Trastuzumab

ACG: A-0489 (AC)
Link to Codes

MCG Health
Ambulatory Care
23rd Edition

Clinical Indications

- Trastuzumab may be indicated for **1 or more** of the following(1)(2):
  - Breast cancer, as indicated by **ALL** of the following(3)(6)(7)(8):
    - Age 18 years or older
    - Disease activity and treatment scenario include **1 or more** of the following:
      - Metastatic disease and **1 or more** of the following[A](7)(9)(10)(11):
        - Initial treatment for metastatic disease, administered as combination therapy[B](17)(18)(19)
        - Relapsed metastatic disease following prior administration of one or more chemotherapy regimens, administered as single-agent therapy(20)(21)
      - Nonmetastatic disease and **ALL** of the following(22)(23)(24):
        - Lymph node status is **1 or more** of the following:
          - Lymph node-negative high-risk disease, as indicated by **1 or more** of the following:
            - Age younger than 35 years
            - Estrogen receptor-negative and progesterone receptor-negative
            - Histologic grade, nuclear grade, or both grade 2 or 3
            - Tumor size 0.6 cm or greater(7)
          - Lymph node-positive disease
        - Trastuzumab regimen needed, as indicated by **1 or more** of the following:
          - Preoperative (ie, neoadjuvant) multiagent treatment regimen (ie, in combination with chemotherapy)[C](15)(28)(29)(30)(31)
          - Postoperative (ie, adjuvant) multiagent treatment regimen (ie, in combination with chemotherapy)[D](32)(33)(34)(35)
          - Postoperative (ie, adjuvant) single-agent therapy following multimodality anthracycline-based chemotherapy[E](7)(32)(35)
    - HER2 overexpression, as indicated by **1 or more** of the following[F](7)(38)(39)(40)(41):
      - Immunohistochemistry showing 3+ positivity for HER2
      - Positive test for HER2 via gene amplification with fluorescence in situ hybridization(42)
      - Positive test for HER2 with chromogenic in situ hybridization
    - Left ventricular ejection fraction measured prior to administration[G](43)(44)(45)(46)(47)(48)
    - Patient not pregnant(49)
  - Gastric or gastroesophageal cancer, as indicated by **ALL** of the following[H](50)(51)(52)(53)(54):
    - Age 18 years or older
    - Disease activity and treatment scenario include **ALL** of the following:
      - Metastatic disease(59)
      - No prior treatment with trastuzumab
      - Trastuzumab will be administered in combination with cisplatin and capecitabine or 5-fluorouracil.(60)
    - HER2 overexpression, as indicated by **1 or more** of the following[F](4)(61):
      - Immunohistochemistry showing 3+ positivity for HER2
      - Positive test for HER2 via gene amplification with fluorescence in situ hybridization(62)
    - Left ventricular ejection fraction measured prior to administration[G](43)(44)(45)(46)
    - Patient not pregnant

Evidence Summary

Background

Trastuzumab is a recombinant monoclonal antibody that binds to the HER2 protein, thereby inhibiting cell proliferation.(1)(3) **(EG 2)** HER2 overexpression (HER2 positivity) occurs in approximately 20% of primary breast cancers(3) and in approximately 22% of patients with advanced gastric or gastroesophageal cancer.(4) **(EG 2)**

Criteria

For metastatic breast cancer that is HER2 positive, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A network meta-analysis of 8 randomized trials (3976 patients) evaluating the efficacy of combinations of HER2-targeted agents for first-line treatment of metastatic HER2-positive breast cancer concluded that the combination of trastuzumab, docetaxel, and pertuzumab was the only regimen that was associated with improved overall and progression-free survival.(12) **(EG 1)** Meta-analyses and systematic reviews of randomized clinical trials reported improved progression-free and overall survival with the addition of HER2-targeted therapies to standard chemotherapy regimens.(13)(14)(15)(16) **(EG 1)** A retrospective review of patients from an administrative database found that 1-year, 2-year, 3-year, 4-year, and 5-year survival rates for patients with HER2-positive metastatic breast cancer on trastuzumab were 82%, 64%, 50%, 41%, and 37%, respectively.(10) **(EG 2)** A randomized controlled trial of 808 patients with metastatic breast cancer found that adding pertuzumab to a regimen containing trastuzumab and docetaxel significantly improved median overall survival from 40.8 months to 56.5 months.(17) **(EG 1)**

