Medical Drug Clinical Criteria

Subject:	Zynyz (retifanlimab-dlwr)		
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Overview

This document addresses the use of Zynyz (retifanlimab-dlwr) 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 (MCC). Zynyz was approved by the FDA based on the single-arm Pod1um-201 trial in which 65 chemotherapy-naïve individuals with metastatic or recurrent locally advanced MCC and treated with Zynyz had complete and partial response rates of 18% and 34% respectively. Serious adverse reactions occurred in 22% of individuals with the most common being fatigue, arrhythmia, and pneumonitis.

NCCN added a 2A recommendation for the use in locally advanced or metastatic squamous carcinoma of the anal cancer as monotherapy post platinum-based therapy.

Definitions and Measures

Merkel cell carcinoma: A rare, aggressive skin cancer.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Programmed death (PD)-1: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. Examples of FDA approved PD-1 inhibitors include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab)

Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved PD-L1 inhibitors include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Zynyz (retifanlimab-dlwr)

Requests for Zynyz (retifanlimab-dlwr) may be approved if the following criteria are met:

I. Individual has a diagnosis of Merkel Cell Carcinoma; **AND**
II. Individual has metastatic or recurrent locally advanced disease not amenable to surgery or radiation (NCCN 2A); **AND**
III. Individual is using as monotherapy; **AND**
IV. Has not received prior treatment with an anti-PD-1 or PD-L1 agent;

OR

V. Individual has a diagnosis of anal carcinoma; **AND**
VI. Individual has locally advanced or metastatic squamous carcinoma of the anal canal; **AND**
VII. Individual is using as monotherapy; **AND**
VIII. Individual is using due to disease progression on or after platinum-based chemotherapy; **AND**
IX. Individual is using as second-line and subsequent therapy; **AND**

X. Individual has not received prior treatment with an anti-PD-1 or PD-L1 agent.

Requests for Zynyz (retifanlimab-dlwr) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Zynz (retifanlimab-dlwr) Quantity Limits

Drug	Limit
Zynyz (retifanlimab-dlwr) 500 mg/ 20 mL vial	500 mg every 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9345	Injection, retifanlimab-dlwr, 1 mg [Zynyz]

ICD-10 Diagnosis

C4A.0-C4A.9	Merkel cell carcinoma
C21.0-C21.8	Malignant neoplasm of anus and anal canal

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: Add 2A recommendation from NCCN for locally advanced or metastatic squamous carcinoma of the anal canal (SCAC). Wording and formatting updates. Coding Reviewed: Added ICD-10-CM C21.0-C21.8.
- 5/19/2023 – Select Review: New clinical criteria and quantity limit for Zynyz (retifanlimab-dlwr). Coding Reviewed: Added HCPCS J9999. All diagnoses pend. Effective 10/1/2023 Added HCPCS J9345. Deleted HCPCS J9999. Added ICD-10-CM C4A.0-C4A.9.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 3, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Updated periodically. Accessed on April 18, 2023.
    a. Merkel Cell Carcinoma. V1.2023. Revised April 10, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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