Nerlynx

Description

Nerlynx (neratinib)

Background

Nerlynx (neratinib) is a tyrosine kinase inhibitor that irreversibly binds to epidermal growth factors, human epidermal growth factor 2 (HER2) and HER4. Nerlynx (neratinib) is clinically approved to be used following adjuvant trastuzumab-based therapy in patients with HER2 protein positive breast cancer. Nerlynx effects have been shown to reduce risk of breast cancer recurrence (1).

Regulatory Status

FDA-approved indication: Nerlynx is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies

Herceptin, Ibrance, Kadcyla, Perjeta, Tykerb

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Nerlynx may be considered medically necessary for patients 18 years of age or older for the treatment of early stage breast cancer and if the conditions indicated below are met.

Nerlynx may be considered investigational in patients under 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Early stage breast cancer

AND ALL of the following:
1. Human epidermal growth factor receptor 2 (HER2)-positive
2. Previously treated with Herceptin (trastuzumab)
3. Prescriber agrees to initiate antidiarrheal prophylaxis with the first dose and continue during the first 2 cycles (56 days) of treatment and as needed thereafter

Prior – Approval Renewal Requirements
None

Policy Guidelines

Pre – PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
None
Rationale

Summary
Nerlynx (neratinib) is a tyrosine kinase inhibitor that irreversibly binds to epidermal growth factors, human epidermal growth factor 2 (HER2) and HER4. Nerlynx (neratinib) is clinically approved to be used following adjuvant trastuzumab-based therapy in patients with HER2 protein positive breast cancer. The safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Nerlynx while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>July 2017</td>
<td>Addition to PA</td>
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<td>September 2017</td>
<td>Annual review</td>
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<td>December 2017</td>
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<td>Addition of the requirement for the prescriber agreeing to initiate antidiarrheal prophylaxis with the first dose and continue during the first 2 cycles (56 days) of treatment and as needed thereafter per SME. Removal of renewal section per SME</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.