

Specialty Guideline Management

Margenza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Margenza	margetuximab-cmkb

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.

FDA-approved Indications¹

Margenza is indicated, in combination with chemotherapy, for the treatment of adult patients 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.

Compendial Uses²

Breast cancer

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

Documentation

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

Coverage Criteria

Breast Cancer^{1,2}

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.

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.

References

1. Margenza [package insert]. Deerfield, IL: TerSera Therapeutics LLC; February 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed December 2, 2025.