Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment

Description

Positron emission tomography (PET) scanning has many established roles in oncology. One potential use of PET scanning is to assess treatment response early in the course of therapy, with the intent of potentially altering the regimen based on PET scan results. While several types of PET scanning are used for interim detection of cancer, this review refers to fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) unless otherwise noted.

OBJECTIVE

The objective of this evidence review is to evaluate the technical reliability, clinical validity, and clinical utility of positron emission tomography in assessing early response to treatment in individuals with various types of cancer.

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POLICY STATEMENT

The use of interim fluorine 18 fluorodeoxyglucose positron emission tomography scans to determine response to tyrosine kinase inhibitor treatment in patients with gastrointestinal stromal tumors is considered medically necessary.

The use of positron emission tomography scans to determine early response to treatment (positron emission tomography scans done during a planned course of chemotherapy and/or radiotherapy) in patients with gastrointestinal stromal tumors on palliative or adjuvant therapy, as well as all other cancers, is considered investigational.

POLICY GUIDELINES

An HCPCS modifier created by Medicare might be helpful:

Modifier PS: Positron emission tomography or positron emission tomography plus computed tomography to inform the subsequent treatment strategy of cancerous tumors when the beneficiary's treating physician determines that the positron emission tomography study is needed to inform subsequent antitumor strategy.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of PET scan platforms have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process since the Penn-PET scanner was approved in 1989. These systems are intended to aid in detecting, localizing, diagnosing, staging, and restaging of lesions, tumors, disease, and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurologic disorders, and cancer. The images produced by the system can aid in radiotherapy treatment planning and interventional radiology procedures.

PET radiopharmaceuticals have been evaluated and approved as drugs by the FDA for use as diagnostic imaging agents. These radiopharmaceuticals are approved for specific conditions. In December 2009, the FDA issued guidance for Current Good Manufacturing Practice for PET drug manufacturers and, in August 2011, issued similar Current Good Manufacturing Practice Guidance for small businesses compounding radiopharmaceuticals. An additional final guidance document issued in December 2012 required all PET drug manufacturers and compounders to operate under an approved new drug application or abbreviated new drug application, or investigational new drug application, by December 12, 2015.

Table 1 lists some of the radiopharmaceuticals granted the FDA approval for use with PET for oncologic-related indications.

Table 1. Radiopharmaceuticals Approved for Use With PET for Carcinoma-Related Indications

<table>
<thead>
<tr>
<th>Agent</th>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>Date Approved</th>
<th>NDA No.</th>
<th>Carcinoma-Related Indication With PET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon 11 choline</td>
<td>NA</td>
<td>Various</td>
<td>2012</td>
<td>203155</td>
<td>Suspected prostate cancer recurrence based on elevated blood PSA after therapy and noninformative bone scintigraphy, CT, or MRI</td>
</tr>
</tbody>
</table>

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### Summary of Evidence

**Breast Cancer**

For individuals with breast cancer who receive interim fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) as an adjunct to interim computed tomography (CT), the evidence consists of several systematic reviews, a randomized controlled trial (RCT), and many observational studies. The relevant outcomes are overall survival (OS), disease-specific survival, change in disease status, quality of life (QOL), morbid events, and treatment-related morbidity. Results from the systematic review have shown wide ranges in sensitivities, specificities, positive predictive values (PPV), and negative predictive values (NPV). The wide ranges might be due to small sample sizes, the use of various definitions of the outcome measure (pathologic complete response), and differences in breast cancer subtype populations. One RCT was identified in which therapy decisions were guided by FDG-PET results. Nonresponders, determined by positron emission tomography (PET) measures, were given more intensive chemotherapy. Clinical outcomes such as progression-free survival and OS are not yet available for this RCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Esophageal Cancer**

For individuals with esophageal cancer who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a meta-analysis, three nonrandomized studies, and two retrospective studies. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. Results on clinical validity were inconsistent across the studies. The meta-analysis reported low pooled sensitivities and specificities, while a subgroup analysis including only patients with squamous cell carcinoma and two studies published after the meta-analysis reported an adequate potential in predicting responders to neoadjuvant therapy. No evidence was identified that examined the clinical utility of PET for patients with esophageal cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Gastrointestinal Stromal Tumors (GIST)**

