Pr nerlynx®
neratinib tablets

Enrollment Form

Fax: 1-833-930-1614 Email: nerlynx@bayshore.ca

This form cannot be processed without Physician AND Patient consent. Please complete ALL fields and submit by Fax or Email.
For any questions, please call 1-855-635-2372, Mon-Fri, 8am-8pm EST.

1. PATIENT INFORMATION

Name _____ Date of Birth (DD/MMM/YYYY) _____ Sex: ☐ F

Home Address _____ Email _____

City _____ Province _____ Postal Code _____ Phone _____

Insurance: ☐ Private ☐ None ☐ Unknown Permission to leave voicemail: ☐ Yes ☐ No

Allergies: _____ Best time to contact: ☐ Morning ☐ Afternoon ☐ Evening

2. PATIENT ELIGIBILITY

☐ **I hereby confirm the patient:**
- **Is ≥18 years old and is being prescribed NERLYNX® for extended adjuvant treatment**
- **Has early-stage hormone receptor positive, HER2-overexpressed/amplified breast cancer**
- **Has completed trastuzumab-based adjuvant therapy within the last 12 months**

OR ☐ **I hereby confirm the patient:**
- **Is ≥18 years old and is being prescribed NERLYNX® in combination with capecitabine**
- **Has metastatic HER2-overexpressed/amplified breast cancer**
- **Received ≥2 prior anti-HER2-based regimens in the metastatic setting**

3. PHYSICIAN INFORMATION

Name _____ Office Contact _____

Office Address _____ Office Email _____

City _____ Province _____ Postal Code _____ Office Phone _____ Office Fax _____

4. PHYSICIAN AUTHORIZATION

By signing below, I certify that: (1) the prescribed therapy is medically necessary and is in the best interest of the patient listed above; (2) I am the patient's attending physician and confirm that the patient has been prescribed NERLYNX® as per the Canadian Product Monograph; (3) I will comply with state-specific prescription requirements and understand non-compliance with these requirements could result in further outreach by the patient's specialty pharmacy. I authorize the NERLYNX® Patient Support Program to be my designated agent to forward this prescription by fax or other mode of delivery to a pharmacy within the patient support network. This prescription represents the original prescription drug order. I consent disclosure of my contact information to Knight and accept that they contact me to support the patient's care. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use Knight medications, or any other Knight product or service, for any other person, (b) my decision to prescribe Knight medications was based solely on my professional determination of medical necessity, and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Knight may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Knight makes no representation or guarantee concerning coverage or reimbursement for any item or service.

Physician Signature _____ Date (DD/MMM/YYYY) _____

5. PRESCRIPTION

Dose Escalation for Diarrhea Prophylaxis

☐ **NERLYNX® (neratinib)**
☐ **Early Breast Cancer** ☐ **Metastatic Breast Cancer**

Recommended:
120 mg (3 x 40 mg tabs) PO QD, days 1–7
160 mg (4 x 40 mg tabs) PO QD, days 8–14
240 mg (6 x 40 mg tabs) PO QD, day 15 and onwards
Dispense 1 month supply.
Refills (240 mg QD): _____ months

☐ **Loperamide**
If diarrhea occurs with dose escalation, loperamide 4 mg should be initiated no later than with the first bout of diarrhea and continued with loperamide 2 mg after every subsequent loose stool, up to 16 mg per day, until diarrhea-free for 12 hours. Then, titrate loperamide to keep diarrhea controlled (1–2 bowel movements per day).

Recommended:
4 mg (2 x 2 mg tabs) PO with first bout of diarrhea
2 mg PO after every subsequent loose stool, max 16 mg QD
Quantity: 100 Repeat _____

Early Breast Cancer

☐ **NERLYNX® (neratinib)**

Recommended:
240 mg (6 x 40 mg tabs) PO QD
Dispense 1 month supply.
Refills: _____ months

☐ **Loperamide prophylaxis**
Antidiarrheal prophylaxis is recommended during the first 56 days of treatment and should be initiated with the first dose of NERLYNX®. Titrate dosing to achieve 1–2 bowel movements per day.

Recommended:
4 mg (2 x 2 mg tabs) PO TID, days 1–14
4 mg (2 x 2 mg tabs) PO BID, days 15–56
4 mg (2 x 2 mg tabs) PO PRN (max 16 mg QD), days 57 onward
Quantity: 200 Repeat _____

Metastatic Breast Cancer

☐ **NERLYNX® (neratinib)**
In combination with capecitabine on Day 1–14 of a 21-day cycle until disease progression or unacceptable toxicities.

Recommended:
240 mg (6 x 40 mg tabs) PO QD, days 1–21
Dispense 1 cycle (21 days) supply.
Refills: _____ cycles

☐ **Loperamide prophylaxis**
Antidiarrheal prophylaxis is recommended during the first 56 days of treatment and should be initiated with the first dose of NERLYNX®. Titrate dosing to achieve 1-2 bowel movements per day.

