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FEP 6.01.51 Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment

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Related Policies:

6.01.06 - Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography
6.01.20 - Cardiac Applications of Positron Emission Tomography Scanning
6.01.26 - Oncologic Applications of Positron Emission Tomography Scanning

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

Description

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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 clinical validity and clinical utility of interim positron emission tomography in assessing early response to treatment in individuals with various types of cancer.

POLICY STATEMENT

The use of interim fluorine 18 fluorodeoxyglucose positron emission tomography scans to determine response to tyrosine kinase inhibitor treatment in individuals 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 individuals with gastrointestinal stromal tumors on palliative or adjuvant therapy, as well as all other cancers, is considered **investigational**.

POLICY GUIDELINES

Coding

A Healthcare Common Procedure Coding System (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[2,] and, in August 2011, issued similar Current Good Manufacturing Practice Guidance for small businesses compounding radiopharmaceuticals.[3,] An additional final guidance document issued in December 2012 required all PET drug manufacturers and compounders to operate under an approved new drug application, abbreviated new drug application, or investigational new drug application, by December 12, 2015.[4,]

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

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

Agent	Brand Name	Manufacturer	Date Approved	NDA No.	Carcinoma-Related Indication With PET
Carbon 11 choline	NA	Various	2012	203155	Suspected prostate cancer recurrence based on elevated blood PSA after therapy and noninformative bone scintigraphy, CT, or MRI
Copper 64 dotatate	Detectnet™	Curium	2020	213227	Localization of somatostatin receptor-positive NETs in adult patients
Fluorine 18 fluorodeoxyglucose	NA	Various	2000	20306	Suspected or existing diagnosis of cancer, all types
Fluorine 18 fluciclovine	Axumin™	Blue Earth Diagnostics	2016	208054	Suspected prostate cancer recurrence based on elevated blood PSA levels after treatment
Fluorine 18 fluoroestradiol	CERIANNA™	Zionexa	2020	212155	Detection of ER-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer
Gallium 68 dotatate	NETSPOT™	Advanced Accelerator Applications	2016	208547	Localization of somatostatin receptor-positive NETs in adult and pediatric patients
Gallium 68 dotatoc	NA	University of Iowa	2019	210828	Localization of somatostatin receptor-positive NETs in adult and pediatric patients
Gallium 68 PSMA-11	NA	University of California, Los Angeles and the University of California, San Francisco	2020	212642	PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum PSA level
Piflufolastat fluorine-18	Pylarify	Progenics Pharmaceuticals, Inc	2021	214793	PSMA positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum PSA level

CT: computed tomography; ER: estrogen receptor; MRI: magnetic resonance imaging; NA: not applicable; NDA: new drug application; NETs: neuroendocrine tumors; PET: positron emission tomography; PSA: prostate-specific antigen; PSMA: prostate-specific membrane antigen.

RATIONALE

Summary of Evidence

Breast Cancer

For individuals with breast cancer who receive interim fluorodeoxyglucose positron emission tomography (FDG-PET) as an adjunct to interim computed tomography (CT), the evidence consists of several systematic reviews, 2 randomized controlled trials (RCTs), long-term results from 1 of the 2 RCTs, and many observational studies. 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 systematic reviews have shown wide ranges in sensitivities, specificities, positive predictive values (PPVs), and negative predictive values (NPVs). 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. Two RCTs were identified in which therapy decisions were guided by FDG-PET results. In the first RCT, nonresponders, determined by PET measures, were given more intensive chemotherapy. Although the results showed initially higher response rates in the more intensive treatment group, this did not translate to long-term improvements in disease-free survival.The second RCT found that patients receiving less intensive initial treatment who were determined to be responders by PET measures had significantly higher response rates to treatment; however, 3-year disease-free survival results have not yet been published. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Esophageal Cancer

For individuals with esophageal cancer who receive interim FDG-PET as an adjunct to interim CT, the evidence includes 2 meta-analyses, 2 nonrandomized studies, and 2 retrospective studies. 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 2 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. Evidence for clinical utility of FDG-PET for patients with esophageal cancer consists of 1 meta-analysis and 1 RCT. The meta-analysis found that patients considered to be responders early in therapy based on FDG-PET assessment were found to have improvements in progression-free survival (PFS) and OS compared to nonresponders. A single RCT found that PET-guided therapy led to improvements in progression-free survival (PFS), but not OS, in patients considered nonresponders to initial therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Gastrointestinal Stromal Tumors

For individuals with gastrointestinal stromal tumors receiving palliative or adjuvant therapy who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. 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 that the technology results in an improvement in the net health outcome.

For individuals with gastrointestinal stromal tumors treated with tyrosine kinase inhibitors (TKIs) for 6 months or less who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. Relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review included 19 studies, 17 of which 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 1 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 an 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. 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 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 that the technology results in an improvement in the net health outcome.

