# Summary

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# Summary: Appropriate Use Criteria for $^{18}$F-FDG PET/CT for Initial Staging of Malignant Disease

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## EXECUTIVE SUMMARY

The appropriate use criteria (AUC) documents are intended to aid medical practitioners in the appropriate use of imaging technology in specific clinical scenarios based on rigorous appraisal of the available published evidence. The purpose of this document is to summarize the appropriate use of PET/CT with $^{18}$F-FDG in the initial staging of malignant disease. A multidisciplinary expert panel convened to appraise an independently performed systematic review and develop the AUC for initial staging of head and neck cancer, lung cancer, breast cancer, esophageal cancer, colorectal cancer, pancreatic cancer, melanoma, lymphoma, myeloma, and sarcoma with an appropriateness score for each clinical scenario established by using a modified Delphi process (Table 1). The full document including the methodology details, discussion of evidence, appendices, and the supplemental material can be accessed at https://snmmi.org/Web/Clinical-Practice/Appropriate-Use-Criteria/Articles/Appropriate_Use_Criteria_for_18F-FDG_PET_CT_for_Initial_Staging_of_Malignant_Disease.

## HEAD AND NECK CANCER

Head and neck cancer includes epithelial malignancies of the oral cavity, nasal cavity, paranasal sinuses, pharynx, and larynx. In the United States, head and neck cancer comprises about 3% of all malignancies, with squamous cell carcinoma accounting for 90% of all head and neck cancers. Tobacco, alcohol, and human papilloma virus infection are recognized risk factors. Other implicated risk factors include betel quid chewing, diet, ultraviolet light exposure, and the herpes simplex and Epstein-Barr viruses. The 5-y relative survival is 69%, depending on the disease stage at diagnosis; that, in turn, determines the types of treatment rendered, including surgery, radiotherapy, and systemic therapy (*1*).

$^{18}$F-FDG PET/CT received an appropriateness score of 6 (may be appropriate) in patients with clinical early-stage T1 or stage I head and neck cancers for the detection of local nodal metastases. In this category, $^{18}$F-FDG PET/CT may also be helpful in detecting occult primary tumors and unrecognized neck nodal metastases based on a conventional imaging work-up. In patients with clinical stage T2–T4 or stage II–IV, the appropriateness score was 8 (appropriate) when the clinical scenario can range from locally advanced but still curable disease, and PET/CT provides critical information for treatment planning to patients with true locoregional nodal metastatic disease when the determination of the extent of locoregional or distant metastatic disease and potential synchronous primary cancers may have implications for subsequent treatment decisions.

## LUNG CANCER

Lung cancer represents 11.7% of all cancers and is the leading cause of cancer death at an estimated 20.4% of all cancer deaths. The 5-y relative survival based on 2014–2020 data is 26.7% (*2*). The main types of lung cancer are non–small cell lung cancer, representing 80%–85% of all cancers, and small cell lung cancer, representing 10%–15% of all cancers. The main non–small cell lung cancer subtypes include adenocarcinoma, squamous cell carcinoma, and large cell carcinoma.

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**TABLE 1**
Summary of Appropriateness Scores for the Use of $^{18}$F-FDG PET/CT in Initial Staging of Cancer

| Cancer type | Appropriateness | Score |
|---|---|---|
| Head and neck cancer: T1 or stage I | May be appropriate | 6 |
| Head and neck cancer: T2–T4 or stage II–IV | Appropriate | 8 |
| Lung cancer: patients with potentially surgically curative disease | Appropriate | 9 |
| Lung cancer: patients with noncurative disease | May be appropriate | 6 |
| Breast cancer: stage I–IIA | Rarely appropriate | 3 |
| Breast cancer: stage IIB–IV | Appropriate | 8 |
| Esophageal cancer: M0 disease | Appropriate | 9 |
| Esophageal cancer: M1 disease | May be appropriate | 5 |
| Colorectal cancer: patients with potentially surgically curative disease | Appropriate | 8 |
| Colorectal cancer: patients with noncurative disease | May be appropriate | 5 |
| Pancreatic cancer: patients with potentially surgically curative disease | Appropriate | 8 |
| Pancreatic cancer: patients with noncurative disease | May be appropriate | 5 |
| Melanoma: stage I–II | May be appropriate | 4 |
| Melanoma: high-risk stage II, stage III, or stage IV | Appropriate | 8 |
| Lymphoma | Appropriate | 9 |
| Multiple myeloma: stage I–II | May be appropriate | 4 |
| Multiple myeloma: stage III–IV | Appropriate | 8 |
| Sarcoma | May be appropriate | 6 |

