Overview

- Most cancers take up and metabolize approximately five times as much glucose as normal tissues. F-18-fluorodeoxyglucose is an analog of glucose which is taken up by cells to the same extent as glucose, but it is not metabolized. Because of these findings the Tumor Glucose Metabolism Study is capable of demonstrating primary and metastatic cancer throughout the body.

Indications:

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</th>
<th>Subsequent Treatment Strategy (formerly “restaging” and “monitoring response to treatment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Head and Neck (not thyroid or CNS)</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Ovary</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Brain</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Cervix</td>
<td>Cover with exceptions*</td>
<td>Cover</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Testes</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Prostate</td>
<td>Non-cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Breast (male and female)</td>
<td>Cover with exceptions*</td>
<td>Cover</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions*</td>
<td>Cover</td>
</tr>
<tr>
<td>All other solid tumors</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover</td>
<td>Cover</td>
</tr>
</tbody>
</table>
CMS _NON-Covered_ Indications for FDG-PET

Initial Treatment Strategy

- Breast cancer diagnosis (to determine if mass on physical examination or mammography is benign or malignant)
- Detection of axillary nodal metastasis in newly diagnosed breast cancer
- Detection of regional nodal metastasis in newly diagnosed malignant melanoma
- Diagnosis of cervical cancer
- Diagnosis and initial staging of prostate cancer

Limitation on Coverage:

- Three (3) FDG-PET scans will be nationally covered for oncologic indications when used to guide _subsequent_ physician management of anti-tumor strategy after initial anticancer therapy.
- Additional scans will be permitted at MAC or MA Plan Contractor discretion.

Initial ATS Nationally Covered Effective June 11, 2013

- CMS continues to _nationally cover one FDG-PET_ study for beneficiaries who have cancers that are _biopsy proven or strongly suspected based on other diagnostic testing_ when the beneficiary’s treating physician determines that the FDG-PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:
  - To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
  - To determine the optimal anatomic location for an invasive procedure; or
  - To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.
Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide subsequent physician management of anti-tumor strategy after initial anticancer therapy.

• **Question:** What if the patient or referring physician tells us that patient has not previously had ≥ 3 PET studies, but we later find out had 3? Will Medicare deny coverage? Can we appeal to the local Medicare contractor?

• **Answer:** The NCD allows for medically necessary scans beyond 3; specifically, if there is medical necessity for more than 3 PET scans, appeal to the local MAC providing documentation. Without documentation of medical necessity, claim likely will not be paid on appeal.

Limitation on Coverage Questions:

Three (3) FDG-PET scans used to guide subsequent physician management of anti-tumor strategy after initial anticancer therapy.

• **Question:** Is there a time limit for a recurrence of a cancer specified in the NCD? Is the limit of three PS scans per year or per patient lifetime?

• **Answer:** The limits are per patient per cancer over the patient’s lifetime (with the count beginning on June 11, 2013).

• A time limit is not referenced in the NCD.

**CANCERS AND INDICATIONS ELIGIBLE FOR ENTRY IN THE NOPR**

Cancers and indications that are reimbursable by Medicare are **NOT** eligible for entry in the NOPR. Cancers and indications that are specifically excluded for Medicare reimbursement are also **not eligible for entry in the NOPR**.

C = covered - Not eligible for entry in the NOPR
NC = non-covered nationally - Not eligible for entry in the NOPR
NOPR = covered only with entry in the NOPR

<table>
<thead>
<tr>
<th>Indications</th>
<th>Initial Treatment Strategy (formerly Diagnosis and initial Staging)</th>
<th>Subsequent Treatment Strategy (includes Treatment Monitoring, Restaging and Detection of Suspected Recurrence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NaF Bone scan for suspected bone mets</td>
<td>C</td>
<td>C</td>
</tr>
</tbody>
</table>
• Evaluation of multiple myeloma.
• Staging of biologically aggressive prostate cancer.
• Evaluation of the effect of therapy on cancer.
• Grading cancers.
• Whole body screening for cancer.
• Selecting lesions for biopsy.
• Detection of neuroendocrine tumors.
• Providing images of viable tumor distribution for target definition for optimal external beam radiation therapy.

