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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: 06/11/2026**

## **Medical Benefit Oncology Drug Class Policy**

**HCPCS:** See Appendix A below

### **Policy:**

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

#### **A. Criteria:**

- a. Coverage of the requested drug is provided for FDA approved indications  
OR
- b. When use is aligned with NCCN guidelines category 1 or 2A  
OR
- c. When use is aligned with NCCN guidelines category 2B recommendations when there is not a higher-rated NCCN category recommendation available  
AND
- d. When ALL of the following criteria are met:
  - i. Prescriber is an oncologist/hematologist OR another board-certified prescriber with qualifications to treat the specified malignancy.
  - ii. Genetic testing results support use based on package labeling/FDA requirements. Consideration may also be given to genetic testing as recommended by NCCN guidelines.
  - iii. Trial of medications and treatments supported by the NCCN guidelines and/or package labeling as prior lines of therapy.
  - iv. If appropriate, trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list
- e. No prior failure based on efficacy of a drug with the same mechanism of action unless retreatment with the same mechanism of action is guideline recommended or supported by a randomized, controlled clinical trial

#### **B. Quantity Limitations, Authorization Period and Renewal Criteria**

- a. Quantity Limits: Align with FDA recommended dosing or NCCN guidelines
- 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: No evidence of disease progression or unacceptable toxicity

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\*\*\*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.

### **Background Information:**

- Definition of an oncology medication: Any drug (chemotherapy, hormone therapy, gene therapy, biological therapy, or other drug) which is used to treat a cancer (a malignant growth or tumor resulting from the division of abnormal cells) diagnosis. Supportive therapy used for cancer is not in scope of this policy.
- The medications added to the Oncology Drug Class Policy go through a detailed review by a pharmacist to determine if the policy covers the intended criteria for the drug. Each drug is evaluated on the following:
  - Indication
  - Place in therapy
  - Category based on uniform NCCN guidance or category 1 and 2A recommendations
  - Cost of the medication
  - Safety of the medication
  - Genetic testing requirements

### **References:**

1. NCCN guidelines for the specific disease state. Available at: [https://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](https://www.nccn.org/professionals/physician_gls/f_guidelines.asp). Accessed October 23, 2017.
2. Drug specific package labeling. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>. Accessed October 23, 2017.

