



Evolut Clinical Guideline 2058 for Tumor Imaging Positron Emission Tomography (PET)

Any Site, Breast Cancer, Melanoma

Guideline Number: Evolut_CG_2058	<u>Applicable Codes</u>	
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TABLE OF CONTENTS

STATEMENT	2
GENERAL INFORMATION	2
SPECIAL NOTE	2
CODING AND STANDARDS	2
CODING	2
APPLICABLE LINES OF BUSINESS	3
SUMMARY OF EVIDENCE	3
ANALYSIS OF EVIDENCE	5
POLICY HISTORY	5
LEGAL AND COMPLIANCE	6
GUIDELINE APPROVAL	6
<i>Committee</i>	6
DISCLAIMER	6
REFERENCES	7

STATEMENT

General Information

- *It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Special Note

- Positron Emission Tomography (PET) imaging, any site, not otherwise specified, is a non-covered CPT code.
- PET scan imaging, full and partial-ring pet scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes) is not medically necessary and is therefore a non-covered study ^(1,2)
- PET scan for whole body; melanoma for non-covered indications is not medically necessary and is therefore a non-covered study ^(3,4)

CODING AND STANDARDS

Coding

G0219, G0235, G0252

Applicable Lines of Business

☒	CHIP (Children’s Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

SUMMARY OF EVIDENCE

Ultrasound, CT, MRI, or PET-CT for staging and re-staging of adults with cutaneous melanoma (Review) ⁽⁴⁾

Study Design: This is a systematic review published in the Cochrane Database of Systematic Reviews. It evaluates the diagnostic accuracy of imaging tests (Ultrasound, CT, MRI, PET-CT) for staging and re-staging adults with cutaneous melanoma.

Target Population: Adults with confirmed cutaneous invasive melanoma undergoing imaging for staging purposes.

Key Factors:

- **Objectives:** To determine the diagnostic accuracy of imaging tests for detecting nodal and distant metastases before sentinel lymph node biopsy (SLNB) and for whole-body imaging.
- **Methods:** Comprehensive search of multiple databases up to August 2016, including studies of any design that evaluated the imaging tests compared with histological confirmation or imaging with clinical follow-up.
- **Results:** 39 publications reporting on 5204 study participants. The accuracy of imaging for detection of regional nodal metastases before SLNB was evaluated in 18 studies. Summary sensitivity of ultrasound alone was 35.4% and specificity was 93.9%. Combining ultrasound with FNAC revealed summary sensitivity of 18.0% and specificity of 99.8%. Limited test accuracy data were available for whole-body imaging via PET-CT for primary staging or re-staging for disease recurrence.
- **Conclusions:** There is a lack of evidence on the accuracy of imaging in people with melanoma at different points on the clinical pathway. Imaging with ultrasound combined with FNAC before SLNB may identify around one-fifth of those with nodal disease, but further work is needed to establish cost-effectiveness.

The role of FDG-PET/CT in preoperative staging of sentinel lymph node biopsy-positive melanoma patient ⁽³⁾

Study Design: This is a retrospective multicenter cohort study conducted in the Region of Southern Denmark.

Target Population: Malignant melanoma (MM) patients with a positive sentinel lymph node biopsy (SLNB) who subsequently underwent FDG-PET/CT prior to lymph node dissection (LND).

Key Factors:

- **Objectives:** To determine FDG-PET/CT's efficacy in finding distant metastasis and its influence on subsequent diagnostic testing and treatment.
- **Methods:** Patient information was acquired from the Danish Melanoma Database and cross-referenced with OUH's patient records. The study included 46 patients from April 1, 2015 to April 1, 2016.
- **Results:** FDG-PET/CT did not uncover any distant metastases or lead to any alterations in treatment strategy. However, it provided false positive findings in 13% of patients, triggering additional procedures that did not impact the therapeutic strategy.
- **Conclusions:** The new diagnostic strategy did not find any MM metastases or uncover anything else of relevance. FDG-PET/CT provided false positive findings, indicating a need for re-evaluation of this strategy and further clinical trials.