For individuals with GIST receiving palliative or adjuvant therapy who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review included 19 studies, 2 of which reviewed FDG-PET scans more than 6 months after the start of treatment. CT is currently recommended for standard long-term follow-up and surveillance of gastrointestinal stromal tumors. FDG-PET is equivalent to CT in the detection of treatment response when follow-up is long-term. No studies were identified that tested outcomes following PET-guided treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

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**RATIONALE**

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For individuals with GIST treated with tyrosine kinase inhibitors (TKIs) for six months or less who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review showed that FDG-PET detected an early response to TKI therapy, which was a strong predictor of clinical outcomes. FDG-PET detected treatment response as early as one week after initiation of treatment. While CT detects anatomic changes in the tumor, PET detects changes in the metabolic activity of the tumor. Because metabolic changes precede anatomic changes by several weeks or sometimes months, PET can detect treatment response earlier than CT. PET is therefore preferred if a rapid read-out of response to targeted therapy is needed to guide treatment decisions (eg, change in targeted therapy or surgery). While no studies were identified that tested outcomes following PET-guided treatment, it is possible to construct a chain of evidence demonstrating improved patient outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### Head and Neck Cancer

For individuals with head and neck cancer who receive interim FDG-PET as an adjunct to CT, the evidence includes several systematic reviews and a retrospective study. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. There was an overlap of studies among the systematic reviews. Most studies included in the reviews showed that FDG-PET used during radiotherapy, with or without chemotherapy, can adequately predict disease-free and OS. Meta-analyses to determine response could not be performed in any of the systematic reviews due to the heterogeneity in the methods across the studies. Most studies used maximum standardized uptake volume (SUVmax), however, threshold values to determine response varied across studies. No studies were identified that provided evidence for the clinical utility of PET. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Lymphoma

For individuals with lymphoma who receive interim FDG-PET as an adjunct to interim CT, the evidence includes systematic reviews with meta-analyses and RCTs. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review evaluating the validity of interim FDG-PET showed high false-positive rates for both Hodgkin and non-Hodgkin lymphomas. After the systematic review, two studies were published; one focused on patients with follicular lymphoma and the other on patients with T-lymphoblastic leukemia/lymphoma. These studies showed a potential for FDG-PET to predict survival rates for these specific lymphomas. Evidence for the clinical utility of interim PET for guiding treatment in patients with lymphoma consists of a Cochrane review and several RCTs. The report reviewed lower progression-free survival (PFS) rates in patients who received PET-guided therapy. The RCTs that compared PET-guided therapy with standard therapy did not demonstrate noninferiority. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Non-Small-Cell Lung Cancer (NSCLC)

For individuals with NSCLC who receive interim FDG-PET as an adjunct to interim CT, the evidence includes numerous small observational studies. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. While most studies showed correlations between FDG-PET measurements and progression-free survival (PFS) and OS, the generalizability of the results is limited. The studies were small, with most population sizes fewer than 50 patients. The studies were also heterogeneous, including patients at different stages of the disease, undergoing different treatment regimens, and receiving PET at different times during treatment cycles. No studies were identified that evaluated outcomes after PET-guided therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Ovarian Cancer

For individuals with ovarian cancer who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. The relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review identified nine studies that calculated hazard ratios (HRs) for various FDG-PET parameters (eg, maximum standardized uptake value, metabolic tumor volume, tumor lesion glycolysis). The only parameter consistently showing prognostic value was tumor lesion glycolysis. Additionally, no studies were identified that evaluated outcomes after PET-guided therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Other Cancers

For individuals with other malignant solid tumors (eg, bladder, colorectal, prostate, thyroid) who receive FDG-PET as an adjunct to interim CT, the evidence includes a systematic review, National Comprehensive Cancer network (NCCN) task force report, and single-arm observational studies published after the task force report. The relevant outcomes are OS, disease-specific survival, change in...
disease status, QOL, morbid events, and treatment-related morbidity. Results have been inconsistent on the use of interim FDG-PET among the various cancers. While some have reported associations between interim FDG-PET and recurrence or survival, there is a lack of comparative trials evaluating outcomes in patients whose treatments were altered based on PET measurements. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Radiology and Society for Pediatric Radiology

