- Ovary / Uterine Adnexa – Treatment Monitoring
- Pancreas – Suspected Primary
Clinical Applications of PET and PET/CT under NOPR Expanded Coverage

**Pitfalls**

- Relatively low FDG uptake in some previously non-covered cancers
- Prostate cancer, hepatoma, mucinous GI-tract cancers, neuroendocrine tumors, low-grade gliomas
- Baseline study at initial staging will help to define those tumors for which FDG-PET not suitable
- Limited published data to guide use for some previously non-covered cancers
- There will be learning curves for both referring physicians and interpreting physicians
NOPR “Forecast”

- Expected to be operational for ≥ 2 years, but details of transitioning from NOPR to coverage remain to be determined
- First data to be sent to CMS in December 2006
- Initial manuscripts are in preparation
- PET report quality assessment under way
- Eventually intend to link NOPR data with CMS claims data to assess “real” outcomes
NOPR Working Group

- Chair, Bruce Hillner, MD, Virginia Commonwealth University
- Co-chair, Barry A. Siegel, MD, Washington University
- R. Edward Coleman, MD, Duke University
- Anthony Shields, MD, Wayne State University
- Statistician: Dawei Liu, PhD, Brown University
- Epidemiologist: Ilana Gareen, PhD, Brown University

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Questions??