Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/13/2025

Bevacizumab Policy

Alymsys® (bevacizumab-maly)
Avastin® (bevacizumab)
Avzivi® (bevacizumab-tnjn)
Mvasi™ (bevacizumab-awwb)
Vegzelma® (bevacizumab-adcd)
Zirabev™ (bevacizumab-bvzr)

HCPCS: Multiple

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

Coverage of the requested drug is provided for FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation OR when all of the criteria are met. Coverage requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria
   a. Prescribed by, or in consultation with a hematologist/oncologist
   b. A diagnosis of persistent, recurrent, or metastatic cervical cancer, when given in combination with paclitaxel and cisplatin or paclitaxel and topotecan
   c. A diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer
      i. Platinum-resistant recurrent disease in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
      OR
      ii. Platinum-sensitive recurrent disease in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by bevacizumab or a bevacizumab biosimilar as a single agent
      OR
      iii. Stage III or IV disease following initial surgical resection in combination with carboplatin and paclitaxel, followed by bevacizumab or a bevacizumab biosimilar as a single agent
   d. A diagnosis of metastatic colorectal cancer (adenocarcinoma)
   e. Recurrent glioblastoma
   f. A diagnosis of unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer
      i. Patient has had no prior chemotherapy

ii. Bevacizumab or a bevacizumab biosimilar is administered in combination with carboplatin and paclitaxel

g. A diagnosis of metastatic renal cell carcinoma
   i. Bevacizumab or a bevacizumab biosimilar is administered in combination with interferon-alfa

h. A diagnosis of unresectable or metastatic hepatocellular carcinoma
   i. Patient has had no prior chemotherapy
   ii. Bevacizumab or a bevacizumab biosimilar is administered in combination with atezolizumab

i. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met

j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing.
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Continuation of therapy until disease progression or unacceptable toxicity

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

BackgroundInformation:

- Bevacizumab and its biosimilars are monoclonal antibodies that bind to and inhibit the activity of vascular endothelial growth factor (VEGF). Bevacizumab is approved for the following indications:

  - In combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment of patients with metastatic colorectal cancer (mCRC)

  - In combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab-containing regimen

  - In combination with carboplatin and paclitaxel for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer (NSCLC)

  - The treatment of recurrent glioblastoma (GBM) in adults

  - In combination with interferon alfa for the treatment of metastatic renal cell carcinoma (mRCC)

  - In combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of patients with persistent, recurrent, or metastatic cervical cancer

  - In combination with carboplatin and paclitaxel followed by bevacizumab as a single agent for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection

- In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens

- In combination with carboplatin and paclitaxel or with carboplatin and gemcitabine followed by bevacizumab as a single agent for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer

- In combination with atezolizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy

- While not specifically indicated for ocular conditions, bevacizumab has been used off-label for years to treat multiple eye disorders including macular degeneration, macular edema, and diabetic retinopathy. Bevacizumab has the same mechanism of action as the other therapies for these diseases and its use is guideline supported.

- NCCN guidelines state an FDA approved biosimilar can be substituted for Avastin. The guidelines do not specify what biosimilars are appropriate for a specific tumor type which allows for use of any of the biosimilars to be used for any indication the innovator product is FDA approved for.

References:

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4. Mvasi [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
5. Avzivi [prescribing information]. Guangzhou, Guangdong Province, China: Bio-Thera Solutions, Ltd.; December 2023.
6. Approved Drugs: "FDA approves bevacizumab in combination with chemotherapy for ovarian cancer". U.S. Food & Drug Administration. June 13, 2018. Accessed on: September 5th, 2018. Available from: https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm610664.htm
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18. National Comprehensive Cancer Network. Cervical cancer (Version 4.2024). 2024 Sept 24. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed December 10, 2024.
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21. Alymsys [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
22. Vegzelma [prescribing information]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023.

Policy History		
#	Date	Change Description
3.0	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made
2.9	Effective Date: 04/01/2024	UM medical management system update for MAPPO and BCNA for Avzivi
2.8	Effective Date: 02/08/2024	Updated to include Avzivi
2.7	Effective Date: 01/01/2024	UM medical management system update for BCBS and BCN for Avzivi
2.6	Effective Date: 12/14/2023	Annual review of criteria was performed, no changes were made
2.5	Effective Date: 03/09/2023	UM medical management system update to Vegzelma for BCBS and BCN
2.4	Effective Date: 03/01/2023	UM medical management system update to Vegzelma for MAPPO and BCNA
2.3	Effective Date: 12/01/2022	Updated to include Vegzelma and reflect an authorization period of at least 60 days
2.2	Effective Date: 06/09/2022	Updated to include Alymsys and change approval length to allow for FDA recommended dosing or up to 6 months at a time
2.1	Effective Date: 08/12/2021	Updated to remove the ophthalmologist requirement when used for ocular indications and the criteria for initiation of use 28 days after wound healing
2.0	Effective Date: 04/01/2021	UM medical management system update to Avastin for BCBS, BCN, MAPPO, and BCNA
1.9	Effective Date: 08/13/2020	Updated to include the new indication of hepatocellular carcinoma
1.8	Effective Date: 03/16/2020	UM medical management system update to Zirabev for MAPPO and BCNA
1.7	Effective Date: 01/01/2020	UM medical management system update to Mvasi for MAPPO and BCNA
1.6	Effective Date: 12/05/2019	Updated criteria to remove taxane requirement with use in mCRC per guidelines and FDA labeling
1.5	Effective Date: 08/15/2019	Updated criteria to allow use when aligned with NCCN guideline recommendations category 1 and 2A and added Zirabev
1.4	Effective Date: 11/01/2018	New Indication Update
1.3	Effective Date: 05/03/2018	Added Mvasi and changed name of policy to Bevacizumab
1.2	Effective Date: 05/04/2017	New Indication Update

<table>
<tr><td>1.1</td><td>Effective Date: 11/10/2016</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 05/07/2015</td><td>New Policy
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
3. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
   ☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please specify location of administration if hospital inpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____
7. **Initiation AND Continuation of therapy:**
   a. What is the patient's diagnosis? _____
   b. What other medication has the patient received for their condition? Please list_____
      i. Please describe the response to previous therapies:
      _____
   c. Will the patient be receiving any other treatment for the listed condition while on this medication? Please list:
      _____
   d. Please list any labs values important for diagnosing or monitoring this patient's condition:
      _____
8. **Continuation of therapy:**
   a. Has the patient progressed while on this medication? ☐ yes ☐ no
   b. How has the patient's condition changed while on this medication?
      ☐ Improved: Please describe: _____
      ☐ Stable: please describe: _____
      ☐ Worsened; Please describe: _____
      ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review **(required)**

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021