| Policy History |                                                              |                                                                                                                                                                                                                                                                                    |
|----------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| #              | Date                                                         | Change Description                                                                                                                                                                                                                                                                 |
| 6.1            | Effective Date:<br>10/01/2026                                | UM medical management system update for MAPPO and BCNA for Avopef, Evdi, Favlyxa, and Vykoura                                                                                                                                                                                      |
| 6.0            | Effective Date:<br>08/12/2026                                | UM medical management system update for BCBS and BCN for Cyramza, Frindovyx, and Rybrevant Faspro<br>UM medical management system update for MAPPO and BCNA for Rybrevant Faspro                                                                                                   |
| 5.9            | Effective Date:<br>06/11/2026                                | Updated to include Evdi                                                                                                                                                                                                                                                            |
| 5.8            | Effective Date:<br>05/13/2026                                | UM medical management system update for BCBS, BCN, MAPPO, and BCNA for Avgemsi , Boruzu, Kyxata, and Vivimusta                                                                                                                                                                     |
| 5.7            | Effective Date:<br>04/16/2026                                | Updated to include Avopef, Cyramza, Favlyxa, Frindovyx, Vivimusta, and Vykoura                                                                                                                                                                                                     |
| 5.6            | Effective Date:<br>03/04/2026                                | UM medical management system update for BCBS, BCN, MAPPO, and BCNA for Beizray, Docivyx, Emrelis, and Zusduri                                                                                                                                                                      |
| 5.5            | Effective Date:<br>02/12/2026                                | Updated to include Rybrevant Faspro, Kyxata, Boruzu, and Avgemsi                                                                                                                                                                                                                   |
| 5.4            | Effective Date:<br>12/04/2025                                | Updated to include Docivyx and Beizray                                                                                                                                                                                                                                             |
| 5.3            | Effective Date:<br>12/01/2025                                | UM medical management system update for BCBS, BCN, MAPPO, and BCNA for Datroway                                                                                                                                                                                                    |
| 5.2            | Effective Date:<br>08/20/2025                                | UM medical management system update for BCBS, BCN, MAPPO, and BCNA for Bizengri, Vyloy, and Ziihera                                                                                                                                                                                |
| 5.1            | Effective Date:<br>08/07/2025                                | Updated to include Emrelis and Zusduri                                                                                                                                                                                                                                             |
| 5.0            | Effective Date:<br>06/01/2025                                | UM medical management system update for MAPPO and BCNA for Lymphir                                                                                                                                                                                                                 |
| 4.9            | Effective Date:<br>05/27/2025<br><br>P&T Date:<br>04/10/2025 | Updated to include the statement that there be no prior failure based on efficacy of a drug with the same mechanism of action unless retrial with the same mechanism of action is guideline recommended or supported by a randomized, controlled clinical trial and added Datroway |
| 4.8            | Effective Date:<br>02/13/2025                                | Added Ziihera and Bizengri                                                                                                                                                                                                                                                         |
| 4.7            | Effective Date:<br>01/01/2025                                | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for J-code J9292                                                                                                                                                                                                 |
| 4.6            | Effective Date:<br>12/12/2024                                | Added Vyloy                                                                                                                                                                                                                                                                        |
| 4.5            | Effective Date:<br>10/03/2024                                | Added Lymphir, Darzalex, and Darzalex FasPro and to remove Adcetris, Besremi, Kyprolis, Romidepsin, and Sylvant                                                                                                                                                                    |
| 4.4            | Effective Date:<br>04/11/2024                                | Added Danyelza                                                                                                                                                                                                                                                                     |
| 4.3            | Effective Date:<br>02/08/2024                                | Added pemetrexed                                                                                                                                                                                                                                                                   |
| 4.2            | Effective Date:<br>01/01/2024                                | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for J-code J9324                                                                                                                                                                                                 |
| 4.1            | Effective Date:<br>08/23/2023                                | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Elahere                                                                                                                                                                                                      |
| 4.0            | Effective Date:<br>02/09/2023                                | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Pemfexy                                                                                                                                                                                                      |

