Clinical Policy: Retifanlimab-dlwr (Zynyz)

Reference Number: PA.CP.PHAR.629
Effective Date: 06/2023
Last Review Date: 04/2024

Description
Retifanlimab-dlwr (Zynyz®) is a programmed death receptor-1 (PD-1)–blocking antibody.

FDA Approved Indication(s)
Zynyz is indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).*

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**This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Zynyz is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Merkel Cell Carcinoma (must meet all)**:**

1. Diagnosis of MCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease meets one of the following (a, b, or c):
   a. Metastatic;
   b. Primary or recurrent, locally advanced;
   c. Recurrent regional disease;
5. Disease meets one of the following (a, b or c):
   a. Not amenable to surgery or radiation therapy;
   b. Progressed on neoadjuvant Opdivo;
   c. M1 disseminated disease;
6. Prescribed as a single agent;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 500 mg (1 vial) every four weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Anal Carcinoma (off-label) (must meet all)**:**

1. Diagnosis of locally recurrent, progressive, or metastatic anal carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Prescribed as a single agent;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 500 mg (1 vial) every four weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 500 mg (1 vial) every four weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MCC: Merkel cell carcinoma
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MCC	500 mg IV infusion every 4 weeks	500 mg IV infusion every 4 weeks

VI. Product Availability

Single-dose vial: 500 mg/20mL (25 mg/mL)

VII. References

1. Zynyz Prescribing Information. Wilmington, DE: Incyte Corporation.; November 2023. Available at: https://www.zynyz.com/. Accessed February 13, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium. Accessed February 13, 2024
3. National Comprehensive Cancer Network. Merkel Cell Carcinoma Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/mcc.pdf. Accessed February 13, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9345	Injection, retifalimab-dlwr, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	05/2023
2Q 2024 annual review: for MCC, added pathways for primary locally advanced disease and recurrent regional disease per NCCN 2A recommendation and added requirement that Zynyz be prescribed as a single agent; added criteria for anal carcinoma per NCCN 2A recommendation; added Zynyz HCPCS code and removed inactive codes; references reviewed and updated.	04/2024