PET Molecular Imaging in Breast Cancer: Current Applications and Future Perspectives ⁽²⁾

Study Design: This is a review article published in the Journal of Clinical Medicine.

Target Population: Breast cancer patients.

Key Factors:

- **Objectives:** To address the role of PET imaging in breast cancer care, focusing on the utility of 18F-fluorodeoxyglucose (FDG) PET in staging, recurrence detection, and treatment response evaluation.
- **Methods:** The review discusses current applications and future perspectives of PET molecular imaging in breast cancer, including novel radiopharmaceuticals and the integration of AI.
- **Results:** PET/CT is not routinely recommended for primary diagnosis due to high cost and limited sensitivity. However, it offers superior performance in detecting extra-axillary nodal and distant metastases in newly diagnosed stage III breast cancer. PET/CT is valuable for evaluating response to neoadjuvant chemotherapy and detecting recurrence. Novel PET radiotracers like 68Ga-FAPI and 18F-FES show promise in assessing various tumor behaviors and enhancing detection precision.
- **Conclusions:** PET/CT plays a crucial role in breast cancer management, with advancements in imaging techniques and precision medicine tracers offering significant improvements in diagnostic accuracy

ANALYSIS OF EVIDENCE

Shared Findings ⁽²⁻⁴⁾:

- **Diagnostic Accuracy:** All three studies highlight the diagnostic accuracy of PET imaging in detecting metastases. Dinnes et al 2019 and Frary et al 2016 focus on melanoma, while Katal et al 2024 discusses breast cancer. PET imaging is recognized for its ability to detect distant metastases, although its accuracy varies depending on the cancer type and stage.
- **False Positives:** Both Frary et al 2016 and Dinnes et al 2019 mention the occurrence of false positives in PET imaging. Frary et al 2016 reports a 13% false positive rate, while Dinnes et al 2019 notes the limited accuracy data available for PET-CT21.
- **Need for Further Research:** All studies emphasize the need for further research to establish the cost-effectiveness and clinical utility of PET imaging. Dinnes et al 2019 calls for more studies on the accuracy of imaging tests, Frary et al 2016 suggests re-evaluation of the diagnostic strategy, and Katal et al 2024 highlights the potential of novel radiotracers.

Conclusion ⁽²⁻⁴⁾:

In summary, while all three studies recognize the importance of PET imaging in cancer management, they differ in their focus on specific cancer types, patient populations, and the integration of innovative imaging techniques. Further research is needed to address the limitations and validate the findings across different clinical settings.

POLICY HISTORY

Date	Summary
June 2025	<ul style="list-style-type: none"> ● Added a subtitle: Any Site, Breast Cancer, Melanoma
May 2025	<ul style="list-style-type: none"> ● This guideline replaces Evolent Clinical Guideline 070-2 for Tumor Imaging PET Any Site (Unlisted PET) ● This guideline replaces Evolent Clinical Guideline 070-3 for Tumor Imaging PET - Breast Cancer - Initial Diagnosis ● This guideline replaces Evolent Clinical Guideline 070-4 for Tumor Imaging PET Melanoma (Noncovered Indications)



LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

REFERENCES

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.2.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed [March 12, 2025]. To view the most recent and complete version of the guideline, go online to NCCN.org. Accessed March 17, 2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Katal S, McKay MJ, Taubman K. PET Molecular Imaging in Breast Cancer: Current Applications and Future Perspectives. *J Clin Med.* 2024;13(12):3459. doi:10.3390/jcm13123459
3. Frary EC, Gad D, Bastholt L, Hess S. The role of FDG-PET/CT in preoperative staging of sentinel lymph node biopsy-positive melanoma patients. *EJNMMI Res.* 2016;6(1):73. doi:10.1186/s13550-016-0228-1
4. Dinnes J, Ferrante di Ruffano L, Takwoingi Y, et al. Ultrasound, CT, MRI, or PET-CT for staging and re-staging of adults with cutaneous melanoma. *Cochrane Database of Systematic Reviews.* 2019;2019(7):CD012806. doi:10.1002/14651858.CD012806.pub2