November 7, 2022

Hon. Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Meeting of the Medicare Evidence Development and Coverage Advisory Committee [CMS-3431-N]

Dear Administrator Brooks-LaSure:

Life Molecular Imaging, Inc. (LMI) appreciates the opportunity to submit our comments on the above-referenced notice. LMI manufactures and markets Neuraceq® (florbetaben F18 for injection), a radiopharmaceutical agent that specifically identifies beta-amyloid (Aβ) plaque deposits when a positron emission tomography (PET) scan of the brain is performed. Neuraceq, along with other Aβ PET drugs, is subject to CED under a Medicare National Coverage Determination (NCD 220.6.20).

We appreciate that the Centers for Medicare and Medicaid Services (CMS) is seeking guidance and input on the requirements for CED protocols. After almost 20 years of NCDs requiring CEDs, and eight years without an update to this topic, we agree that it is time to refresh criteria, and urge CMS to examine the extent and level of evidence needed in each CED protocol to determine whether to cover, whether not to cover, or whether to delegate coverage at the local level.

We agree with CMS's notion that not every CED question requires a randomized controlled trial to derive an answer. In fact, through the National Oncologic PET Registry (NOPR), CMS accepted the results of a registry to change a coverage determination. However, we encourage CMS to accept data from registries, real world evidence, electronic health records, and administrative claims in a proportion that would lead to a reasonable conclusion based on the target (Medicare) population, rather than an unwieldy large multi-center registry or other data collection effort that may not provide any different conclusions.

To determine the appropriate study type, we encourage CMS not to mandate the type of study in a proposed NCD. Rather, we suggest that CMS pose the questions to be answered by the evidence collected that would be subsequently considered for coverage of the item or service, allowing stakeholders to suggest the type of study that would yield the data CMS finds useful to answer the questions. CMS could respond to these suggestions as part of the final NCD, and then require the data collection and analysis that was publicly deliberated.

We look forward to a robust discussion at the MEDCAC meeting and request your consideration of these comments. If you have any questions, please contact me at c.herring@life-mi.com .

Sincerely,

/s/

Cynthia Herring, MHA. BSNM, CPC
Head of Market Access