I. Medication Description

Human epidermal receptor type 2 (HER2), also known as ErbB-2, is a cell membrane surface-bound receptor tyrosine kinase and is involved in the signal transduction pathways leading to cell growth and differentiation. Overexpression of HER2 in women with breast cancer is associated with greater risk of disease progression and death than women whose tumors do not overexpress HER2. Tykerb® is a kinase inhibitor of both epidermal growth factor receptor (EGFR) and human epidermal receptor type 2 receptors (HER2) which inhibits ErbB-driven tumor cell growth. Tykerb® enters the cell and blocks the function of HER2 and EGFR. Tykerb® differs from trastuzumab in that trastuzumab targets the exterior of the cell. This difference accounts for the utility of Tykerb® in HER2 positive patients that have not responded adequately to trastuzumab.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Tykerb is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- HER2-positive disease with overexpression has been confirmed by:
  - Immunohistochemistry (IHC) assay 3+ or fluorescence in situ hybridization (FISH) assay ratio of at least 2.0
  - If IHC is 2+, must confirm with FISH assay of ratio of at least 2.0 AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Quantity is limited to 180 tablets per each 30 days.

V. Coverage Duration

Coverage is provided for 6 months and may be renewed.
VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Tykerb is available as 250mg oral tablets

VIII. Summary of Policy Changes

- 9/1/11: Added indication for combination use with trastuzumab; Added Black box warning and contraindications; HER-2 testing requirements added to criteria; Renewal criteria added
- 9/15/12: Coverage criteria modified to reflect current NCCN guidelines; Male breast cancer and brain metastases indication information added
- 9/15/13: Policy wording edited to mimic NCCN guidelines; Addition of 198.3 to pertinent diagnoses; Updated to allow FISH ratio of at least 2.0 to be considered positive
- 9/15/14: no policy changes
- 7/1/15: formulary distinctions made
- 3/15/16: Updated coverage to coincide with current NCCN treatment guidelines
- 1/1/17: no policy changes
- 1/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines

IX. References

1. Up-to-date Online, retrieved October 2017
3. Facts and Comparisons Online, retrieved October 2016

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.
The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.