This letter is only intended as a SAMPLE Letter of Medical Necessity For NERLYNX™ (neratinib) tablets

To Prescriber: Please refer to the IMPORTANT SAFETY INFORMATION in the Full Prescribing Information when determining whether therapy is medically appropriate for the individual patient.

[Date]

[Contact Name]

[Insurance Company Name]

[Insurance Company Address]

[City, State, Zip Code]

[Fax Number]

ATTN: Prior Authorizations/Appeals

Re: Coverage of NERLYNX

[Patient's first name] [Patient Last Name]

[Policy Number][Group Number]

Patient Date of Birth: [XX/XX/XXXX]

Diagnosis: [Diagnosis]

To Whom It May Concern:

I am submitting this letter to document the medical necessity of NERLYNX for my patient, [patient name] [policy number] for the treatment of _____. The FDA approved the use of NERLYNX for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. I am requesting authorization to treat [him/her] with [dosage amount] of NERLYNX for [length of time]. Please see Full Prescribing Information and Patient Information including additional safety information at NERLYNX.com.

The most common adverse reactions associated with NERLYNX (≥5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

[Describe the patient's history, diagnostic test results, previous and current treatment regimens, etc.]

[Patient's name's] current condition is [list the clinical reasons that have led to the decision to initiate or continue therapy]. As a result, I am requesting authorization to treat [him/her] with [dosage amount] of NERLYNX for [length of time].

In summary, NERLYNX is medically necessary and reasonable for [Patient Name's] medical condition. Please contact me if any additional information is required to ensure the prompt

approval of this course of treatment. Should you have any questions, please do not hesitate to call me at [phone number].

Sincerely,

[Physician name and credentials]

[NPI Number]