**Examination Time**

• Allow approximately 2 – 2.5 hours for the entire PET/CT

• Prior to Scan: Allow 15 minutes for interview, IV, BGL, and changing followed by 1 hour uptake post injection.

• Image acquisition:
  1. 78815 (skull base to mid-thigh)  
     ~30 minutes for average size patient.
  2. 78816 (full body – includes legs)  
     ~45 minutes for average patient
  3. 78608 (brain)  
     ~10 minutes
  4. 78614 (limited scan)  
     ~dependent on number of beds acquired

**Patient Preparation**

• NPO 4-6 hours prior to exam (water is okay). No carbs/sugar starting at noon the day before scan.
• No strenuous exercise 24 hours prior to exam
• No sugar containing meds (cough syrup, cough drops, sugar coated aspirins, etc.)
• No oral diabetic meds day of exam (can take after exam.)
• No insulin within 4 hours of exam time.
**Diet**

Refrain from the following foods starting at noon the day before your scan.

**Sugars**
- fruit/fruit juice
- soft drinks
- jellies
- coffee
- yogurt
- desserts
- oatmeal
- alcohol (any)

**Starches/Carbs**
- bread/rolls/cakes/tortillas
- rice/pasta/crackers
- potatoes or corn
- snack chips (corn, potato, popcorn)
- pastries
- candy
- pizza dough

**Diabetic Patients:**

**Insulin Dependent (including Insulin Pump):**
- Schedule PET/CT in the afternoon.
- Light Breakfast (no carbs or sugars) *only* if scheduled in the afternoon.
  - i.e. eggs, bacon, and water 4-6 hours prior to PET injection
- No Insulin within 4 hrs of PET injection.

**Oral Diabetic:**
- Schedule PET/CT in the morning.
- Light Breakfast (no carbs or sugars) *only* if scheduled in the afternoon. i.e.
  - eggs, bacon, and water
- Take Oral diabetic meds with you to exam.

**Diagnostic CT and Labwork**

In accordance with the recommendations made by the American College of Radiology, every effort will be made to obtain Creatinine on patients with the risk factors listed below:

- Oral Diabetic Patients > 5yrs.
- Insulin Dependent Diabetics (IDDM) > 2 yrs.
- Patients with history of kidney disease (including tumor or transplant).
- Family history of kidney failure.
- Creatinine > 1.3 check with radiologist – may switch to visipaque or lower volume of contrast
- Paraproteinemia syndromes or diseases (e.g. myeloma)
- Collagen vascular disease (e.g. lupus)
- *Creatinine labs performed at ARA*

**Allergies to Contrast**

Patients with known iodine contrast allergies must be pre-medicated before starting the PET/CT exam. The paramedic will give instructions or administer the medication to the patient and fill out appropriate documentation.
**Patient Interview and IV**

- **Blood Glucose Level (BGL)**
  - Fasting blood sugar should be obtained on all patients. PET scan preferred blood sugar $\leq 200$ mg/dl.
  - Normal range 70-110 mg/dl.
  - If blood sugar is low (i.e. $< 50$ mg/dl) consult the radiologist.
  - If the blood glucose is between 200 mg/dl and 225 mg/dl, try oral hydration and walking the patient to lower the blood sugar.
  - If the BGL is between 225 mg/dl and 250 mg/dl, consult the radiologist.
  - If the BGL is over 250 mg/dl, cancel the exam.

- **Recent Surgery**
  - Record all surgeries. Be sure to note the date of all surgeries within the last 6 months. These areas may appear “hot” on the PET scan (including biopsies).
  - Preference: no surgeries within 1-2 months.

- **Chemotherapy**
  - For restaging: at least 3 weeks after completion of chemo, preferably 6-8 weeks after completion of chemo.
  - For response to therapy, PET can be performed after 1-2 cycles of chemotherapy. Check insurance carrier for approved indications.

