Clinical Policy: Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri)

Reference Number: CP.PHAR.228
Effective Date: 06.01.16
Last Review Date: 05.18 Coding Implications
Line of Business: Medicaid, HIM*-Medical Benefit Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Trastuzumab (Herceptin®) and trastuzumab-dkst (Ogivri™) are HER2/neu receptor antagonists.

**For Health Insurance Marketplace (HIM),* *Ogivri is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Herceptin and Ogivri are indicated for:

- Adjuvant breast cancer
  - For adjuvant treatment of HER2-overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:
    - As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
    - As part of a treatment regimen with docetaxel and carboplatin
    - As a single agent following multi-modality anthracycline based therapy
- Metastatic breast cancer
  - In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
  - As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
- Metastatic gastric cancer
  - In combination with cisplatin and capecitabine or 5-fluorouracil for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease
- Note: select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Herceptin and Ogivri are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of HER2-positive breast cancer;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 8 mg/kg for adjuvant therapy or 4 mg/kg for treatment of metastatic disease.

Approval duration: 6 months

B. Gastric and Esophageal Cancer (must meet all):
1. Diagnosis of HER2-positive metastatic gastric, esophageal, or gastroesophageal junction adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with cisplatin and capecitabine or 5-fluorouracil;
5. Dose does not exceed 8 mg/kg.

Approval duration: 6 months

C. Central Nervous System Cancer (off-label) (must meet all):
1. Diagnosis of leptomeningeal metastases from breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose (intrathecal administration) is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Herceptin/Ogivri for HER2-positive breast or gastric cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. Breast cancer: New dose does not exceed 8 mg/kg for adjuvant therapy or 4 mg/kg for treatment of metastatic disease;
   b. Gastric cancer: New dose does not exceed 8 mg/kg;
   c. CNS breast cancer metastasis: New dose (intrathecal administration) is supported by practice guidelines or peer-reviewed literature for the relevant off-label use.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2 protein

Appendix B: Therapeutic Alternatives
Not applicable

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri)	Adjuvant treatment, breast cancer	Administer according to one of the following doses and schedules for a total of 52 weeks: During and following paclitaxel, docetaxel, or docetaxel/carboplatin: • Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). • One week following the last weekly dose of Ogivri, administer Ogivri at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks. As a single agent within three weeks following completion of multi-modality, anthracyclinebased chemotherapy regimens: • Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes.	8 mg/kg

Drug Name	Indication	Dosing Regimen	Maximum Dose
		• Subsequent doses at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks	
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri)	Metastatic treatment, breast cancer	Alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression.	4 mg/kg
Trastuzumab (Herceptin), Trastuzumab-dkst (Ogivri)	Metastatic gastric cancer	Administer at an initial dose of 8 mg/kg as a 90 minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks until disease progression.	8 mg/kg

VI. Product Availability

Drug Name	Availability
Trastuzumab (Herceptin)	Multi-use vial: 420 mg Single-dose vial: 150 mg
Trastuzumab-dkst (Ogivri)	Multi-use vial: 420 mg

VII. References

1. Herceptin Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2017. Available at http://www.gene.com/download/pdf/herceptin_prescribing.pdf. Accessed December 2017.
2. Ogivri Prescribing Information. Morgantown, WV: Mylan GmbH.; December 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761074s000lbl.pdf. Accessed December 2017.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed December 2017.
4. National Comprehensive Cancer Network. Breast Cancer Version 3.2017. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed December 2017.
5. National Comprehensive Cancer Network. Gastric Cancer Version 5.2017. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed December 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9355	Injection, trastuzumab, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.67.HER2 BrCa Tx and converted to new template. Requests for documentation removed. Reasons for discontinuation limited to absolute requirements per the PI. Definition of adjuvant therapy added to the criteria per NCI definition. NCCN compendial recommended uses added.	05.16	06.16
Initial: Updated off-label NCCN uses for non-metastatic breast cancer (specified disease stages) and metastatic gastric/esophageal adenocarcinomas (added performance score requirement). Re-auth: Removed reasons to discontinue. Added requirement for documentation of positive response to therapy. Increased approval durations from 3 & 6 months to 6 & 12 months. Added Appendix B with definition of performance scores.	04.17	06.17
Policy converted to new template. Ogivri added. Age, specialist and dosing added. Breast cancer criteria sets combined; criteria limited to a diagnosis of HER2+ breast cancer. CNS breast cancer metastatic disease off-label criteria limited to diagnosis. Off-label uses removed from gastric cancer criteria - FDA indications cover through NCCN category 2A. HER2-positive lung cancer removed as an off-label indication per NCCN. Removed Appendix B. References reviewed and updated.	01.16.18	02.18
2Q 2018 annual review: no significant changes; HIM line of business added; references reviewed and updated.	02.13.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.