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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.

Effective Date: 04/11/2024

Medical Benefit Oncology Drug Class Policy

HCPCS: See 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
- When use is aligned with NCCN guidelines category 1 or 2A OR
- 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
- 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

***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.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

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. 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 I	Policy History				
#	Date	Change Description			
4.1	Effective Date: 04/11/2024	Added Danyelza			
4.0	Effective Date: 02/08/2024	Added pemetrexed			
3.9	Effective Date: 01/01/2024	UM medical management system update to PPO, BCN, MAPPO, and BCNA for J-code J9324			
3.8	Effective Date: 08/23/2023	UM medical management system update to BCNA, MAPPO, BCN, and BCBS for Elahere			
3.7	Effective Date: 02/09/2023	UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Pemfexy			
3.6	Effective Date: 02/02/2023	Added Elahere and removed Asparlas, Doxil, Evomela, Imlygic, Istodax, Ixempra, Lipodox, Mylotarg, Portrazza, and Zepzelca			
3.5	Effective Date: 01/01/2023	UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Asparlas, Doxil, Evomela, Imlygic, Istodax, Ixempra, Lipodox, Mylotarg, Portrazza, and Zepzelca			
3.4	Effective Date: 01/01/2023	UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Pemetrexed			
3.3	Effective Date: 12/01/2022	Added Pemfexy			

3.2	Effective Date: 10/06/2022	Added Kyprolis	
3.1	Effective Date: 05/23/2022	UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Tivdak and Kimmtrak	
3.0	Effective Date: 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	
2.9	Effective Date: 02/10/2022	Added Fyarro	
2.8	Effective Date: 12/09/2021	Added Tivdak and Besremi	
2.7	Effective Date: 09/27/2021	UM medical management system update to BCBS, BCN, BCNA, and MAPPO for Rybrevant	
2.6	Effective Date: 08/12/2021	Added Rybrevant	
2.5	Effective Date: 07/26/2021	UM medical management system update to BCBS, BCN, MAPPO, and BCNA for Zynlonta	
2.4	Effective Date: 06/10/2021	Added Zynlonta	
2.3	Effective Date: 02/04/2021	Added Asparlas and Elzonris	
2.2	Effective Date: 10/08/2020	Added Beleodaq and Sylvant	
2.1	Effective Date: 08/24/2020	UM medical management system update to BCNA and MAPPO for Imlygic	
2.0	Effective Date: 08/13/2020	Removed Herceptin and added Zepzelca	
1.9	Effective Date: 07/24/2020	UM medical management system update to BCNA and MAPPO for Jelmyto and Trodelvy	
1.8	Effective Date: 06/11/2020	Added Jelmyto and Trodelvy	
1.7	Effective Date: 04/16/2020	Added Sarclisa and romidepsen	
1.6	Effective Date: 03/16/2020	UM medical management system update to Polivy for MAPPO and BCNA	
1.5	Effective Date: 02/06/2020	Added Padcev	
1.4	Effective Date: 08/15/2019	Added Polivy	
1.3	Effective Date: 05/09/2019	Added Herceptin, Doxil, and Lipodox. Removed Treanda and Ogivri.	
1.2	Effective Date: 02/14/2019	Updated to allow for NCCN category 1 and 2A recommendations only	
1.1	Effective Date: 02/01/2019	UM medical management system update to BCNA and MAPPO for Sylvant	

1.0	Effective Date: 11/01/2018	New medical benefit specific oncology policy due to the retirement of the joint medical/pharmacy benefit Oncology Drug Class Policy			
		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		

^{*} 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:

Medication Name	Benefit	HCPCS
Adcentris (brentuximab)	Medical	J9042
Alimta (pemetrexed)	Medical	J9305
Besremi (ropeginterferon alfa-2b-njft)	Medical	J9999, C9399
Danyelza (naxitamab-gqgk)	Medical	J9348
Elahere (mirvetuximab soravtansine-gynx)	Medical	J9063
Elzonris (tagraxofusp-erzs)	Medical	J9269
Erbitux (cetuximab)	Medical	J9055
Fyarro (sirlimus protein-bound particles)	Medical	J9999, C9091
Jelmyto (mitomycin)	Medical	J9281
Kimmtrak (tebentafusp-tebn)	Medical	J9999, C9399, J3590
Kyprolis (carfilzomib)	Medical	J9047
Padcev (enfortumab vedotin-ejfv)	Medical	J9177
Pemetrexed	Medical	J9324, J9296, J9294, J9297, J9314, J9323, J9322
Pemfexy (pemetrexed)	Medical	J9304
Polivy (polatuzumab vedotin-piiq)	Medical	J9309
Romidepsen	Medical	J9318
Rybrevant (amivantamab-vmjw)	Medical	J9061
Sarclisa (isatuximab-irfc)	Medical	J9227
Sylvant (situximab)	Medical	J2860
Tivdak (tisotumab vedotin-tfttv)	Medical	J9273
Trodelvy (sacituzumab govitecan-hziy)	Medical	J9317
Yondelis (trabectedin)	Medical	J9352
Zynlonta (loncastuximab tesirine-lpyl)	Medical	J9359