SNMMI AUC Factsheet for Estrogen Receptor-Targeted PET Imaging with 16α-^{18}F-Fluoro-17β-Fluoroestradiol (^{18}F-FES)

AUC INTRODUCTION

Nuclear medicine imaging studies are essential for the diagnosis and management of many diseases. The ready availability of medical imaging studies in conjunction with concerns about missed diagnoses has, at times, resulted in inappropriate use and overuse of all medical imaging technology, including nuclear imaging. The overuse may have resulted in an unnecessary financial burden on the healthcare system and in some cases unnecessary exposure to ionizing radiation. Overuse and inconsistent use of imaging procedures has prompted a push for multi-stakeholder consensus documents outlining the most appropriate and cost-effective use of advanced medical imaging studies.

It is hoped that this document, developed by medical experts knowledgeable in the appropriate use of 16α-^{18}F-Fluoro-17β-Fluoroestradiol (^{18}F-FES), will improve healthcare outcomes for the intended patient population while helping to decrease unnecessary imaging costs.

The purpose of this document is to describe the appropriate use criteria (AUC) of ^{18}F-FES imaging for patients with estrogen receptor positive breast cancer.

This document is presented to assist healthcare practitioners considering ^{18}F-FES imaging; however, each patient is unique, as is each clinical presentation, and therefore this document cannot replace clinical judgment.

CLINICAL SCENARIOS FOR ^{18}F-FES IMAGING IN BREAST CANCER

Positron emission tomography (PET) imaging with 16α-^{18}F-fluoro-17β-fluoroestradiol (^{18}F-FES), a radiolabeled form of estradiol, allows whole-body, noninvasive evaluation of estrogen receptor (ER). ^{18}F-FES is approved by the U.S. Food and Drug Administration as a diagnostic agent “for the detection of ER-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.”

^{18}F-FES detects ER that is functional for ligand binding. ER-negative breast cancers and most malignancies that arise from other body sites are unlikely to be detected on ^{18}F-FES PET. Some breast cancers that are ER-positive by standard immunohistochemistry testing may not express ligand-binding ER and thus will not be apparent on ^{18}F-FES PET.

Clinical Scenarios for Breast Cancer

Scenario #	Description	Appropriateness	Score
1	Diagnosing primary breast cancer	Rarely Appropriate	2
2	Diagnosing malignancy of unknown primary when a biopsy is not feasible or is nondiagnostic	May be Appropriate	5
3	Routine staging of the primary tumor (T staging)	Rarely Appropriate	1
4	Routine staging of axillary nodes	Rarely Appropriate	3
5	Routine staging of extra-axillary nodes and distant metastases	May be Appropriate	5
6	Staging invasive lobular carcinoma and low-grade invasive ductal carcinoma	May be Appropriate	5
7	Assessing ER status, in lieu of biopsy, in lesions that are easily accessible for biopsy	May be Appropriate	5
8	Assessing ER status in lesions that are difficult to biopsy, or when biopsy is nondiagnostic	Appropriate	8
9	After progression of metastatic disease, for considering second line of endocrine therapy	Appropriate	8
10	At initial diagnosis of metastatic disease, for considering endocrine therapy	Appropriate	8
11	At initial diagnosis of primary breast cancer, for considering endocrine therapy	Rarely Appropriate	1
12	Measuring response to therapy	Rarely Appropriate	1
13	Detecting lesions in patients with suspected/known recurrent or metastatic breast cancer	May be Appropriate	5
14	Detecting ER status when other imaging tests are equivocal or suspicious	Appropriate	8

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Rating and Scoring

The above clinical scenarios are scored as “appropriate,” “may be appropriate,” or “rarely appropriate” on a scale from 1 to 9. Scores 7–9 indicate that the use of the procedure is appropriate for the specific clinical scenario and is generally considered acceptable. Scores 4–6 indicate that the use of the procedure may be appropriate for the specific clinical scenario. This implies that more research is needed to classify the use of FES imaging in the particular clinical scenario definitively, or that some patient sub-populations in the described clinical scenario may benefit more than others. Scores 1–3 indicate that the use of the procedure is rarely appropriate for the specific clinical scenario and generally is not considered acceptable.

Methodology

The process for AUC development was modeled after the RAND/UCLA Appropriateness Method for AUC development. It includes multi-stakeholder identification of a list of relevant clinical scenarios, a systematic review of evidence in the literature, and a systematic synthesis of available evidence, while adhering to the Institute of Medicine’s standards for developing trustworthy clinical guidance.

This AUC was developed by the Society of Nuclear Medicine and Molecular Imaging with participation from experts affiliated with the following organizations: American College of Nuclear Medicine, Korean Society of Nuclear Medicine and the Lobular Breast Cancer Alliance.

For the complete manuscript and listing of references, visit:
https://s3.amazonaws.com/rdcms-snmmi/files/production/public/FileDownloads/Procedure_Standards/FES%20AUC%20revised%20%2D%202022%2D10%2D05%20Final%20BOD%20Approval.pdf

For a complete list of Appropriate Use Criteria (AUC) documents go to: www.snmmi.org/auc.