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Effective Date: 06/06/2024

Zynyz™ (retifanlimab-dlwr)

HCPCS: J3590, J9999, C9399

Policy:

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

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
 - i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
 - b. Must be prescribed by, or in consultation with, an oncologist or hematologist
 - c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor
 - d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant
- 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: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***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:

- Zynyz is a programmed death receptor-1 (PD-1)–blocking antibody indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma.
- The National Comprehensive Cancer Network (NCCN) guidelines category 1 and 2A recommendations are based on uniform NCCN consensus that the recommendations are appropriate. Treatment regimens have been studied and shown to be efficacious when administered as listed in the guidelines. Category 2B and 3 recommendations do not have a high level of evidence to support use and also do not have a uniform consensus from the NCCN panel that the recommendations are appropriate.
- There are no studies to support use of Zynyz following failure. NCCN treatment guidelines also do not recommend use of Zynyz or other PD-L1 checkpoint inhibitors following a previous failure.
- Zynyz has not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants.

References:

1. Zynyz [prescribing information]. Wilmington, DE: Incyte Corporation; April 2024.
2. National Comprehensive Cancer Network. Merkle cell carcinoma (Version 1.2024). 2023 Nov 22. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mcc.pdf. Accessed on April 19, 2024.
3. Clinicaltrials.gov. A phase 2 study of INCMGA00012 in participants with metastatic merkel cell carcinoma (POD1UM-201) (NCT03599713). Available at: <https://clinicaltrials.gov/ct2/show/NCT03599713>. Accessed on March 24, 2023.

Policy History												
#	Date	Change Description										
1.2	Effective Date: 06/06/2024	Updated to remove the ECOG score requirement										
1.1	Effective Date: 12/10/2023	UM medical management system update for BCNA, MAPPO, BCN, and BCBS <table border="1" style="margin-left: 20px; width: 80%;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 06/08/2023	New 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>.*

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