



Prior Authorization Approval Criteria

Herceptin (trastuzumab)

Generic name: Trastuzumab

Brand name: Herceptin

Medication class: Monoclonal antibody

FDA-approved uses: Treatment of HER2-overexpressing breast cancer.

- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Available dosage forms: Injection, powder for reconstitution (440mg)

Usual doses: Loading dose: 4 mg/kg intravenous infusion over 90 minutes
Maintenance dose: 2 mg/kg intravenous infusion over 90 minutes (can be administered over 30 minutes if prior infusions are well tolerated) weekly until disease progression

Duration of therapy: Indeterminate - depending on clinical responses and patient tolerability

Approximate yearly cost (based on ASP 7/20/06): \$882

Criteria for use: *(bullet points below are all inclusive unless otherwise noted)*

The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.

Adjuvant Breast Cancer

Clinically diagnosed with 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

or

with docetaxel and carboplatin

or

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 As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. Patient must undergo thorough baseline cardiac assessment including history and physical exam and one or more of the following: EKG, echocardiogram, and MUGA scan

Metastatic Gastric Cancer

Clinically diagnosed with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in combination with cisplatin and capecitabine or 5-fluorouracil who have not received prior treatment for metastatic disease.

Criteria for continuation of therapy:

- Patient does not develop clinically significant congestive heart failure
- Patient is not intolerant to treatment regimen

Cautions:

- Cardiotoxicity and infusion reactions
- Pre-medicate with antihistamines and/or corticosteroids is recommended
- Safety and efficacy in pediatric population have not been established

Monitoring: Cardiac exam, vital signs during infusion, baseline and periodic LVEF

Contraindications: Hypersensitivity to trastuzumab or Chinese hamster ovary cell protein

Not approved if: Above criteria are not met or patient is hypersensitive to trastuzumab.

P&T Approval: _____ Date: _____