Zynyz (retifanlimab-dlwr)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Zynyz (retifanlimab-dlwr) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

Limitations of use:
Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

POLICY

Criteria for Initial Approval

Merkel Cell Carcinoma (MCC)
Authorization of 6 months may be granted for treatment of metastatic or recurrent locally advanced MCC.

Continuation of Therapy

Merkel Cell Carcinoma (MCC)

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Zynyz is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

Zynyz (retifanlimab-dlwr) is an anti-PD-1 monoclonal antibody indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). Zynyz is the 3rd FDA-approved agent for MCC and is currently under accelerated approval with its confirmatory trial estimated to be completed in June 2024. The recommended dosage of Zynyz is 500 mg administer intravenously every 4 weeks until disease progression, unacceptable toxicity or up to 24 months total duration. The efficacy and safety of Zynyz (retifanlimab-dlwr) were established in the unpublished, ongoing, phase II, open-label, single-arm, multicenter POD1UM-201 trial, with an objective response rate of 52% (95% CI 40 to 65). Among the 34 responding patients, 76.5% had a duration of response of at least 6 months, and 61.8% had a duration of response of at least 12 months. The median progression-free survival was 16 months (95% CI 9.3 to not estimable) and the median overall survival was not reached (95% CI 25.8 months to not estimable).

Among all patients who had received Zynyz (retifanlimab-dlwr) (N = 87), 75.9% had a treatment-emergent adverse event, 28.7% had a Grade 3 or higher treatment-emergent adverse event, and 26.4% had an immune-related adverse event (Grignani, 2021). Warnings and precautions for Zynyz (retifanlimab-dlwr) include serious and fatal immune-mediated adverse events, infusion-related reactions, complications of allogenic HSCT, and reproductive risk. The most common adverse events in the POD1UM-201 trial (≥ 10%) were fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, and nausea. Overall, Zynyz (retifanlimab-dlwr) provides an additional treatment option for metastatic or recurrent Merkel cell carcinoma.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9345 – Injection, retifanlimab-dlwr, 1 mg (effective 10/1/2023)
- J3490 – Unclassified drugs (when specified as [Zynyz] (retifanlimab-dlwr))
- J3590 – Unclassified biologics (when specified as [Zynyz] (retifanlimab-dlwr))
- J9999 – not otherwise classified, antineoplastic drugs (when specified as [Zynyz] (retifanlimab-dlwr))
- C9399 – Unclassified drugs or biologics (when specified as [Zynyz] (retifanlimab-dlwr))

REFERENCES

- Zynyz [package insert]. Wilmington, DE: Incyte Corporation; March 2023.
- The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 23, 2023.

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POLICY HISTORY

Policy #: 05.04.99

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