Utilization Review Policy 307

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Zynyz Utilization Management Medical Policy

- Zynyz™ (retifanlimab-dlwr intravenous infusion – Incyte)

EFFECTIVE DATE: 06/15/2023
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Zynyz, a programmed death receptor-1 blocking antibody, is indicated for the treatment of metastatic or recurrent locally advanced **Merkel cell carcinoma** in adults.[1]

Guidelines

Zynyz is addressed in the National Comprehensive Cancer Network (NCCN) clinical practice guidelines:

- The **Merkel Cell Carcinoma** (version 1.2024 – November 22, 2023) treatment guidelines recommend Zynyz as a "Preferred Regimen" for recurrent locally advanced and recurrent regional disease if curative surgery and radiation therapy are not feasible, and for disseminated disease. In addition, Zynyz is recommended as an "Other Recommended Regimen" for primary locally advanced disease if curative surgery and radiation therapy are not feasible (all category 2A).[2,3]
- The **Anal Carcinoma** (version 1.2024 – December 20, 2023) treatment guidelines recommend Zynyz as a "Preferred Regimen" for the second-line and subsequent treatment of metastatic disease if no prior immunotherapy received (category 2A).[2,4] In addition, NCCN states that Zynyz should be considered prior to abdominoperineal resection for locally recurrent, progressive disease (category 2B).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Zynyz. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zynyz as well as the monitoring required for adverse events and long-term efficacy, approval requires Zynyz to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zynyz is recommended in those who meet the following criteria:

FDA-Approved Indication

2. Merkel Cell Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i, ii, or iii):
  - **i.** Patient has metastatic disease; OR
  - **ii.** Patient has locally advanced disease; OR
  - **iii.** Patient has recurrent regional disease; AND
- **C)** Patient has not received prior systemic therapy for Merkel cell carcinoma; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 500 mg administered by intravenous infusion no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

3. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has locally recurrent, persistent disease; OR
  - **ii.** Patient has metastatic disease; AND
- **C)** Medication is used for subsequent treatment; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 500 mg administered by intravenous infusion no more frequently than once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zynyz is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zynyz™ intravenous infusion [prescribing information]. Wilmington, DE: Incyte; March 2023.

2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 25, 2024. Search term: retifanlimab.
3. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – November 22, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 25, 2024.
4. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 20, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 25, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/29/2023
Selected Revision	**Merkel Cell Carcinoma.** Patient has recurrent regional disease added as new option of approval.	04/19/2023
Annual Revision	**Merkel Cell Carcinoma.** Removed "recurrent" from criterion "Patient has locally advanced disease". **Anal Carcinoma.** Added condition of approval.	03/27/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024