POLICY Document for TYKERB (lapatinib)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

Section 1: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT
TYKERB (lapatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Tykerb is indicated in combination with:
1. Capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab
2. Letrozole for the treatment of postmenopausal women with hormone receptor (HR)-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated

B. Compendial Uses
1. Recurrent or metastatic HER2-positive breast cancer in combination with trastuzumab
2. Recurrent or stage IV hormone receptor-positive, HER2-positive breast cancer in combination with aromatase inhibition in postmenopausal women
3. Metastatic central nervous system (CNS) lesions if active against primary tumor (breast)
4. Recurrent EGFR-positive chordoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer

Authorization of 12 months may be granted for the treatment of HER2-positive breast cancer when Tykerb is used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane), trastuzumab, or capecitabine.

B. Metastatic CNS lesions
Authorization of 12 months may be granted for the treatment of metastatic CNS lesions from HER2-positive breast cancer.

C. Chordoma
Authorization of 12 months may be granted for the treatment of EGFR-positive recurrent chordoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Section 2: Oncology Clinical Policy

Oncology Clinical Policy

Program Description

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN templates are based on NCCN Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

- Category 1: Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

This policy provides coverage of a regimen review when *all* of the following criteria are met:

a. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: https://provider.carefirst.com/providers/home.page
b. If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.

2. The prior authorization review is requested for an oncology drug or biologic that requires prior authorization on the medical benefit.
3. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
4. The member is eligible for regimen review.

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Authorizations may be granted for 12 months.
Further review may be indicated where the above criteria are not met.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.
2. The NCCN Drugs & Biologics Compendium™ © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 16, 2019.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: central nervous system cancer. Version 2.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.

5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: bone cancer. Version 1.2019. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2019.

SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/about/default.aspx, accessed September 16, 2019.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website. https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx, accessed September 16, 2019.
3. National Comprehensive Cancer Network. NCCN Guidelines website. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp, accessed September 16, 2019. *(Note: An account may be required.)*
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium® website. http://www.nccn.org/professionals/drug_compendium/content/contents.asp, accessed September 16, 2019. *(Note: A subscription may be required.)*
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. https://www.nccn.org/professionals/OrderTemplates/Default.aspx, accessed September 16, 2019. *(Note: A subscription may be required.)*