The American College of Radiology and the Society for Pediatric Radiology (2016; revised 2019) updated their joint practice guidelines for performing fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) coupled with computed tomography (CT) in oncology. The guidelines stated that FDG-PET/CT imaging in oncology patients "should only be performed when there is reasonable expectation that the results will have an impact on patient care." Examples of indications for imaging included "Monitoring response to therapy to include determining whether residual abnormalities identified with another imaging modality represent persistent viable tumor or post-treatment changes (inflammation, fibrosis, or necrosis)" and "Guiding specific clinical strategies, such as radiation therapy planning or directed biopsy." Further clarification was not provided.

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network recommendations for interim PET scanning during treatment to assess early response in a variety of cancers are summarized in Table 1.

Table 1. Recommendations for Interim PET Scanning

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Version</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder cancer 110</td>
<td>4.2019</td>
<td>Interim PET for assessing response to ongoing treatment is not addressed.</td>
</tr>
<tr>
<td>Breast cancer   111</td>
<td>2.2019</td>
<td>&quot;Studies of functional imaging [for monitoring metastatic disease], such as radionuclide bone scans and PET imaging, are particularly challenging when used to assess response... PET imaging is challenging because of the absence of a reproducible, validated, and widely accepted set of standards for disease activity assessment.&quot;</td>
</tr>
<tr>
<td>CNS cancers     112</td>
<td>1.2019</td>
<td>Interim PET for assessing response to ongoing treatment is not addressed.</td>
</tr>
<tr>
<td>Cervical cancer 113</td>
<td>4.2019</td>
<td>&quot;For patients with International Federation of Gynecology and Obstetrics (FIGO) stage IB2 or patients who required postoperative adjuvant radiation or chemoradiation due to high-risk factors, a whole-body PET/CT may be performed at 3-6 months after completion of treatment.&quot; &quot;Patients with stage II-IV, whole-body PET/CT is preferred or chest/abdomen/pelvic CT with contrast within 3-6 months of completion of therapy.&quot;</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Condition</th>
<th>Year</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon cancer</td>
<td>2.2019</td>
<td>&quot;PET/CT should not be used to monitor progress of therapy. PET/CT scans should not be used to assess response to chemotherapy because a PET/CT scan can become transiently negative after chemotherapy. False-positive PET/CT scan results can occur in the presence of tissue inflammation after surgery or infection.&quot;</td>
</tr>
<tr>
<td>Esophageal and EGJ cancers</td>
<td>2.2019</td>
<td>In the clinical setting of patients with squamous cell carcinoma or adenocarcinomas following preoperative chemoradiation or definitive chemoradiation, the response to treatment assessment using PET/CT or PET is preferred.</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>2.2019</td>
<td>&quot;PET/CT may be useful in determining response to neoadjuvant chemotherapy for lesions that are larger than 3 cm, firm, deep (not superficial)&quot; &quot;PET may give an indication of imatinib activity after 2-4 weeks of [primary or preoperative] therapy when rapid readout of activity is necessary.&quot;</td>
</tr>
<tr>
<td>Head and neck cancers</td>
<td>2.2019</td>
<td>After either radiation therapy or chemoradiation, post-treatment evaluation with imaging (ie, CT and/or MRI with contrast, FDG-PET/CT) guides the use of neck dissection. If PET/CT is used for follow-up, the first scan should be performed at a minimum of 12 weeks after treatment to reduce the false-positive rate.</td>
</tr>
<tr>
<td>Hepatobiliary cancers</td>
<td>2.2019</td>
<td>&quot;In PET/CT it is not recommended for detection of HCC because of limited sensitivity. When an HCC is detected by CT or MRI and has increased metabolic activity on PET/CT, higher intralesional standardized uptake value is a marker of biologic aggressiveness and might predict less optimal response to locoregional therapies.&quot;</td>
</tr>
<tr>
<td>Hodgkin lymphoma</td>
<td>2.2019</td>
