Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

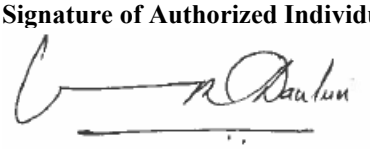
Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PHAR.522	**Effective Date: 01/2022** **Revision Date: 01/2022**
Policy Name: Margetuximab-cmkb (Margenza)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Margetuximab-cmkb (Margenza)

Reference Number: PA.CP.PHAR.522
Effective Date: 01/2022
Last Review Date: 01/2022

Coding Implications
Revision Log

Description
Margetuximab-cmkb (Margenza™) is a human epidermal growth factor receptor 2 (HER2)/neu receptor antagonist.

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

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Margenza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of metastatic or recurrent unresectable (local or regional) HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of at least two anti-HER2-based regimens (*see Appendix B*), at least one of which was for metastatic disease, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for anti-HER2-based regimens*
5. Prescribed in combination with chemotherapy (e.g., capecitabine, eribulin, gemcitabine, vinorelbine);
6. Request meets one of the following (a or b):
   a. Dose does not exceed 15 mg/kg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 15 mg/kg every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Herceptin® (trastuzumab) ± any of the following: • Aromatase inhibitor • Aromatase inhibitor ± Tykerb® (lapatinib) • Fulvestrant (Faslodex®) • Tamoxifen	Varies	Varies
Aromatase inhibitor ± Tykerb (lapatinib)		
Perjeta® (pertuzumab) + Herceptin (trastuzumab) + either of the following:		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Docetaxel • Paclitaxel		
Kadcyla® (ado-trastuzumab emtansine)	3.6 mg/kg IV every 3 weeks (21-day cycle)	3.6 mg/kg
Herceptin (trastuzumab) + any of the following: • Paclitaxel ± carboplatin • Docetaxel • Vinorelbine • Xeloda® (capecitabine) • Tykerb (lapatinib)	Varies	Varies
Tykerb (lapatinib) + Xeloda (capecitabine)	Tykerb 1,250 mg PO QD days 1-21 + Xeloda 1,000 mg/m^2 PO BID days 1-14 (21-day cycle)	Tykerb 1,250 mg/day Xeloda 2,000 mg/m^2/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): left ventricular dysfunction; embryo-fetal toxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	15 mg/kg IV every 3 weeks	15 mg/kg

VI. Product Availability

Single-dose vial: 250 mg/10 mL

VII. References

1. Margenza Prescribing Information. Rockville, MD: MacroGenics, Inc.; December 2020. Available at: www.margenza.com. Accessed November 20, 2021.
2. National Comprehensive Cancer Network. Breast Cancer Version 8.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 20, 2021.
3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 20, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2022	