



Prior Authorization Approval Criteria
Department of Pharmacy Services

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 Dose:

- 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

- Clinically diagnosed with HER2 overexpressing metastatic 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 is not met or patient is hypersensitive to trastuzumab

P&T Approval: _____ Date: _____