This letter is only intended as a SAMPLE Letter of Medical Necessity

For NERLYNX[™] (neratinib) tablets. Prescribing physician is solely responsible for the content contained in any letter of this kind depending on the patient's condition and other relevant information.

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]

[Insurance Company Name]

[Insurance Company Address]

[City, State, Zip Code]

[Fax Number]

ATTN: Prior Authorizations/Appeals

Re: Coverage of NERLYNX® (neratinib) tablets

[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:

[Sample introduction paragraph] I am writing to request urgent prior authorization of NERLYNX for my patient, [patient name], whose medical history and current condition meet the FDA-approved indication[s] and demonstrate a compelling clinical necessity for immediate initiation of this treatment. The FDA has approved NERLYNX as a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy]. Please see Full Prescribing Information and Patient Information including important safety information at www.nerlynxhcp.com.

[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 clinically appropriate for [Patient Name's] medical condition. I respectfully request that this prior authorization be approved promptly. If additional information or documentation is needed, please contact me directly at [phone number].

Sincerely,

[Physician name and credentials]

[Physician address and contact information]

[NPI Number]