- **Radiation Therapy**
  - For restaging, preferably 6-8 weeks after completion of radiation therapy.
  - If you are looking for distant mets (not the area of radiation), PET can be performed immediately post XRT.

- **Bone Marrow Stimulants**
  - BM stimulants will cause increased bone marrow uptake. Preference: wait 2 weeks after last injection.
  - **Red Blood Cell stimulants**: Aranesp, Epogen, Procrit
  - **White Blood Cell**: Leukine, Neupogen, Neulasta

- **Infection**
  - Indicate any recent infections on the patient history. These will have areas of increased uptake. Be sure to question pneumonia, other lung diseases, diverticulitis, MRSA, Kaposi Sarcoma, sarcodosisis, or other infections.

- **Oral Contrast**
  - 16 oz of water is given to all PET/CT (body) patients who are not receiving sedation. This will help differentiate the colon and aid in interpretation.
• **IV Contrast**
  - When ordered by the referring physician, IV contrast is given during the CT portion of the PET/CT. The contrast form must be filled out and signed by the patient prior to contrast administration. See *Diagnostic CT and Lab work* listed earlier in protocol for more information.
  - Omnipaque 300 or Visipaque 320 is administered.
  - Standard adult dose is 100 cc.
  - Pediatric dose is 1cc per lb.

**Sedations (oral)**
- Patients getting sedation must not take their own sedation medication within 4 hours prior to their arrival. Patients who do take their own medication will not be provided sedation by ARA.
- Sedation may be needed for claustrophobia. Alprazolam (Xanax) at 1 mg is commonly used to treat panic disorders including claustrophobia. These patients should arrive 1 hour prior to their injection. The paramedic will assess the patient and consult with the radiologist to determine the appropriate dosage.
- Head and Neck cancers are sedated to decrease the amount of brown fat and relax the muscles in the head and neck region. These patients should arrive 90 minutes prior to their injection.
- Patients requiring sedation must have a driver.

**Patient Uptake Phase**
- Take appropriate measures to limit muscle uptake of F-18-fluorodeoxyglucose:
  1. The patient should lie still throughout the uptake period.
  2. The patient should not talk to minimize the uptake of F-18-fluorodeoxyglucose in the laryngeal muscles.
- Keep the patient warm during the uptake period to minimize uptake of F-18-fluorodeoxyglucose in brown adipose tissue.
- If the order includes a CT scan, give negative oral contrast appropriate for CT imaging: 16 oz. of water prior to imaging. Intravenous contrast is used when indicated by physician order.
- Bowel uptake is not decreased by administration of spasmolytic medication.

**Equipment & Energy Windows**
- Imaging system:
  - Siemens Biograph Horizon 16 PET-CT scanner.
  - United Imaging uMI 550
- Collimators:
  - 3D mode (septa out or absent) (*Siemens Biograph Horizon only performs 3D*)
  - 3D mode for United Imaging PET/CT
• Energy windows (may vary with manufacturer and machine design): 30% window centered at 511 keV.

**Radiopharmaceutical, Dose, & Technique of Administration**

• Radiopharmaceutical: F-18-fluorodeoxyglucose

• Dosing:
  
  Average Adult 8 - 12 mCi

  Pediatric Patients – use North American Consensus Guidelines for Administered Radiopharmaceuticals in Children or Adolescents. ARA RAM Licensure allows +/- 20% dose variance.

• Technique of administration: Standard intravenous injection.

**Patient Positioning & Imaging Field**

• Patient position:
  
  1. Supine with a triangular bolster under the knees.
  2. Arms:
     - Over head for most studies (if patient is able to tolerate).
     - At sides if patient is here for a head and neck cancer, CT neck is ordered, or if patient cannot tolerate arms above head.
  3. Place Velcro strap around patient to assist patient in lying still.

• Imaging field of view: Usually from the base of the brain to the upper thighs.
  - The field of view may be made smaller for certain tumors, e.g. the abdomen and pelvis may be eliminated for head and neck cancer.
  - The field of view may be made larger for certain tumors, e.g. the legs may be added in some cases of melanoma. (The emission acquisition time is decreased for the legs.)

