EXPANDED ACCESS/COMPASSIONATE USE POLICY

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LIST OF ABBREVIATIONS

EA	Expanded Access
CU	Compassionate Use
EAP	Expanded Access Policy
LOA	Letter of Authorization
ICF	Informed Consent Form
IND	Investigational New Drug Application
IRB	Institutional Review Board
AD	Alzheimer's Disease
LMI	Life Molecular Imaging
HCP	Health Care Professional

1 PURPOSE

This policy has been created to allow the use of LMI products for "expanded access" or "compassionate use" across the countries where LMI is responsible to supply investigational products. This document will outline the policy and requirements for requesting expanded access/compassionate use of LMI investigational products for patients who are unable to participate in clinical trials sponsored by LMI or other studies using LMI investigational products.

2 SCOPE

This policy is for health care professionals (HCP) requesting access to investigational products developed by LMI for diagnostic PET imaging. The policy also applies to provision of access to any product not approved for any purpose in the country from which the request is intended to be used. This also includes the time period between regulatory approval of an investigational product and its commercial availability in a country.

Any use of an unapproved, investigational product outside a clinical study in a country must be in accordance with local laws and regulations governing such programs.

In general, where permitted by local regulation, the investigational product supplied via expanded access (EA)/compassionate use (CU) may no longer be provided by LMI when it becomes available via the local healthcare system.

LMI may decide not to provide an investigational product. For example, if under this policy they do not intend to market the product in the country, or if the clinical site requesting access is not easily reachable from a production site.

This policy does not apply to marketed products approved for PET imaging of β-amyloid plaques for Alzheimer's disease (AD), including Neuraceq®. Off label use of Neuraceq® may be covered by this policy depending on the circumstances.

This policy may not be applicable in some territories where LMI has provided third parties with permission to run expanded access programs. In this case, LMI will inform the requester and facilitate contact to the respective third party.

3 ROLES AND RESPONSIBILITIES

- **Patient**
  Consults with licensed physician to explore and decide about alternative options.
- **Licensed Physician or Health Care Professional**
  Agrees to oversee the patient's treatment and works with LMI, files paperwork with appropriate regulatory authorities and ethics committees if requesting outside of LMI sponsored treatment protocol, and is responsible for patient care and reporting according to 21 CFR 312.60 or other applicable local legislation.
- **LMI**
  Willing to provide the investigational medical product and either submits the expanded access request to regulatory authority, allows the regulatory authority to cross-reference their investigational dossier on behalf of the requesting sponsor-investigator (an external HCP who both initiates and

conducts a clinical investigation) through a letter of authorization, or provides the necessary investigational medical product information for the sponsor-investigator to support an expanded access/compassionate use request.

- **Institutional Review Board (IRB) / Ethics Committee** Reviews expanded access protocol and consent to ensure that the patient is informed about the nature of the treatment.
- **Competent Authority** Reviews the expanded access or compassionate use request and determines if the treatment may proceed.

4 POLICY

4.1 Introduction

LMI is committed to developing innovative imaging solutions for patients with serious or life-threatening conditions. We recognize that there may be situations where patients with no alternative diagnostic options may seek access to our investigational products outside of clinical trials. This policy outlines our approach to Expanded Access for products under investigation at LMI.

The diagnostics LMI are developing for rare and difficult to treat disorders are a less invasive and well tolerated alternative to other diagnostics available in the clinic. For patients who do not qualify for ongoing clinical trials conducted by LMI or other sponsors, expanded access/compassionate use is a way to ensure they may get the appropriate diagnoses to support their treatment plan and/or be counselled.

4.2 Patient Eligibility Criteria

To be eligible for access to an investigational product, patients must meet the following criteria:

- Suffer from a serious or immediately life-threatening disease or condition.
- Have undergone appropriate standard diagnostic test without success/with inconclusive results and no comparable or satisfactory alternative diagnostic test is available or exists to test for the disease or condition.
- Are ineligible for participation in any ongoing clinical study of the investigational product conducted by LMI or other sponsor, which includes lack of access due to geographic limitations.
- Has a disease for which there is sufficient evidence of a projected benefit from the use of the investigational product and the benefit outweighs the known or anticipated risks.
- There is adequate information to support appropriate dosing for a special population patients such as pediatric, elderly, renal or hepatic disease, etc.

