Reference number(s)
4405-A

SPECIALTY GUIDELINE MANAGEMENT

MARGENZA (margetuximab-cmkb)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Margenza is indicated, in combination with chemotherapy, for the treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

B. Compendial Use
Breast cancer

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer
Authorization of 12 months may be granted for treatment of HER2-positive breast cancer with no response to preoperative systemic therapy or HER2-positive recurrent unresectable or metastatic breast cancer, in combination with chemotherapy, for members who have received two or more prior regimens.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for breast cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Margenza [package insert]. Rockville, MD: MacroGenics, Inc.; May 2023.
2. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 29, 2023.