PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Margenza Prior Authorization Policy
- Margenza® (margetuximab-cmbk intravenous infusion – MacroGenics)

REVIEW DATE: 02/09/2022

OVERVIEW

Margenza, in combination with chemotherapy, is indicated for the treatment of adults with metastatic human epidermal growth factor receptor 2 (**HER2)-positive breast cancer** who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 2.2022 – December 20, 2021) recommend Margenza as a third-line and beyond treatment for recurrent unresectable (local or regional) or stage IV disease. Margenza should be used in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine). Other third-line and beyond therapies include Tukysa (tucatinib tablets) + trastuzumab + capecitabine; trastuzumab + docetaxel or vinorelbine; trastuzumab + paclitaxel ± carboplatin; capecitabine + trastuzumab or lapatinib; trastuzumab + lapatinib (without cytotoxic therapy); trastuzumab + other agents; and Nerlynx (neratinib tablets) + capecitabine. NCCN recommends the following therapies as first-line: Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel; and Perjeta + trastuzumab + paclitaxel. The following therapies are recommended for second-line use: Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) and Kadcyla (ado-trastuzumab emtansine intravenous infusion).

Safety

Margenza has a Boxed Warning regarding left ventricular dysfunction and embryo-fetal toxicity.[1] Margenza may lead to reductions in left ventricular ejection fraction (LVEF); treatment should be discontinued for a confirmed clinically significant decrease in left ventricular function. Exposure to Margenza during pregnancy can cause embryo-fetal harm; patients should be advised of the risk and need for effective contraception.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Margenza. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Margenza as well as the monitoring required for adverse events and long-term efficacy, approval requires Margenza to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Margenza is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **D)** Patient has tried at least two prior anti-HER2 regimens; AND
     Note: Some examples of anti-HER2 regimens are Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine intravenous infusion), Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), Tukysa (tucatinib tablets) + trastuzumab + capecitabine, trastuzumab + lapatinib, trastuzumab + docetaxel, trastuzumab + vinorelbine, Nerlynx (neratinib tablets) + capecitabine.
   - **E)** At least one of the prior anti-HER2 regimens was used for metastatic disease; AND
   - **F)** The medication is used in combination with chemotherapy; AND
     Note: Examples of chemotherapy are capecitabine, eribulin, gemcitabine, vinorelbine.
   - **G)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Margenza is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Margenza® intravenous infusion [prescribing information]. Rockville, MD: MacroGenics; December 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 4, 2022.