4.3 Investigational product criteria

In addition to the patient eligibility requirements, the investigational product must meet the following criteria:

- The product is under investigation and may be used in one or more clinical studies sponsored by LMI.
- There is sufficient evidence to expect that the investigational product will have an acceptable safety profile for the intended patient population.
- The provision of the investigational product will not interfere with or compromise the clinical development of the product by LMI.

4.4 Treating HCP criteria and responsibilities

The health care professional(s) (HCP) attending to the patient(s) who are approved to receive an investigational product through expanded access or compassionate use must be properly licensed and fully qualified to recommend and oversee administration of the product.

The HCP must be able to comply with the following:

- Any applicable country-specific legal and regulatory requirements related to administering an investigational product to patients under expanded access or compassionate use.
- Any LMI requirements in terms of medical criteria, safety reporting, drug supply/use and protection of intellectual property. A treating HCP may submit questions or requests regarding expanded access and compassionate use to expaccess@life-mi.com.
- Providing in the EA request all relevant medical documentation, including the patient's medical history, diagnosis, and justification for requesting access to the investigational product.
- Provide to LMI a current signed curriculum vitae and investigator information according to regional requirements.
- Upon request, provide LMI with details on the success/failure of the procedure.
- Report all adverse drug reactions to LMI

4.5 Request for Expanded Access or Compassionate Use (EA/CU)

HCPs may request expanded access or compassionate use of LMI investigational products by accessing the fillable form on the website https://life-mi.com/expanded-access-program/. They may additionally send an email to the attention of Medical Affairs at expaccess@life-mi.com.

Receipt of all requests for EA/CU will be acknowledged within 5 business days. HCPs may request updates by email on the progress of review by the competent regulatory authority, if applicable. LMI will aim to respond within 2 business days to any follow up inquiries from HCPs requesting EA/CU. LMI may contact the

qualified HCP for more information at any time to help support and fully evaluate the request.

HCPs with patients who meet requirements outlined in this policy and are approved for EA/CU will be provided with any treatment protocol and associated informed consent form (ICF) available for the investigational product of interest, if applicable.

Generally, if HCPs are interested in EA/CU, they should confirm their ability to comply with the following:

- Will obtain the appropriate regulatory and/or ethics committee approvals and informed patient consent
- Will comply with all applicable legal and regulatory requirements associated with the EA/CU request.
- Will comply with all medical requirements, safety reporting, and other data provisions requested by LMI or the competent authority. This may be outlined in a prepared contract with LMI, if applicable.

HCPs may need to request the Letter of Authorization (LOA) to cross reference the relevant chemistry, manufacturing and controls information on the investigational product with their inquiry to LMI if they are submitting an individual patient IND. This is not required if LMI provides a treatment protocol to the HCP. If needed, LMI will provide the LOA upon request.

LMI will facilitate providing the relevant investigational product if the EA/CU request is granted and the HCP meets all specifications outlined in this policy. The granting of EA will be dependent on the competent health authority review of the request for the requesting country.

4.6 Charging policy

A patient treated may be charged for use of an investigational product for expanded access/compassionate use. Charging will be conducted as outlined below.

4.6.1 Costs Recoverable

When charging for doses of an investigational product used for EA/CU, LMI will recover only the direct costs of manufacture of the investigational product. Direct costs include those that are specifically and exclusively attributed to providing the drug for the investigational use. Examples include:

- Raw materials
- Manufacturing and quality control of the product
- Nonreusable supplies and equipment for manufacturing
- Shipping and handling
- Costs to acquire from another manufacturing source

LMI may also charge for costs of monitoring the EA/CU treatment protocol, complying with IND reporting requirements, and other administrative costs associated with maintaining the protocol.

Discussion of costs with the patient/HCP will commence once EA/CU is granted to the requesting HCP.

5 LIMITATIONS

- **No Guarantee of Access:** Submission of a request does not guarantee access to an investigational product sponsored by LMI. Each request will be considered on a case-by-case basis.
- **Supply Constraints:** Expanded access/compassionate use may be limited by the availability of the requested product. LMI prioritizes supply for clinical trials and regulatory submissions.
- **Termination of Access:** LMI reserves the right to discontinue Expanded Access to any investigational product at any time, particularly if new safety or efficacy data suggest that the risks outweigh the benefits.