In this AUC, particularly for non–small cell lung cancer, $^{18}$F-FDG PET/CT received an appropriateness score of 9 (appropriate) in patients with potentially surgically curative disease. $^{18}$F-FDG PET/CT also enabled the detection of lymph node metastasis, confirmed bone metastases or oligometastatic disease, and improved radiotherapy planning. In patients with noncurative disease, the appropriateness score was lowered to 6 (may be appropriate) because, although in many cases $^{18}$F-FDG PET/CT provides valuable clinical information about the extent of disease or the presence or absence of bony metastases and facilitates palliative radiotherapy to involved sites to optimize care, in cases with unequivocal findings of advanced disease on conventional imaging modalities, its additional value might be less clear.

## BREAST CANCER

Breast cancer is the main cancer in women, but it also represented the second most frequently diagnosed cancer in 2022 (corresponding to 11.6% of all cancers) and the fourth leading cause of mortality worldwide (6.9%) (*3*).

The most common histologic type is no special type (NST) (75%–80%), followed by invasive lobular carcinoma (10%–15%) and special types such as medullary, apocrine, neuroendocrine, mucinous, tubular, and metaplastic carcinomas in up to 5% of cases (*4*). Breast cancer is a heterogeneous disease with different biologic subtypes, depending on the expression of hormone receptors (HRs), including estrogen receptors or progesterone receptors, and the levels of the human epidermal growth factor receptor 2 (HER2). There are 4 main subtypes of breast cancer that are based on receptor expression: luminal A-like (HR-positive [+]/HER2 and low grade or low proliferation); luminal B-like (HR+/HER2 and high grade or high proliferation), with luminallike corresponding to 65% of cases; HER2+ (HR+ or HR-negative [−]/HER2+), corresponding to 15%–20% of cases; and triple negative (HR−/HER2−) corresponding to 10%–15% of cases.

According to the joint European Association of Nuclear Medicine/Society of Nuclear Medicine and Molecular Imaging guideline on the role of $^{18}$F-FDG PET/CT in NST breast cancer published in 2024 (*5*), $^{18}$F-FDG PET/CT is recommended for baseline staging of patients with clinical stage IIB and stage III NST breast cancer. It has been accepted that invasive lobular carcinomas are less FDG avid than NSTs, and invasive lobular carcinoma metastases are less likely to be detected on FDG PET (*6*). Thus, the recommendation for using FDG PET/CT for patients with invasive lobular carcinoma is still a debatable topic.

$^{18}$F-FDG PET/CT received an appropriateness score of 8 (appropriate) in patients with stage IIB–IV NST breast cancer and may replace systemic staging that uses conventional imaging modalities. This appropriateness applies regardless of receptor status and includes ER+, HER2+, and triple-negative tumors. In patients with stage I–IIA, the appropriateness score was lowered to 3 (rarely appropriate).

## ESOPHAGEAL CANCER

Esophageal cancer is the sixth leading cause of cancer deaths worldwide, with an incidence that is increasing. Although squamous cell carcinoma remains the most common histologic type worldwide, adenocarcinoma of the esophagus or gastroesophageal junction has become the more common subtype in the United States. In 2024, there were an estimated 22,370 cases of esophageal cancer diagnosed and 16,310 deaths in the United States, with a male-to-female ratio of 4:1 (*7*). Curative treatment of esophageal cancer might involve surgical resection, many times after neoadjuvant therapy (except for early-stage disease) or definitive chemoradiation, with more recent integration of immune and other

novel treatment approaches to the management of localized and advanced disease.

