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| **Clinical Policy Title:** | lapatinib |
| **Policy Number:** | RxA.525 |
| **Drug(s) Applied:** | Tykerb® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 08/28/2024 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

**A. Breast Cancer** (must meet all)**:**

1. Diagnosis of breast cancer;
2. Disease is recurrent or metastatic (stage IV), and HER2-positive;
3. Prescribed in combination with one of the following (a, b, or c):
   a. Capecitabine;
   b. Trastuzumab;
   c. If HR-positive, an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane), and:
      i. If male, an agent that suppresses testicular steroidogenesis (e.g., gonadotropin-releasing hormone agonists);
4. If member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression.

**Approval Duration**

**All Lines of Business (except Medicare):** 6 months

**B. Bone Cancer chordoma (off-label)** (must meet all):

1. Diagnosis of recurrent chordoma;
2. Disease is EGFR-positive;
3. Prescribed as a single agent.

**Approval Duration**

**All Lines of Business (except Medicare):** 6 months

**C. Colon Cancer or Rectal Cancer (off-label)** (must meet all):

1. Diagnosis of advanced or metastatic colorectal cancer and member meets both of the following (a and b):
   a. Disease is HER-2 positive;
   b. Disease is RAS and BRAF wild-type;
2. Member had no previous treatment with a HER-2 inhibitor (e.g., trastuzumab, Kadcyla®, Tykerb® Perjeta®);
3. Prescribed in combination with trastuzumab.

**Approval Duration**

**All Lines of Business (except Medicare):** 6 months

**D. Central Nervous System (CNS) Cancers (off label)** (must meet all):
1. Diagnosis of extensive brain metastases or limited brain metastases with HER-2 positive breast cancer;
2. Prescribed in combination with capecitabine.

**Approval Duration**
**All Lines of Business (except Medicare):** 6 months

**II. Continued Therapy Approval**

**A. All Indications in Section I** (must meet all):
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

**Approval Duration**
**All Lines of Business (except Medicare):** 12 months

**References**


1. National Comprehensive Cancer Network. Breast Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Bone Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Colon Cancer Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Rectal Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed August 28, 2024.


| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Clinical policy title table was updated.<br>2. "Line of Business Policy Applies" to was updated to All lines of business.<br>3. Approval duration was updated for Commercial and removed HIM .<br>4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance".<br>5. Added initial therapy criteria for colon and rectal cancer<br>6. References was reviewed and updated. | 10/07/2020 | 12/07/2020 |
| Policy was reviewed:<br>1. Initial approval criteria I.C.5 & I.C.6 was updated to include new criteria "Patient has RAS and BRAF wild-type..." & "Patient has previously | 09/24/2021 | 12/07/2021 |

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| been...". respectively<br>2. Initial Approval Criteria was updated to include a new off label indication "Central Nervous System Cancers".<br>3. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>4. References were reviewed and updated. | | |
| Policy was reviewed:<br>1. Initial Approval Criteria, I.C.4: Updated previous treatment criteria Member had no previous treatment with a HER-2 inhibitor (e.g., trastuzumab, Kadcyla®, Perjeta®) to Member had no previous treatment with a HER-2 inhibitor (e.g., trastuzumab, Kadcyla®, Tykerb® Perjeta®).<br>2. Initial Approval Criteria, I.C.5: Updated to include new combination therapy criteria Prescribed in combination with trastuzumab.<br>3. Initial Approval Criteria, I.D.3: Updated to include new combination therapy criteria to Prescribed in combination with capecitabib.<br>4. Initial Approval Criteria, I.D.3: Updated to remove prior criteria pertaining to indication Central Nervous System (CNS) Cancers (off label),"Tykerb® will be approved if member meets all of the following (a, b or c):<br>a. Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions;<br>b. Tykerb® is active against primary (breast) tumor;<br>c. Used in combination with capecitabine. | 9/8/2022 | 10/19/2022 |

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| 5. Initial Approval Criteria, I.D.4: Updated to remove prior criteria pertaining to indication Central Nervous System (CNS) Cancers (off label), "Member is treated in combination with temozolomide for progression or recurrent disease in patients who are refractory to surgery or radiation therapy (RT), if received prior RT and any of the following (a, b or c):<br>a. Gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology;<br>b. Subtotal resection and evidence of metastasis (brain, spine, or CSF);<br>c. Unresectable disease.<br>6. Reference were reviewed and updated. | | |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed age restrictions.<br>2. Removed prescriber restrictions.<br>3. Removed dose restrictions.<br>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.<br>5. Removed reauthorization requirement for positive response to therapy.<br>6. Updated approval duration verbiage.<br>7. References were reviewed and updated. | 8/28/2024 | 9/13/2024 |