VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Zynyz Utilization Management Medical Policy
- Zynyz™ (retifanlimab-dlwr intravenous infusion – Incyte)

REVIEW DATE: 03/29/2023, selected revision 04/19/2023

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

The National Comprehensive Cancer Network clinical practice guidelines for **Merkel Cell Carcinoma** (version 1.2023 – April 10, 2023) recommend Zynyz as an "other recommended regimen" for the treatment of recurrent, locally advanced or regional disease (category 2A) and for disseminated disease, all in patients not amenable to surgery or radiation therapy.[2,3]

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

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1. **Merkel Cell Carcinoma.** Approve for 1 year if the patient meets the following criteria (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 recurrent 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.

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. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 14, 2023. Search term: retifanlimab.
3. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – April 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 14, 2023.

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