

Kanjinti (trastuzumab-anns)

Kanjinti is a HER2/neu receptor antagonist, and is biosimilar to HERCEPTIN® (trastuzumab). Kanjinti is indicated for:

- The treatment of HER2 overexpressing breast cancer.
- The treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (GJA).

Kanjinti will be considered for coverage when **ALL** of the criteria below are met, confirmed with supporting medical documentation.

I. Criteria for Initial Approval

Adjuvant Therapy of HER2-Overexpressing Breast Cancer

Kanjinti is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer, **when all of the following criteria are met:**

- Adult patients 18 years of age or older.
- Used in one of the following treatment plans:
 - 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.*

*Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

- Patient has a documented complete blood count without evidence of neutropenia prior to initiation of therapy. Prescriber agrees to continue monitoring complete blood counts, prior to each subsequent dose, and as clinically indicated.

- Patient has a normal left ventricular ejection fraction (LVEF) prior to initiation of therapy. Prescriber agrees to continue monitoring the patient for left ventricular dysfunction at regular intervals during treatment as clinically indicated.
- Females of reproductive potential will have a documented negative pregnancy test prior to initiation of therapy and be advised to use effective contraception during treatment.

Therapy for Metastatic HER2-Overexpressing Breast Cancer

Kanjinti is indicated for the treatment of metastatic HER2-Overexpressing breast cancer, **when all of the following criteria are met:**

- Adult patients 18 years of age or older.
- Used in one of the following treatment plans:
 - 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 regimen(s) for metastatic disease.*

*Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

- Patient has a documented complete blood count without evidence of neutropenia prior to initiation of therapy. Prescriber agrees to continue monitoring complete blood counts, prior to each subsequent dose, and as clinically indicated.
- Patient has a normal left ventricular ejection fraction (LVEF) prior to initiation of therapy. Prescriber agrees to continue monitoring the patient for left ventricular dysfunction at regular intervals during treatment as clinically indicated.
- Females of reproductive potential will have a documented negative pregnancy test prior to initiation of therapy and be advised to use effective contraception during treatment.

Therapy for Metastatic HER2-Overexpressing Gastric Cancer or GJA

Kanjinti is indicated for the treatment of HER2-Overexpressing Gastric Cancer or GJA **when all of the following criteria are met:**

- Adult patients 18 years of age or older.
- Used in one of the following treatment plans:
 - 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.*

*Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

- Patient has a documented complete blood count without evidence of neutropenia prior to initiation of therapy. Prescriber agrees to continue monitoring complete blood counts, prior to each subsequent dose, and as clinically indicated.
- Patient has a normal left ventricular ejection fraction (LVEF) prior to initiation of therapy. Prescriber agrees to continue monitoring the patient for left ventricular dysfunction at regular intervals during treatment as clinically indicated.
- Females of reproductive potential will have a documented negative pregnancy test prior to initiation of therapy and be advised to use effective contraception during treatment.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in Section I.) must be met; AND

- The provider attests to a positive clinical response.
- Ongoing assessment does NOT show:
 - $\geq 16\%$ absolute decrease in LVEF from pretreatment values, OR
 - LVEF below institutional limits of normal and $\geq 10\%$ absolute decrease in LVEF from pretreatment values, OR
 - A persistent (> 8 weeks) LVEF decline or for suspension of Kanjinti dosing on more than 3 occasions for cardiomyopathy.

III. Dosing/Administration

Kanjinti must be administered according to the current FDA-labeling guidelines for dosage and timing. The recommended dosing is as follows:

Adjuvant Treatment of HER2-Overexpressing Breast Cancer

Administer at either:

- Initial dose of 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with Paclitaxel or Docetaxel) or 18 weeks (with Docetaxel and Carboplatin). One week after the last weekly dose of Kanjinti, administer 6 mg/kg as an IV infusion over 30 to 90 minutes every three weeks to complete a total of 52 weeks of therapy, **OR**

- Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30 to 90 minutes IV infusion every three weeks for 52 weeks.

Treatment of Metastatic HER2-Overexpressing Breast Cancer

- Initial dose of 4 mg/kg as a 90 minute IV infusion, followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions.

Treatment of Metastatic HER2-Overexpressing Gastric Cancer or GJA

- Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.

IV. Length of Authorization For initial therapy

Kanjinti will be authorized for 6 months when criteria for initial approval are met. Continuing therapy with Kanjinti will be authorized for 12 months.

V. Billing Code/Information

- Q5117 - Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg; 1 billable unit = 10 mg

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 10/29/2020

Last Reviewed Date: 10/29/2020