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|     |                               |                                                                                                                                                                                                                                           |
|-----|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.9 | Effective Date:<br>02/02/2023 | Added Elahere and removed Asparlas, Doxil, Evomela, Imlygic, Istodax, Ixempra, Lipodox, Mylotarg, Portrazza, and Zepzelca                                                                                                                 |
| 3.8 | Effective Date:<br>01/01/2023 | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Asparlas, Doxil, Evomela, Imlygic, Istodax, Ixempra, Lipodox, Mylotarg, Pemetrexed, Portrazza, and Zepzelca                                                         |
| 3.7 | Effective Date:<br>12/01/2022 | Added Pemfexy                                                                                                                                                                                                                             |
| 3.6 | Effective Date:<br>10/06/2022 | Added Kyprolis                                                                                                                                                                                                                            |
| 3.5 | Effective Date:<br>05/23/2022 | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Tivdak and Kimmtrak                                                                                                                                                 |
| 3.4 | Effective Date:<br>04/14/2022 | Added Kimmtrak, removed Adriamycin, Beleodaq, Dacarbazine, Lartruvo, Oncovin, Pemetrexed, Proleukin, Rubex, Synribo, Torisel, Velcade, and Vyxeos, and updated approval length to allow for FDA recommended dosing or up to 6 months at a |
| 3.3 | Effective Date:<br>02/10/2022 | Added Fyarro                                                                                                                                                                                                                              |
| 3.2 | Effective Date:<br>12/09/2021 | Added Tivdak and Besremi                                                                                                                                                                                                                  |
| 3.1 | Effective Date:<br>09/27/2021 | UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Rybrevant                                                                                                                                                           |
| 3.0 | Effective Date:<br>08/12/2021 | Added Rybrevant                                                                                                                                                                                                                           |
| 2.9 | Effective Date:<br>07/26/2021 | UM medical management system update to BCBS, BCN, MAPPO, and BCNA for Zynlonta                                                                                                                                                            |
| 2.8 | Effective Date:<br>06/10/2021 | Added Zynlonta                                                                                                                                                                                                                            |
| 2.7 | Effective Date:<br>02/04/2021 | Added Asparlas and Elzonris                                                                                                                                                                                                               |
| 2.6 | Effective Date:<br>12/01/2020 | UM medical management system update for PPO for Darzalex and Darzalex FasPro                                                                                                                                                              |
| 2.5 | Effective Date:<br>10/08/2020 | Added Beleodaq and Sylvant                                                                                                                                                                                                                |
| 2.4 | Effective Date:<br>08/24/2020 | UM medical management system update to BCNA and MAPPO for Imlygic                                                                                                                                                                         |
| 2.3 | Effective Date:<br>08/13/2020 | Removed Herceptin and added Zepzelca                                                                                                                                                                                                      |
| 2.2 | Effective Date:<br>07/24/2020 | UM medical management system update to BCNA and MAPPO for Jelmyto, Trodelvy, and Darzalex Faspro                                                                                                                                          |
| 2.1 | Effective Date:<br>06/11/2020 | Added Jelmyto and Trodelvy                                                                                                                                                                                                                |
| 2.0 | Effective Date:<br>05/26/2020 | UM medical management system update for Darzalex Faspro                                                                                                                                                                                   |
| 1.9 | Effective Date:<br>04/16/2020 | Added Sarclisa and romidepsen                                                                                                                                                                                                             |
| 1.8 | Effective Date:<br>03/16/2020 | UM medical management system update to Polivy for MAPPO and BCNA                                                                                                                                                                          |
| 1.7 | Effective Date:<br>02/06/2020 | Added Padcev                                                                                                                                                                                                                              |
| 1.6 | Effective Date:<br>08/15/2019 | Added Polivy                                                                                                                                                                                                                              |

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| 1.5              | Effective Date:<br>07/22/2019                     | UM medical management system update for BCNA and MAPPO for Darzalex                                                                                                                                                                                                                                                                                                                                                                                            |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
|------------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------------------------|------|-----|-----|-----|-------|-----------------------------------|------|-----------------------------------|
| 1.4              | Effective Date:<br>05/09/2019                     | Added Herceptin, Doxil, and Lipodox. Removed Treanda and Ogivri.                                                                                                                                                                                                                                                                                                                                                                                               |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| 1.3              | Effective Date:<br>02/14/2019                     | Updated to allow for NCCN category 1 and 2A recommendations only                                                                                                                                                                                                                                                                                                                                                                                               |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| 1.2              | Effective Date:<br>02/01/2019                     | UM medical management system update to BCNA and MAPPO for Sylvant                                                                                                                                                                                                                                                                                                                                                                                              |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| 1.1              | Effective Date:<br>11/01/2018                     | <div>New medical benefit specific oncology policy due to the retirement of the joint medical/pharmacy benefit Oncology Drug Class Policy</div> <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes – Adcentris and Yondelis Only</td></tr><tr><td>BCNA</td><td>Yes – Adcentris and Yondelis Only</td></tr></table> | Line of Business | PA Required in Medical Management System (Yes/No) | BCBS | Yes | BCN | Yes | MAPPO | Yes – Adcentris and Yondelis Only | BCNA | Yes – Adcentris and Yondelis Only |
| Line of Business | PA Required in Medical Management System (Yes/No) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| BCBS             | Yes                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| BCN              | Yes                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| MAPPO            | Yes – Adcentris and Yondelis Only                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| BCNA             | Yes – Adcentris and Yondelis Only                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                                   |      |     |     |     |       |                                   |      |                                   |
| 1.0              | Effective Date:<br>08/10/2016                     | New Criteria and UM medical management system update for BCN for Darzalex                                                                                                                                                                                                                                                                                                                                                                                      |                  |                                                   |      |     |     |     |       |                                   |      |                                   |

