

Margenza (margetuximab-cmkb)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Margenza (margetuximab-cmkb)

APPROVAL CRITERIA

Requests for Margenza (margetuximab-cmkb) may be approved if the following criteria are met:

- I. Individual has a diagnosis of metastatic HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by one of the following:
 - A. Immunohistochemistry (IHC) is 3 +; **OR**
 - B. In situ hybridization (ISH) positive;

AND

- II. Individual has had at least two or more prior anti-HER2 therapies, and at least one in the metastatic setting (Label, NCCN 2A);

AND

- III. Individual is using in combination with chemotherapy, capecitabine, eribulin, gemcitabine, or vinorelbine (NCCN 2A; Rugo 2021).

Requests for Margenza (margetuximab-cmkb) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 15, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Margenza (margetuximab-cmkb) intravenous infusion [product information]. Rockville, MD: MacroGenics; December 2020.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 15, 2022
 - a. Breast Cancer. V2.2022. Revised December 20, 2021.
7. Rugo HS, Im SA, Cardoso F, et al. Efficacy of Margetuximab vs Trastuzumab in Patients With Pretreated ERBB2-Positive Advanced Breast Cancer: A Phase 3 Randomized Clinical Trial. *JAMA Oncol* 2021 Apr 1;7(4):573-584. Available at: <https://jamanetwork.com/journals/jamaoncology/fullarticle/2775599> Accessed January 19, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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