Reference number(s)
4407-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

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

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

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:
A. The member is currently receiving therapy with requested medication

B. The requested medication is being used to treat an indication enumerated in Section III
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen or
   2. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Margenza.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. 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:

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

VI. 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 (local or regional) 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).

VII. REFERENCES

1. Margenza [package insert]. Rockville, MD: MacroGenics, Inc.; December 2020.
2. The NCCN Drugs & Biologics Compendium 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 6, 2022.