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. 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, 2 studies were published; 1 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 2 Cochrane reviews and several RCTs. One Cochrane review reported lower PFS in patients receiving PET-guided therapy compared with patients receiving standard care. Another Cochrane review found moderate-certainty evidence that interim PET scan results predict OS, and very low-certainty evidence that interim PET scan results predict PFS in treated individuals with Hodgkin lymphoma. The RCTs that compared PET-guided therapy with standard therapy did not demonstrate noninferiority. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Non-Small-Cell Lung Cancer

For individuals with non-small-cell lung cancer (NSCLC) who receive interim FDG-PET as an adjunct to interim CT, the evidence includes numerous small observational studies. 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 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 that the technology results in an improvement in the net health outcome.

Ovarian Cancer

For individuals with ovarian cancer who receive interim FDG-PET as an adjunct to interim CT, the evidence includes a systematic review. Relevant outcomes are OS, disease-specific survival, change in disease status, QOL, morbid events, and treatment-related morbidity. The systematic review identified 9 studies that calculated hazard ratios for various FDG-PET parameters (eg, SUVmax, MTV, 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 that the technology results in an improvement in the net health outcome.

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. 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology and Society for Pediatric Radiology

The American College of Radiology and the Society for Pediatric Radiology (2016; revised 2021amended 2018) updated their joint practice parameterguidelines for performing fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) coupled with computed tomography (CT) in oncology.[112,]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. The practice parameter states that examples of indications for FDG-PET/CT include, but are not limited to, the following:

- "Staging on presentation for guiding initial treatment strategy in patients with a known malignancy;
- Monitoring response to therapy to include determining whether residual abnormalities identified with another imaging modality represent persistent viable tumor or posttreatment changes (inflammation, fibrosis, or necrosis);
- Restaging in the setting of relapse;
- Attempting to localize the site of primary tumor when metastatic disease is the initial manifestation of malignancy;
- Verifying and localizing "occult" disease, especially in the presence of clinical indicators such as elevated tumor markers;
- Evaluating an abnormality considered "indeterminate" by another imaging modality to determine wheter glucose metabolism in that abnormality favors a benign or malignant process;
- Guiding treatment goals, such as curative versus palliative therapy;
- Guiding biopsy and radiation therapy planning."

European Association of Nuclear Medicine

The European Association of Nuclear Medicine (2021) published guidelines on FDG-PET/CT in the management of ovarian cancer, which are endorsed by the American College of Nuclear Medicine, the Society of Nuclear Medicine and Molecular Imaging, and the International Atomic Energy Agency.[113,] The guidelines acknowledge the lack of clinical trials evaluating the role of FDG-PET scanning when used for assessment of response to therapy in patients with ovarian cancer (Level of evidence, II; grade B recommendation). Further recommendations are 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 2.

Table 2. Recommendations for Interim PET Scanning

Guideline	Version	Recommendation
Bladder cancer[114],	2.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Breast cancer[115],	4.2022	"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."
CNS cancers[116],	1.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Cervical cancer[117],	1.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Colon cancer[118],	1.2022	"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."
Esophageal and EGJ cancers[119],	3.2022	"Regardless of the cut-off values used,...studies...concluded that FDG-PET is predictive of pathologic response and survival in patients with esophageal cancer who undergo preoperative treatment." "Increased FDG uptake due to radiation-induced inflammation limits the use of FDG-PET for early response assessment of esophageal carcinomas. To reduce the incidence of false-positive results due to inflammation, the guidelines recommend that FDG-PET/CT (preferred) or FDG-PET should be performed at least 5 to 8 weeks after the completion of preoperative therapy. However, the guidelines caution that post-treatment FDG-PET results should not be used to select patients for surgery since FDG-PET cannot distinguish microscopic residual disease."
Soft tissue sarcoma[120],	2.2022	Interim PET for assessing response to ongoing treatment is not addressed. "PET/CT scan may be useful in staging, prognostication, grading, and determining response to neoadjuvant therapy."
Head and neck cancers[121],	2.2022	Short-term (<6 months) locoregionally advance disease: "FDG PET/CT should be performed within 3 to 6 months of definitive radiation of systemic therapy/RT for assessment of treatment response and to identify any residual tumor." "Early FDG-PET/CT scans before 12 weeks are associated with significant false-positive rates and should be avoided in the absence of signs of recurrence or progression." "The optimal timing of PET scans after radiation treatment appears to be at the 3- to 6-month window. A negative PET at this time point predicts improved overall survival at 2 years."
Hepatobiliary cancers[122],	2.2022	Interim PET for assessing response to ongoing treatment is not addressed. "PET/CT has limited sensitivity but high specificity, and may be considered when there is an equivocal finding. When an HCC is detected by CT or MRI and has increased metabolic activity on PET/CT, higher intralesional SUV is a marker of biologic aggressiveness and might predict less optimal response to locoregional therapies."
Hodgkin lymphoma[123],	2.2022	"Interim PET scans can be prognostic and are increasingly being used to assess treatment response during therapy as they can inform treatment adaptation, including treatment escalation and de-escalation. Early interim PET imaging after chemotherapy has been shown to be a sensitive prognostic indicator of treatment outcome in patients with advanced-stage disease. Interim PET scans may be useful to identify a subgroup of patients with early- and advanced-stage disease that can be treated with chemotherapy alone. The NCCN Guidelines emphasize that the value of interim PET scans remains unclear for some 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."
Cutaneous melanoma[124],	3.2022	Interim PET for assessing response to ongoing treatment is not addressed. "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."
Malignant pleural mesothelioma[125],	1.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Multiple myeloma	5.2022	Interim PET for assessing response to ongoing treatment is not addressed.