<td>&quot;PET scans are increasingly being used to assess treatment response during therapy. Interim PET scans may be useful to identify a subgroup of patients with early-stage disease that can be treated with chemotherapy alone. The NCCN Guidelines emphasize that the value of interim PET scans remains unclear for many clinical scenarios and all measures of response should be considered in the context of management decisions. It is important that the Deauville score be incorporated into the nuclear medicine PET scan report, since subsequent management is often dependent upon that score. Suggested treatment regimens for stage I-II unfavorable or stage III-IV disease: &quot;A (B) VD (2 cycles) followed by AVD (4 cycles), if PET scan is negative after 2 cycles of ABVD. Patients with positive PET scan after 2 cycles of ABVD need individualized treatment.&quot;</td>
</tr>
<tr>
<td>Melanoma</td>
<td>2.2019</td>
<td>&quot;Recent studies in patients with stage III or IV melanoma... indicated that additional information provided by PET/CT may impact treatment decisions in up to 30% of patients, with the greatest impact seen in surgical management.&quot;</td>
</tr>
<tr>
<td>MPM</td>
<td>2.2019</td>
<td>Interim PET for assessing response to ongoing treatment is not addressed.</td>
</tr>
<tr>
<td>Multiple myelomas</td>
<td>3.2019</td>
<td>Interim PET for assessing response to ongoing treatment is not addressed.</td>
</tr>
</tbody>
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| Non-Hodgkin lymphoma: B-cell | 4.2019 | "Further prospective studies are warranted to determine whether interim PET scans have a role in guiding post-induction therapeutic interventions.**" A negative PET scan after 2 to 4 cycles of induction therapy has been associated with significantly higher EFS and OS rates in several studies. However, interim PET scans can produce false-positive results and many patients treated with chemoinmunotherapy have a favorable long-term outcome despite a positive interim PET scan.** |
| Non-Hodgkin lymphoma: T-cell | 2.2019 | "The guidelines recommend interim restaging with PET/CT or CT scan for all patients." |
| NSCLC | 5.2019 | Interim PET for assessing response to ongoing treatment is not addressed. |
| Ovarian cancer | 1.2019 | Primary chemotherapy regimens include monitoring with chest/abdominal/pelvic CT or MRI with contrast, PET/CT (skull base to mid-thigh), or PET as indicated. |
| Pancreatic adenocarcinoma | 3.2019 | "PET/CT scan may be considered after formal pancreatic CT protocol of high-risk patients to detect extrapancreatic metastases. It is not a substitute for high-quality, contrast-enhanced CT. See Principles of Diagnosis, Imaging, and Staging (PANC-A)." |
| Prostate cancer | 2.2019 | "F-18 FDG-PET/CT should not be used routinely since data are limited in patients with prostate cancer." |
| Rectal cancer | 2.2019 | "Chest/abdominal/pelvic ST with contrast or chest CT and abdominal/pelvic MRI with contrast to monitor progress of therapy. PET/CT should not be used. See Principles of Imaging (REC-A)." |
| SCLC | 1.2019 | "Patients most likely to benefit from surgery are those with SCLC that is clinical stage I-IIA (T1-2,N0, M0) after standard staging evaluation (including CT of the chest and upper abdomen, brain imaging, and PET/CT imaging)." |
| Thyroid carcinoma | 1.2019 | Post-treatment 131 I imaging may indicate the location of metastases when the serum Tg level is increased, but a tumor [or metastases] cannot be found by physical examination or other localizing techniques such as diagnostic 131 I imaging, neck ultrasonography, CT, MRI, or PET. |
| Uterine neoplasms | 3.2019 | Interim PET for assessing response to ongoing treatment is not addressed. |

**F-18 FDG-PET/CT should not be used routinely since data are limited in patients with prostate cancer.**

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ABVD: doxorubicin, bleomycin, vinblastine, dacarbazine; AVD: doxorubicin, vinblastine, dacarbazine; CNS: central nervous system; CT: computed tomography; DLBCL: diffuse large B-cell lymphoma; EGJ: esophagogastric junction; FDG: fluorine 18 fluorodeoxyglucose;

This statement is a footnote to epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer treatment recommendations and is uncited.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The national coverage determination on FDG-PET for oncologic conditions (220.6.17) makes the following coverage decisions:

"Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors."

REFERENCES


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