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Effective Date: 12/01/2022

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
- 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 Wellmark Advantage Health Plan
 - v. 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 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

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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. 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
1.2	Effective Date: 12/01/2022	Added Pemfexy
1.1	Effective Date: 10/06/2022	Added Kyprolis
1.0	Effective Date: 01/01/2022	Effective date of policy

** 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

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

Medication Name	Benefit	HCPCS
Adcentris (brentuximab)	Medical	J9042
Alimta (pemetrexed)	Medical	J9305
Asparlas (calaspargase pegol-mknl)	Medical	J9118
Besremi (ropeginterferon alfa-2b-njft)	Medical	J9999, C9399
Doxil (liposomal doxorubicin)	Medical	Q2050
Elzonris (tagraxofusp-erzs)	Medical	J9269
Erbix (cetuximab)	Medical	J9055
Evomela (melphalan)	Medical	J9246
Fyarro (sirinimus protein-bound particles)	Medical	J9999, C9091
Imlygic (talimogene laherparepvec)	Medical	J9325
Istodax (romidepsin)	Medical	J9319
Ixempra (ixabepilone)	Medical	J9207
Jelmyto (mitomycin)	Medical	J9281
Kimmtrak (tebentafusp-tebn)	Medical	J9999, C9399, J3590
Kyprolis (carfilzomib)	Medical	J9047
Lipodox (liposomal doxorubicin)	Medical	Q2049
Mylotarg (gemtuzumab ozogamicin)	Medical	J9203
Padcev (enfortumab vedotin-ejfv)	Medical	J9177
Pemfexy (pemetrexed)	Medical	J9304
Polivy (polatuzumab vedotin-piiq)	Medical	J9309
Portrazza (necitumumab)	Medical	J9295
Romidepsen	Medical	J9318
Rybrevant (amivantamab-vmjw)	Medical	J9061
Sarclisa (isatuximab-irfc)	Medical	J9227
Sylvant (situximab)	Medical	J2860
Tivdak (tisotumab vedotin-tfttv)	Medical	J9273
Trodelyv (sacituzumab govitecan-hziy)	Medical	J9317
Yondelis (trabectedin)	Medical	J9352
Zepzelca (lurbinectedin)	Medical	J9223
Zynlonta (loncastuximab tesirine-lpyl)	Medical	J9359

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