$^{18}$F-FDG PET/CT received an appropriateness score of 9 (appropriate) for the initial staging of esophageal cancer in patients who are potential candidates for definitive therapy with intent to cure on the basis of detection of distant metastases, leading to a significant percentage of treatment changes. Endoscopic ultrasound provides more accurate information about nodal involvement and T stage; therefore, these modalities complement each other in initial staging of patients with potentially curable disease. Imaging with $^{18}$F-FDG PET/CT can also be useful in radiotherapy planning, for example, in the context of definitive chemoradiation or neoadjuvant chemoradiation. In patients who are not candidates for definitive therapy, $^{18}$F-FDG PET/CT received an appropriateness score of 5 (may be appropriate), with value in specific clinical scenarios, such as the confirmation of suspected metastases on other modalities or the planning of palliative therapeutic interventions. Moreover, initial baseline $^{18}$F-FDG PET/CT facilitates comparison to follow-up $^{18}$F-FDG PET/CT for treatment response assessment and restaging.

## COLORECTAL CANCER

Colorectal cancer is the fourth most diagnosed cancer and the third leading cause of cancer death in the United States. The National Cancer Institute estimated that 152,810 people would be diagnosed with colorectal cancer and 53,010 would die from this disease in the United States in 2024 (*8*). The current literature review shows that $^{18}$F-FDG PET/CT offers significant value in determining initial management of this cancer, with particular interest in assessing the presence of metastatic disease as a determinant of course of therapy (*9*,*10*).

$^{18}$F-FDG PET/CT received an appropriateness score of 8 (appropriate) for the initial staging of colorectal cancer in patients who are potential candidates for surgical intervention with intent to cure from the detection of nodal metastases, especially distant metastases. Studies consistently show changes in management in a significant percentage of such patients from PET/CT findings. Patients with findings indeterminate for metastases on other modalities and those with apparently limited hepatic metastasis often benefit from preoperative $^{18}$F-FDG PET/CT. Imaging with $^{18}$F-FDG PET/CT can also be useful in radiotherapy planning, such as in the neoadjuvant treatment of patients with rectal carcinoma. In patients for whom curative surgery is not an option, $^{18}$F-FDG PET/CT received an appropriateness score of 5 (may be appropriate), with value in specific clinical scenarios, such as the confirmation of suspected metastases on other modalities or the planning of palliative therapeutic interventions. Moreover, initial baseline $^{18}$F-FDG PET/CT facilitates comparison to follow-up $^{18}$F-FDG PET/CT for treatment response assessment and restaging.

## PANCREATIC CANCER

Pancreatic cancer more commonly arises from the exocrine cells of the organ (adenocarcinoma) and is typically diagnosed at an advanced stage with an overall poor prognosis. Pancreatic cancer comprises 3.3% of all new cancer cases and 8.5% of all cancer deaths. The 5-y relative survival is 12.8% (*11*). Patients with clinically suspected pancreatic cancer undergo pancreatic protocol CT or MRI of the abdomen for initial imaging evaluation of the extent of disease. Additional diagnostic studies may include endoscopic retrograde cholangiopancreatography, endoscopic ultrasonography, tissue biopsy with molecular profiling, and genetic testing for inherited mutations, which inform optimal management decisions, including whether the disease is resectable or unresectable (*12*). Resection of the primary tumor may allow for potential cure in less than 20% of patients with localized disease at diagnosis.

$^{18}$F-FDG PET/CT received an appropriateness score of 8 (appropriate) in patients with potentially surgically curative disease, given the major management impact from detecting unrecognized metastases. In patients with nonresectable locally advanced or metastatic disease based on a non-PET imaging work-up, the appropriateness score was lowered to 5 (may be appropriate), for example, to decipher the extent of metastatic disease and the total tumor volume and metabolism that may impact subsequent management decisions.

