| Reference number(s) |
| --- |
| 4407-A |

# Standard Medicare Part B 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 Indications[1]

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 Uses[2]

Breast Cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

## Documentation


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Documentation of human epidermal growth factor receptor 2 (HER2) status must be available, upon request, for all submissions.

# 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

# Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Margenza.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Breast cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Margenza are covered in addition to the following:

- HER2-positive breast cancer, if no response to preoperative systemic therapy
- HER2-positive breast cancer, recurrent unresectable disease


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# Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Margenza to treat HER2-positive breast cancer after no response to preoperative systemic therapy or disease that is recurrent unresectable  can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic 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.



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