Recommended:
4 mg (2 x 2 mg tabs) PO TID, days 1–14
4 mg (2 x 2 mg tabs) PO BID, days 15–56
4 mg (2 x 2 mg tabs) PO PRN (max 16 mg QD), days 57 onward
Quantity: 200 Repeat _____

☐ **Prescription Attached** Expected Start Date: _____ (DD/MMM/YYYY)

Physician Signature _____ Licence Number _____ Date (DD/MMM/YYYY) _____

Privacy Authorization

By signing below, I authorize my physician(s), healthcare provider(s) and staff to use and disclose my information (including but not limited to my name, address, phone number, email address, sex and insurance policy number) and my medical condition (including but not limited to, my diagnosis or medications) (collectively "Personal Information") to Knight Therapeutics Inc. and its affiliates ("Knight"), and its representatives, agents, and contractors including, but not limited to Bayshore Specialty Rx Ltd ("Bayshore"), collected in the documentation of the NERLYNX® Patient Support Program ("Program").

My Personal Information will be collected, used and disclosed for the following purposes: (i) to evaluate my eligibility to the Program; (ii) to enable and facilitate my participation in the Program and to meet the Program's objectives; (iii) communicate with my Healthcare Providers about my treatment or condition and related products; (iv) for processing, if applicable, laboratory results in relation to my treatment; (v) provide support services including patient education; and (vi) for processing reimbursement requests with insurance providers (collectively the "Purpose").

For my own clarity and acknowledgement, Bayshore has been retained by Knight to manage the collection and processing of my Personal Information under the Program. Except for legal requirements and duties detailed herein, Knight will not have access to any of my Personal Information, but for aggregated and unidentifiable information. Knight is contractually ensured that such Bayshore provides a high level of Personal Information protection and will be responsible for the security of my Personal Information. Bayshore is not authorized to collect, use or disclose the Personal Information except as necessary to perform services in relation to the Program's Purposes, or to comply with legal requirements.

My Personal Information will not be shared, disclosed or transferred to Knight. Knight will only receive reports from Bayshore describing the Program data only in an aggregated and anonymous manner. More specifically, I understand that the statistical data related to the Program will be rendered in an aggregated and anonymous manner and shared with Knight, healthcare practitioners and other third parties, as the case may be.

Marketing Material Consent

☐ By checking this box, I also authorize Knight to send me marketing information or offer me products and services related to my treatment or condition (or other products or services in which I might be interested) and to contact me occasionally to obtain my feedback (for market research purposes only) about my treatment, my condition, or my experience with the Program and/or Knight otherwise as required or permitted by law.

Patient Consent

I understand that completing this form does not ensure that I will qualify for the Program. I represent that the information provided in this enrollment form is complete and accurate. My decision to sign this form will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage.

I acknowledge that the collection, use, and disclosure of my information contemplated herein may involve a transfer of my information to jurisdictions located outside my country of residence that may not have equivalent privacy laws. I understand that Knight may take reasonable contractual measures to protect my Personal Information while processed or handled by any third parties which may subject to applicable foreign legal requirements, for example lawful requirements to disclose my Personal Information to government authorities in those countries.

Except where prohibited by applicable laws, I understand that I can withdraw my consent at any time by contacting the Program at 1-855-635-2372. I may also obtain a copy of this form and/or correct/update any information by contacting the Program at 1-855-635-2372. I understand that withdrawing my consent will result in the termination of my enrollment in the Program, but such withdrawal will not be retroactive and any activities relating to my Personal Information that has been collected, used, disclosed and/or stored prior to my withdrawal will not be affected.

Unless required by provincial law or, unless I cancel it before, this Form is valid for whichever is longer: (a) the duration of remaining on this treatment; or (b) 10 years from the date signed below.

6. PATIENT CONSENT

I have read and understand the **Patient Consent and Privacy Information** above and agree to the collection, use and disclosure of my personal information and health information in accordance with those terms.

Patient Signature _____ Date (DD/MMM/YYYY) _____

NERLYNX® is indicated:

- For the extended adjuvant treatment of women with early-stage hormone receptor positive and HER2-overexpressed/amplified breast cancer within one year after completion of trastuzumab-based adjuvant therapy.
- In combination with capecitabine for the treatment of patients with metastatic HER2-overexpressed/amplified breast cancer, who have received two or more prior anti-HER2-based regimens in the metastatic setting.

For more information:

Consult the Product Monograph at **health-products.canada.ca/dpd-bdpp/** for important information regarding contraindications, warnings, precautions, adverse reactions, drug interactions, dosing instructions and conditions of clinical use which have not been discussed in the piece. The Product Monograph is also available by calling 1-844-483-5636.

Knight

REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

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