*This template of medical necessity is available to all clinicians with patients diagnosed with HER2-positive metastatic breast cancer for whom they want to administer MARGENZA 250mg/10mL injection for intravenous use. Company personnel cannot assist with the completion of this template letter or customize it in any way. Only clinicians may complete the patient-specific clinical information and must determine the accuracy of all statements in the template. This template letter may be used regardless of identity of the potential payer of MARGENZA and the Company makes no representation or guarantee of the outcome or expected results of the use of this template.*

*Example only. For your convenience, we have highlighted the patient-specific fields on the template below. Please cite all product information in this template appropriately, using the provided references.*

[Physician’s Letterhead]

[Name of Insurance Co] [Date]

[Address of Insurance Co] ]

[City, State, ZIP of Insurer]

**Re: Statement of Medical Necessity for MARGENZA 250mg/10mL injection for intravenous use for:**

[Patient Name]

[Name of Policyholder]

[Patient Date of Birth}

[Insurance ID Number of Patient]

Insurance Group Number of Patient]

To Whom It May Concern:

I am writing on behalf of my patient [Patient’s name], to document the medical necessity for the use of MARGENZA to treat their metastatic breast cancer [ICD-10 code].

[Patient’s name] was diagnosed with HER2-positive metastatic breast cancer on [original diagnosis date]. [Patient’s name] has experienced [add any recent symptoms, conditions, treatments affecting the patient’s struggle with metastatic breast cancer. Omit If nothing pertinent.]

 Treatment with MARGENZA is medically necessary because of [Choose any or all of the following in your judgment (or add additional reasons based on your clinical judgment): radiological progression, clinical progression, adverse effects and/or poor quality of life (with or without progression) ].

This patient has previously received the following anti-HER2 regimens [indicate which prior therapies the patient has received, including all anti-HER2 medications].

***MARGENZA*** *is an FDA-approved HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.* ***MARGENZA*** *plus chemotherapy demonstrated a significant patient benefit in the SOPHIA pivotal trial supporting its approval: a 24% reduction in the risk of progression or death vs. trastuzumab plus chemotherapy. Results from SOPHIA have been recently published in the journal JAMA Oncology. MARGENZA has also been included in the NCCN Guidelines for the treatment of metastatic HER2-positive Breast Cancer with a Category 2A recommendation.*

Thus, I believe that treatment with MARGENZA is medically necessary and will provide essential clinical benefit in [patient name]’s current course of care.

Please do not hesitate to contact me at [physician’s telephone number] if you require any further information to approve this request.

Thank you for an expedient response,

[Physician Signature]

[Physician Name, M.D.]

[Practice Name]