



MEDICATION POLICY

Generic Name: Lapatinib

Therapeutic Class or Brand Name: Tykerb®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 9/24/16

GPI Code: 2153405010

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Advanced or metastatic HER2 positive breast cancer AND criteria 1 and 2 are met:
 1. Must be used in combination with capecitabine (Xeloda®).
 2. Documentation of prior therapy, including the following 3 agents listed a through c:
 - a. An anthracycline (i.e. daunorubicin, doxorubicin, epirubicin, idarubicin, or valrubicin).
 - b. A taxane (i.e. paclitaxel or docetaxel).
 - c. Trastuzumab (Herceptin®).
 - B. Hormone receptor positive, HER2 positive metastatic breast cancer AND criteria 1 and 2 are met:
 1. Patient is a postmenopausal woman.
 2. Must be used in combination with letrozole (Femara®).
- II. Minimum age requirement: 18 years old.
- III. Prescriber is an oncologist.

Exclusion Criteria:

- N/A

Other Criteria:

- Use of Tykerb® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 660 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Tykerb® serum concentrations) cannot be avoided (see Appendix).

Quantity/Days Supply Restrictions:

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- Quantities of up to 180 tablets per 30 days. See under Other Criteria for possible exceptions for higher doses (up to 660 tablets per 30 days).

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

Examples of Strong CYP3A4 Inducers (Reduce Tykerb® Serum Concentrations)

Carbamazepine (Tegretol®, Epitol®)	Phenytoin (Dilantin®)
Dexamethasone	Rifabutin (Mycobutin®)
Efavirenz (Sustiva®)	Rifapentine (Priftin®)
Nevirapine (Viramune®)	Rifampin (Rifadin®)
Phenobarbital	St. John's Wort

References:

1. <http://blue.regence.com/trgmedpol/drugs/dru145.pdf>.
2. <https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Tykerb.pdf>.
3. [Medi-Span](#).
4. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf>.

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Historical Tracking Of Changes Made To Policy																																											
9/24/2016	1. Updated “ http://us.gsk.com/products/assets/us_tykerb.pdf ” to “ https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf ” under References.																																										
4/6/2015	1. Changed “B. Hormone receptor positive, HER2 positive metastatic breast cancer and criterion 1 is met: 1. Must be used in combination with letrozole (Femara®)” to “B. Hormone receptor positive, HER2 positive metastatic breast cancer AND criteria 1 and 2 are met: 1. Patient is a postmenopausal woman; Must be used in combination with letrozole (Femara®)” under Prior Authorization Criteria. 2. Changed “Use of Tykerb® with strong CYP3A4 inhibitors or inducers should be avoided (See Appendix). If concomitant use with CYP3A4 inhibitors or inducers cannot be avoided, the dose of Tykerb® must be adjusted. Exceptions for higher doses may be made (up to 660 tablets per 30 days) when Tykerb® must be administered concomitantly with medications that are strong CYP3A4 inducers (see Appendix)” to “Use of Tykerb® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 660 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Tykerb® serum concentrations) cannot be avoided (see Appendix)” under Other Criteria. 3. Changed “Up to 180 tablets per 30 days (quantity is limited to a maximum of a 30 day supply per fill). See under Other Criteria for possible exceptions for higher doses (up to 660 tablets per 30 days)” to “Quantities of up to 180 tablets per 30 days. See under Other Criteria for possible exceptions for higher doses (up to 660 tablets per 30 days)” under Quantity/Days Supply Restrictions. 4. Changed table under Appendix from: <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th colspan="2" style="text-align: center; padding: 2px;">Potent Inhibitors and Inducers of CYP3A4.</th> </tr> <tr> <th style="width: 50%; padding: 2px;">POTENT INHIBITORS:</th> <th style="width: 50%; padding: 2px;">INDUCERS:</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">amiodarone (Cordarone®, Pacerone®)</td> <td style="padding: 2px;">carbamazepine (Tegretol®, Eptol®)</td> </tr> <tr> <td style="padding: 2px;">atazanavir (Reyataz®)</td> <td style="padding: 2px;">efavirenz (Sustiva®)</td> </tr> <tr> <td style="padding: 2px;">cisapride (Propulsid®)</td> <td style="padding: 2px;">nevirapine (Viramune®)</td> </tr> <tr> <td style="padding: 2px;">clarithromycin (Biaxin®)</td> <td style="padding: 2px;">phenytoin (Dilantin®)</td> </tr> <tr> <td style="padding: 2px;">indinavir (Crixivan®)</td> <td style="padding: 2px;">phenobarbital</td> </tr> <tr> <td style="padding: 2px;">itraconazole (Sporanox®)</td> <td style="padding: 2px;">rifabutin (Mycobutin®)</td> </tr> <tr> <td style="padding: 2px;">ketoconazole (Nizoral®)</td> <td style="padding: 2px;">rifapentine (Priftin®)</td> </tr> <tr> <td style="padding: 2px;">nefazodone (Serzone®)</td> <td style="padding: 2px;">rifampin (Rifadin®)</td> </tr> <tr> <td style="padding: 2px;">nelfinavir (Viracept®)</td> <td style="padding: 2px;">St. John’s Wort</td> </tr> <tr> <td style="padding: 2px;">ritonavir (Norvir®)</td> <td></td> </tr> <tr> <td style="padding: 2px;">telithromycin (Ketek®)</td> <td></td> </tr> <tr> <td style="padding: 2px;">troleandomycin (TAO®)</td> <td></td> </tr> <tr> <td style="padding: 2px;">voriconazole (Vfend®)</td> <td></td> </tr> </tbody> </table> <p style="margin: 5px 0;">to:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th colspan="2" style="text-align: center; padding: 2px;">Examples of Strong CYP3A4 Inducers (Reduce Tykerb® Serum Concentrations)</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; padding: 2px;">Carbamazepine (Tegretol®, Eptol®)</td> <td style="width: 50%; padding: 2px;">Phenytoin (Dilantin®)</td> </tr> <tr> <td style="padding: 2px;">Dexamethasone</td> <td style="padding: 2px;">Rifabutin (Mycobutin®)</td> </tr> <tr> <td style="padding: 2px;">Efavirenz (Sustiva®)</td> <td style="padding: 2px;">Rifapentine (Priftin®)</td> </tr> <tr> <td style="padding: 2px;">Nevirapine (Viramune®)</td> <td style="padding: 2px;">Rifampin (Rifadin®)</td> </tr> <tr> <td style="padding: 2px;">Phenobarbital</td> <td style="padding: 2px;">St. John’s Wort</td> </tr> </tbody> </table>	Potent Inhibitors and Inducers of CYP3A4.		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1/25/2014	1. Adapted policy to new format. 2. Added GPI Code. 3. Updated references to include Medi-Span.																																										

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