## MELANOMA

According to the American Cancer Society, 100,640 new cases of invasive melanoma were expected be diagnosed and 8,290 people expected to die from melanoma in the United States in 2024. Melanoma represents about 1% of skin cancers but is the most common cause of skin cancer mortality (*7*). Risk factors for melanoma include sun exposure; number of moles; lighter skin, hair, and eye color; family history; and genetics (*13*). Melanoma death rates declined rapidly (about 6%–7% per year) from 2013 to 2017, largely due to advances in melanoma treatment. Staging of melanoma is based on the depth of invasion of the primary tumor (Breslow thickness): T0 melanoma in situ, T1 less than 1 mm, T2 less than 2 mm, T3 equal to 2–4 mm, and T4 greater than 4 mm. Ulceration and mitotic rate increase the risk of disease spread for any given thickness. Sentinel lymph node biopsies are typically performed for patients with tumors greater than 0.8-mm Breslow thickness or with other risk factors. Patients with sentinel lymph node involvement or clinically detectable regional lymph node disease are classified as having stage III disease, and those with distant metastases are classified as having stage IV disease. It is no longer standard of care for patients with sentinel lymph node involvement to undergo completion lymph node dissection. Adjuvant checkpoint inhibitor immunotherapy is recommended for patients with high-risk stage II disease (T3 with ulceration or T4 with or without ulceration). Adjuvant immunotherapy or B-Raf protooncogene/serine/threonine kinase/mitogen-activated extracellular signal-regulated kinase inhibitor therapy is recommended for patients with resected stage III disease. Patients with palpable regional nodal disease are increasingly being considered for neoadjuvant immunotherapy followed by surgical resection. Most patients presenting with stage IV disease will receive combination systemic immunotherapy, with long-term survival approaching 50%. Some patients with oligometastatic distant disease may be considered for surgery followed by adjuvant therapy.

The utility of $^{18}$F-FDG PET/CT relative to sentinel lymph node biopsy for picking up regional nodal disease in patients with stage I and II primary cutaneous melanoma was felt to be relatively low, receiving an appropriateness score of 4 (may be appropriate). In contrast, the utility of $^{18}$F-FDG PET/CT in picking up distant metastases (or in-transit metastases) in patients with high-risk stage II, stage III, or oligometastatic stage IV disease (in general, those being considered for surgery plus adjuvant therapy or, increasingly, neoadjuvant immunotherapy) was felt to be high, receiving an appropriateness score of 8 (appropriate), as it had reasonable sensitivity (40%–80%) and high specificity (>90%) and could prompt a change in treatment approach (e.g., a direct application of systemic combination immunotherapy) for those determined to have distant

metastatic disease. Patients with stage IIB or stage IIIA disease, in which the risk of distant metastases at presentation is low (<5%), fall into a gray area, for which the application of $^{18}$F-FDG PET/CT may be individualized on the basis of patient preference and their interest in receiving adjuvant therapy.

## LYMPHOMA

Lymphoma represents a broad group of hematologic malignancies with sometimes diverse presentations and clinical courses, divided into Hodgkin lymphoma (HL) and several subtypes of non-Hodgkin lymphomas (NHLs). The National Cancer Institute estimated 80,620 new diagnoses of NHL and 20,140 deaths related to this disease in the United States in 2024 (*14*). HL is less common, with an estimated 8,570 new diagnoses and 910 related deaths in the United States in 2024 (*15*). Based on clinical behavior, lymphomas are typically classified as aggressive or indolent. Traditionally, FDG PET has been considered useful primarily in HL and aggressive NHL. However, the heterogeneous presentation of many NHL subtypes that are generally considered indolent and the clinical importance of identification of unsuspected aggressive lesions has led to the incorporation of FDG PET/CT in the staging and follow-up algorithms for a wide variety of lymphomas. In most cases, FDG PET imaging has proved superior to the previous imaging standard of diagnostic CT in initial staging (*16*,*17*). Because of the broad scope of this topic, the current review addresses the use of FDG PET imaging in the global category of lymphoma, with the caveat that truly indolent lesions may be poorly visualized.

FDG PET/CT received an appropriateness score of 9 (appropriate) for the initial staging of lymphoma overall. The overwhelming preponderance of the literature demonstrates superiority of FDG PET/CT over other imaging modalities in the staging of nodal, extranodal, and bone marrow involvement, with generally high sensitivity and specificity. Major clinical guidelines list FDG PET/CT as routinely appropriate in the initial staging of HL and aggressive NHL. Despite a lower sensitivity in patients with indolent lymphomas, current data support broader use of FDG PET/CT in such patients than previously thought. Because of its excellent specificity in such cases and its superiority over other modalities in the detection of unsuspected aggressive lesions, FDG PET/CT is now considered appropriate in such cases, especially in patients being considered for localized therapy.