*\* 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>.*

# Appendix A

Medications covered by this policy include, but not limited to the following:

| Drug                                                          | HCPs                                            |
|---------------------------------------------------------------|-------------------------------------------------|
| <b>Avgemsi™</b> (gemcitabine)                                 | J9184                                           |
| <b>Alimta®</b> (pemetrexed)                                   | J9305                                           |
| <b>Avopel™</b> (etoposide)                                    | J9999                                           |
| <b>Beizray™</b> (docetaxel)                                   | J9174                                           |
| <b>Bizengri®</b> (zenocutuzumab-zbco)                         | J9382                                           |
| <b>Boruzu®</b> (bortezomib)                                   | J9054                                           |
| <b>Danyelza®</b> (naxitamab-ggqk)                             | J9348                                           |
| <b>Cyamza®</b> (ramucirumab)                                  | J9308                                           |
| <b>Darzalex®</b> (daratumumab)                                | J9415                                           |
| <b>Darzalex FasPro®</b> (daratumumab and hyaluronidase-fihj)  | J9144                                           |
| <b>Datroway®</b> (datopotamab deruxtecan-dlnk)                | J9011                                           |
| <b>Docivvy®</b> (docetaxel)                                   | J9172                                           |
| <b>Elahere®</b> (mirvetuximab soravtansine-gynx)              | J9063                                           |
| <b>Elzonris®</b> (tagraxofusp-erzs)                           | J9269                                           |
| <b>Emrelis™</b> (telisotuzumab vedotin-tllv)                  | J9326                                           |
| <b>Erbitux®</b> (cetuximab)                                   | J9055                                           |
| <b>Evdi</b> (trabectedin)                                     | J9999                                           |
| <b>Favlyxa™</b> (fluorouracil)                                | J9999                                           |
| <b>Frindovyx™</b> (cyclophosphamide)                          | J9072                                           |
| <b>Fyarro™</b> (sirolimus protein-bound particles)            | J9331                                           |
| <b>Jelmyto®</b> (mitomycin)                                   | J9281                                           |
| <b>Kimmtrak®</b> (tebentafusp-tebn)                           | J9274                                           |
| <b>Kyxata™</b> (carboplatin)                                  | J9278                                           |
| <b>Lymphir™</b> (denileukin diftitox-cxdl)                    | J9161                                           |
| <b>Padcev®</b> (enfortumab vedotin-ejfv)                      | J9177                                           |
| <b>Pemetrexed</b>                                             | J9296, J9294, J9297, J9314, J9323, J9322, J9292 |
| <b>Pemfexy™</b> (pemetrexed)                                  | J9304                                           |
| <b>Pemrydi RTU®</b> (pemetrexed)                              | J9324                                           |
| <b>Polivy®</b> (polatuzumab vedotin-piiq)                     | J9309                                           |
| <b>Rybrevant®</b> (amivantamab-vmjw)                          | J9061                                           |
| <b>Rybrevant Faspro®</b> (amivantamab and hyaluronidase-lpuj) | J9062                                           |
| <b>Sarclisa®</b> (isatuximab-irfc)                            | J9227                                           |
| <b>Tivdak®</b> (tisotumab vedotin-tftv)                       | J9273                                           |
| <b>Trodelvy®</b> (sacituzumab govitecan-hziy)                 | J9317                                           |
| <b>Vivimusta®</b> (bendamustine)                              | J9056                                           |
| <b>Vykoura™</b> (leucovorin calcium)                          | J3490                                           |
| <b>Vyloy®</b> (zolbetuximab-clzb)                             | J1326                                           |
| <b>Yondelis®</b> (trabectedin)                                | J9352                                           |
| <b>Ziihera®</b> (zanidatamab-hrii)                            | J9276                                           |
| <b>Zusduri™</b> (mitomycin)                                   | J9282                                           |
| <b>Zynlonta®</b> (loncastuximab tesirine-lpyl)                | J9359                                           |

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