124,		
Non-Hodgkin lymphoma: B-cell[126],	5.2022	"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 chemoimmunotherapy have a favorable long-term outcome despite a positive interim PET scan."
Non-Hodgkin lymphoma: T-cell[127],	2.2022	"The guidelines recommend interim restaging with PET/CT or CT scan after 3 to 4 cycles of chemotherapyfor all patients."
Non-Hodgkin lymphoma: PCBCL[128],	2.2022	Interim PET for assessing response to ongoing treatment is not addressed.
NSCLC[129],	3.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Ovarian cancer[130],	3.2022	Interim PET for assessing response to ongoing treatment is not addressed. 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[a]
Pancreatic adenocarcinoma[131],	1.2022	Interim PET for assessing response to ongoing treatment is not addressed. "PET/CT scan may be considered after formal pancreatic CT protocol in high-risk patients to detect extrapancreatic metastases. It is not a substitute for high-quality, contrast-enhanced CT."
Prostate cancer[132],	4.2022	"F-18 FDG-PET/CT should not be used routinely since data are limited in patients with prostate cancer."
Rectal cancer[133],	1.2022	"Chest/abdominal/pelvic CT with contrast or chest CT and abdominal/pelvic MRI with contrast to monitor progress of therapy. PET/CT should not be used. "
SCLC[134],	2.2022	"PET/CT is not recommended for routine follow-up."
Thyroid carcinoma[135],	2.2022	Interim PET for assessing response to ongoing treatment is not addressed.
Uterine neoplasms[136],	1.2022	Interim PET for assessing response to ongoing treatment is not addressed.

CNS: central nervous system; CT: computed tomography; EFS: event-free survival; EGJ: esophagogastric junction; FDG: fluorine 18 fluorodeoxyglucose; HCC: hepatocellular carcinoma; MRI: magnetic resonance imaging; NCCN: National Comprehensive Cancer Network; NSCLC: non-small-cell lung cancer; OS: overall survival; PCBCL: primary cutaneous B-cell lymphoma; PET: positron emission tomography; SCLC: small-cell lung cancer; SUV: standardized uptake value.

[a] 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:[137],

"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."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
December 2013	Replace policy	Policy updated with literature review. References 1-3, 5-11, 18, 20, 21, and 23 added. Others removed or renumbered. No change in policy statement.
December 2014	Replace policy	Policy updated with literature search; adding references 3, 9-12, 17-25, and 27-67; updating references 13, 16, and 68; references 1-11 (trial registrations) deleted. No change to policy statements. Title revised, added "Interim€ .
December 2015	Replace policy	Policy updated with literature review through July 8, 2015; references 13- 16, 18-9, 25, and 27 (NCCN) deleted; references 3-5, 24, and 36 added; reference 58 updated. Policy statement unchanged.
December 2016	Replace policy	Policy updated with literature review; references 1-2, 5-10, 16-19, 23, 28- 31, 42-44, 55-60, 68-69, 71, 74, and 78 were added. Policy statement unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; references 5, 19, 20, 24-27, 30-34, 44-56, 66-68, 71, 84, and 94-95 were added. The following policy statement was added: The use of interim positron emission tomography scans to determine response to tyrosine kinase inhibitor treatment in patients with gastrointestinal stromal tumors is considered medically necessary.
December 2018	Replace policy	Policy updated with literature review through July 26, 2018; references 5, 7, 19-21, 26, 31, 34, 39, 80, 134 added; references 38 and 111-133 updated. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through July 8, 2019; references added, references on NCCN updated. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 30, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through August 6, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through August 1, 2022; reference added. Minor editorial refinements to policy statements; intent unchanged.