PRESS RELEASE

FDA Expands Indications for Neuraceq®, an Amyloid PET Imaging Agent, to Enhance Diagnosis and Care of Patients with Alzheimer's Disease

New indication added for selection of patients for amyloid-directed therapies
Quantitative image analysis added
Previous limitations of use removed

BOSTON, June 30th, 2025 – Life Molecular Imaging, Ltd. (LMI) announced that the U.S. Food and Drug Administration (FDA) has approved updated labeling for Neuraceq® (florbetaben F18 injection), expanding its indication for selecting patients for amyloid-targeting therapies, as described in the prescribing information of the therapeutic products, and including the utilization of quantitative analysis for positron emission tomography (PET) scans.

Key updates to the Neuraceq® label include:

- Expanded clinical indication to include use in both diagnostic assessment and identification of appropriate candidates for FDA-approved amyloid-targeting therapies.
- Utilization of quantitative amyloid plaque metrics in conjunction with visual image interpretation.
- Broader use for monitoring of therapy and following progression to Alzheimer's disease (AD).

Amyloid, a naturally occurring protein, can accumulate into harmful plaques in the brain, thereby causing AD. Neuraceq® binds selectively to these plaques, enabling detection via PET imaging. This capability assists clinicians in determining whether or not AD is contributing to a patient's cognitive symptoms, when combined with other diagnostic evaluations. This aligns with the prescribing information of FDA approved amyloid-targeting therapeutic products. The clinical studies section now includes that amyloid PET scans have been utilized in certain clinical trials to evaluate reductions in amyloid plaque following treatment with amyloid-targeting therapies.

"This FDA action is a major advancement in Alzheimer's diagnostics," said Andrew Stephens, Chief Medical Officer at Life Molecular Imaging. "Updating the Neuraceq® label to reflect the revised Appropriate Use Criteria for amyloid PET[1] enhances clinicians' ability to support patient decision making and identify individuals who may benefit from amyloid-targeting treatment - ultimately contributing to improved patient outcomes."

The safety profile of Neuraceq® has been confirmed to remain unchanged with the new indication.

Neuraceq® PET imaging is widely covered under Medicare and many private insurance plans, although policy specifics can vary. Clinicians and patients are encouraged to verify individual coverage details.

About Neuraceq® (florbetaben F 18 injection)

Indication (approved by FDA on 23 June 2025)
Neuraceq® is indicated for positron emission tomography (PET) of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment for:

- Evaluation of Alzheimer's disease (AD) and other causes of cognitive decline
- Selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products

Important Safety Information

Risk for Image Interpretation and Other Errors

Errors may occur in the estimation of brain amyloid beta neuritic plaque density during Neuraceq® image interpretation. The use of clinical information in the interpretation of Neuraceq® images has not been evaluated and may lead to an inaccurate assessment. Severe brain atrophy as well as motion artifacts that result in image distortion may limit the ability to distinguish gray and white matter on a Neuraceq® scan.

Perform image interpretation independently of the patient's clinical information. For cases where there is uncertainty as to the location of cortical signal, use co-registered anatomical imaging to improve localization of signal.

Radiation Risk

Neuraceq® contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe drug handling to protect patients and health care providers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Common Adverse Reactions

The overall safety profile of Neuraceq® is based on data from 1,090 administrations of Neuraceq® to 872 subjects. No serious adverse reactions related to Neuraceq® administration have been reported. The most frequently observed adverse drug reactions in subjects receiving Neuraceq® were injection site reactions consisting of pain (3.4%), erythema (1.7%), and irritation (1.1%).

Please see the Full Prescribing Information for Neuraceq® at Neuraceq.com

About Life Molecular Imaging (LMI)
Life Molecular Imaging GmbH, together with its affiliates in the UK and US (LMI) is a radiopharmaceutical company dedicated to developing and offering novel cutting-edge PET radiopharmaceuticals for imaging of neurodegenerative and cardiovascular diseases. The organization strives to be a leader in the molecular imaging field. Our mission is to pioneer innovative PET products that improve early detection and characterization of chronic and life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. By advancing novel PET radiopharmaceuticals for molecular imaging, LMI is focusing on a key field of modern medicine. To learn more about LMI, please visit https://life-mi.com. LMI, a member of the Life Healthcare group of companies, is being acquired by Lantheus Holdings, Inc. For more information about the pending acquisition, please visit https://www.lifehealthcare.co.za/news-and-info-hub/latest-news/life-healthcare-proposed-disposal-of-lmi/.

References

1) Rabinovici et al. Updated appropriate use criteria for amyloid and tau PET: A report from the Alzheimer's Association and Society for Nuclear Medicine and Molecular Imaging Workgroup. Alzheimers Dement. 2025 Jan;21(1):e14338. doi: 10.1002/alz.14338

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