JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS038
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	Subject **Tykerb**	*Revision Date*	01/19/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Tykerb

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I. POLICY

A. Tykerb (lapatinib) will require prior authorization for outpatient prescription drug benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Tykerb may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing one of the following:
      a. Diagnosis of advanced or metastatic breast cancer with the following:
         I. Tumors overexpressing human epidermal growth factor receptor 2 (HER2)
         II. Patient has had trial and inadequate responses to an anthracycline, a taxane, and trastuzumab
         III. Tykerb will be used in combination with capecitabine
      b. Diagnosis of postmenopausal metastatic breast cancer with the following:
         I. Patient has hormone receptive positive (HR+) cancer
         II. Tumors overexpressing HER2
         III. Tykerb will be used in combination with letrozole

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be granted for 6 months.

B. Continuation of therapy may be approved in 12- month intervals with documentation showing that the patient has experienced a clinical benefit from treatment.

IV. EXCLUSIONS

A. Tykerb will not be approved for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported.

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Tykerb [prescribing information]. Research Triangle Park, NC :GlaxoSmithKline; December 2018.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background/definitions information
07/27/2017	Updated Exclusions section regarding physician samples
01/19/2022	Updated clinical criteria section

Review/Revision Dates: 02/01/2008, 1/14/2009, 7/18/2012, 3/1/2014, 04/20/2016, 07/27/2017, 01/19/2022