For nonmetastatic breast cancer that is HER2 positive, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A network meta-analysis of 13 randomized trials (3160 patients) evaluating the effectiveness of neoadjuvant therapies for HER2-positive breast cancer concluded that the combination of trastuzumab, pertuzumab, and chemotherapy had the highest probability of success in terms of pathologic complete response (defined as the absence of invasive neoplastic cells in the breast tissue or lymph nodes at the time of surgery).(25) **(EG 1)** Systematic reviews, a meta-analysis, and other randomized clinical trials reported effectiveness of trastuzumab in significantly prolonging disease-free as well as overall survival when administered as adjuvant therapy in patients with early-stage node-positive disease or high-risk node-negative disease, the latter with either negative hormone receptors or one high-risk feature, when such patients are also receiving docetaxel and carboplatin, or paclitaxel or docetaxel following administration of doxorubicin and cyclophosphamide.(22)(23)(24)(26)(27) **(EG 1)**

For metastatic gastric or gastroesophageal cancer that is HER2 positive, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A multicenter randomized phase III study of 594 patients comparing trastuzumab plus chemotherapy (capecitabine or 5-fluorouracil and cisplatin) with chemotherapy alone reported a statistically significant benefit in median overall survival (13.8 vs 11.1 months). Subanalysis revealed that patients in the trastuzumab plus chemotherapy arm who were positive for HER2 via gene amplification with fluorescence in situ hybridization or had immunohistochemistry showing 3+ positivity for HER2 had an overall median survival of 16.0 months as compared with 11.8 months in the chemotherapy-alone arm.(55) **(EG 1)** A systematic review of chemotherapy for advanced gastric cancer concluded that all patients should be tested for HER2 status and that trastuzumab should be added to a standard fluoropyrimidine/cisplatin regimen in patients with HER2-positive tumors.(56) **(EG 1)** Expert consensus guidelines and review articles recommend trastuzumab for patients with advanced HER2-positive gastric cancer.(50)(51)(57)(58) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For leptomeningeal metastases from HER2-positive breast cancer, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** While case studies report successful treatment of leptomeningeal metastases from HER2-positive breast cancer with intrathecal trastuzumab as part of a regimen that may include chemotherapy, systemic anti-HER2 therapy, and radiotherapy, additional trials are needed to better define dosing and determine efficacy.(5) **(EG 2)**

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Footnotes

[A] For metastatic breast cancer, trastuzumab is administered as an initial 90-minute intravenous infusion, followed by weekly 30-minute intravenous infusions until disease progression occurs.(1) [A in Context Link 1]

[B] Trastuzumab is administered in combination with pertuzumab and either docetaxel or paclitaxel. Other combination chemotherapy regimens may also be used for initial treatment of metastatic disease, including trastuzumab with one of the following: paclitaxel (with or without carboplatin), docetaxel, vinorelbine, or capecitabine.(7) [B in Context Link 1]

[C] For preoperative (neoadjuvant) treatment of HER2-positive breast cancer, an expert consensus guideline recommends doxorubicin plus cyclophosphamide followed by paclitaxel plus trastuzumab (either with or without pertuzumab). Alternatively, trastuzumab may be administered in combination with docetaxel and carboplatin, either with or without pertuzumab.(7) [C in Context Link 1]

[D] For postoperative (adjuvant) treatment of breast cancer in combination with chemotherapy, trastuzumab is administered for a total of 52 weeks, as an initial 90-minute intravenous infusion, followed by a weekly 30-minute intravenous infusion for 12 weeks (if paclitaxel or docetaxel is administered concurrently), or for 18 weeks (if docetaxel-carboplatin is administered concurrently).(1) One week following the last weekly dose, trastuzumab is then administered as a 30-minute to 90-minute intravenous infusion every 3 weeks, to complete the total 52-week course.(1) [D in Context Link 1]

[E] For postoperative (adjuvant) treatment of breast cancer, trastuzumab is administered as a single-agent therapy within 3 weeks of multimodality anthracycline-based chemotherapy, as an initial 90-minute intravenous infusion, followed by a 30-minute to 90-minute infusion every 3 weeks for a total of 52 weeks.(1) Addition of pertuzumab during adjuvant therapy has been shown to significantly increase disease-free survival, especially in node-positive patients.(36) [E in Context Link 1]

[F] HER2 testing should be performed by a laboratory with documented proficiency in the testing technology.(37) [F in Context Link 1, 2]

[G] Deterioration in ejection fraction may require temporary or permanent discontinuation of trastuzumab.(1) [G in Context Link 1, 2]

[H] For metastatic gastric or gastroesophageal cancer, trastuzumab is administered as an initial 90-minute intravenous infusion, followed by a 30-minute to 90-minute intravenous infusion every 3 weeks until disease progression.(1) [H in Context Link 1]

Codes

HCPCS: J9354, J9355

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