## MULTIPLE MYELOMA

Plasma cell dyscrasias encompass a heterogeneous group of disorders because of monoclonal proliferation of lymphoplasmacytic cells in the bone marrow, that is, a spectrum of monoclonal gammopathies. The most prevalent and gravest is multiple myeloma, accounting for approximately 10% of hematologic malignancies and 2% of all cancer diagnoses (*18*). According to National Cancer Institute estimates, there was expected to be 35,780 new cases of multiple myeloma and 12,540 related deaths in 2024. The 5-y relative survival from 2014 to 2020 was 61.1% (*19*).

The tumor, node, and metastasis staging system is not used for multiple myeloma but rather a combination of laboratory and imaging findings. Imaging for multiple myeloma has 2 primary purposes: detecting myeloma bony involvement or detecting extramedullary disease. $^{18}$F-FDG PET/CT has relatively high sensitivity and specificity for these purposes.

The Durie and Salmon PLUS staging system presented in 2003 first incorporated advanced imaging such as $^{18}$F-FDG PET/CT or MRI for myeloma staging (*20*). In 2021, the National Comprehensive Cancer Network guidelines suggested CT or PET/CT to be used in place of a skeletal survey when evaluating for osteolytic lesions (*21*). The latest International Myeloma Working Group consensus guideline states that patients with myeloma can be initially evaluated by $^{18}$F-FDG PET/CT or low-dose whole-body CT with level IV evidence (*22*). The most recent International Myeloma Working Group guidelines recommend $^{18}$F-FDG PET/CT or low-dose whole-body CT as first-line imaging in patients with myeloma and that MRI should be performed in the case of negative or inconclusive findings. The CT portion of PET/CT is appropriate for evaluating osteolytic lesions, and the PET portion may demonstrate early marrow uptake before osteolysis. MRI can complement $^{18}$F-FDG PET/CT for the evaluation of diffuse myeloma marrow involvement. $^{18}$F-FDG PET/CT is also valuable for the detection of extramedullary disease.

$^{18}$F-FDG PET/CT received an appropriateness score of 4 (may be appropriate) for stage I–II and an appropriateness score of 8 (appropriate) for stage III–IV in the initial staging of untreated multiple myeloma.

## SARCOMA

Sarcoma is a heterogeneous family of relatively rare cancers that may form from connective, cartilage, fibrous, and fat tissues; muscles; blood vessels; and bone. Risk factors for sarcoma include prior external-beam irradiation and certain chemical exposure and are linked with genetic cancer predisposition diseases. Treatment and prognosis are highly dependent on the type, location, extent, and grade of cancer. Localized low-grade tumors may be cured by surgical excision, whereas metastatic and high-grade tumors require systemic therapy and are generally associated with poor outcome (*23*,*24*).

The American Cancer Society estimated that 13,590 individuals (adults and children) would be diagnosed with soft-tissue sarcomas in the United States in 2024 and about 5,200 would die from these tumors (*25*). Liposarcoma and leiomyosarcoma are the most common types of soft-tissue sarcomas. Other soft-tissue sarcomas include synovial sarcoma, angiosarcoma, dermatofibrosarcoma protuberans, Kaposi sarcoma, gastrointestinal stromal tumor, desmoid tumor, rhabdomyosarcoma, and primary alveolar soft-part sarcoma.

The most common primary sarcomas of the bone include osteosarcoma, the Ewing sarcoma family of tumors, and undifferentiated pleomorphic sarcoma (previously called malignant fibrous histiocytoma) of bone. According to the American Cancer Society, each year, about 1,000 new cases of osteosarcoma are diagnosed in the United States and about half of these are in patients between the ages of 10 and 30 y. About 10% of osteosarcomas occur in individuals older than 60 y. Ewing tumors account for 1% of childhood cancers in the United States each year, and most occur in teens.

Although there is supportive evidence for certain sarcoma types, such as rhabdomyosarcoma, Ewing sarcoma, and osteosarcoma, there is little evidence for the numerous other sarcomas and the notion that primary sarcomatous tumors may exhibit a wide range of metabolic activities from low to high. Therefore, $^{18}$F-FDG PET/CT received a midrange appropriateness score of 6 (may be appropriate) in the initial staging of sarcoma primarily influenced by the heterogeneity of disease.

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