**Acquisition Protocol**

• Approximately 45-60 minutes post injection, have the patient empty his/her bladder and drink water (unless the patient is sedated in which case no water is given).

• Begin image acquisition approximately 60 minutes following injection of F-18-fluorodeoxyglucose.

• Have the patient empty his/her bladder after image acquisition. Give instructions to hydrate and void often.

• CT parameter values vary with patient size and machine specific factors:
1. Kilovolts peak (kVp) guidelines:
   a) refer to pediatric protocols for all pedi’s
   b) average adult: 120 kVp.
   c) obese adult: 140 kVp.
2. Milliampere-seconds (mAs) guideline: Varies between approximately 200 and 400 mAs depending on patient size. Utilize care dose when indicated.
3. Lung inspiration CT acquisition obtained on all but pediatric patients
4. CT acquisition performed on head / neck cancer indications when diagnostic CT neck is ordered:
   a. AP and Lateral Topogram
   b. Axial imaging – acquire with 100 cc I.V. contrast.

Data Processing

- The PET images are reconstructed using iterative reconstruction. Settings for the Siemens PET/CT scanner include: 180 matrix, 4 iterations, 10 subsets, Gaussian filter, filter FWHM 3.0, zoom 1.0, T.O.F. Settings for the United uMI 550 include: 3D reconstruction, HYPER DPR, Strength 3, TOF, PSF, 192 matrix, measured attenuation.

- Construct tomographic images with and without attenuation correction. In general, attenuation corrected images are used for primary interpretation and non-attenuation corrected images may be used in problem solving.

- A rotating maximum intensity projection (MIP) display facilitates lesion detection.

Optional Maneuvers

- Use of intravenous contrast during the CT acquisition in PET-CT imaging: A modified intravenous injection protocol allows acquisition of contrast enhanced CT images without creating artifacts in the PET images.

- Elevated TSH levels and thyroid cancer imaging: Withdrawal of thyroid replacement hormone or administration of recombinant TSH prior to FDG-PET imaging increases FDG uptake in thyroid cancer.

- Oral administration of F-18-fluorodeoxyglucose: In patients without intravenous access, the radiopharmaceutical may be given orally.

Principle Radiation Emission Data - F-18
• Physical half-life = 109.8 minutes.

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean % per disintegration</th>
<th>Mean energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positron</td>
<td>100</td>
<td>250</td>
</tr>
<tr>
<td>Gamma ±</td>
<td>200</td>
<td>511</td>
</tr>
</tbody>
</table>

**Dosimetry - F-18-Fluorodeoxyglucose**

<table>
<thead>
<tr>
<th>Organ</th>
<th>rads/15 mCi</th>
<th>mGy/555 MBq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder</td>
<td>2.21</td>
<td>22.1</td>
</tr>
<tr>
<td>Heart</td>
<td>0.80</td>
<td>8.0</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.80</td>
<td>8.0</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.42</td>
<td>4.2</td>
</tr>
<tr>
<td>Brain</td>
<td>0.41</td>
<td>4.1</td>
</tr>
<tr>
<td>Liver</td>
<td>0.38</td>
<td>3.8</td>
</tr>
<tr>
<td>Testes</td>
<td>0.35</td>
<td>3.5</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.26</td>
<td>2.6</td>
</tr>
<tr>
<td>Total body</td>
<td>0.20</td>
<td>2.0</td>
</tr>
</tbody>
</table>

**Dosimetry - Computed Tomography**

• Actual effective doses will depend on the user-specific exam protocol and the specific CT scanner used. Care dose should be used when indicated.

<table>
<thead>
<tr>
<th>Effective dose</th>
<th>rem</th>
<th>mSv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic CT</td>
<td>1.9</td>
<td>19.0</td>
</tr>
<tr>
<td>Low dose CT</td>
<td>0.3</td>
<td>3.0</td>
</tr>
</tbody>
</table>