Medical Policy:

Zynyz (retifanlimab-dlwr) intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.384	January 2, 2025	May 11, 2023

Definitions

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

Length of Authorization

12 months at a time- up to 24 months total therapy

Dosing Limits [Medical Benefit]

500 mg IV infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months

Guideline

1. **Merkel Cell Carcinoma (MCC)**
   A. Patient must be ≥18 years of age**; AND**

B. Patient must have a diagnosis of recurrent, locally advanced, or metastatic Merkel cell carcinoma (MCC)**; AND**
C. Patient must **NOT** have received prior PD-1, PD-L1, CTLA-4, or LAG-3 directed therapy for recurrent locally advanced or metastatic MCC**; AND**
D. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

Applicable Procedure Codes

Code	Description
J9345	Zynyz 500mg/20mL Solution Injection, retifanlimab-dlwr, 1 mg

Applicable NDCs

Code	Description
50881-0006-03	Zynyz 25mg/1ml, 20mL vial

ICD-10 Diagnoses

Code	Description
C4A	Merkel Cell Carcinoma, unspecified
C4A.0	Lip
C4A.1	Eyelid (including canthus)
C4A.10	Eyelid, unspecified
C4A.11	Eyelid, right
C4A.12	Eyelid, left
C4A.2	Ear (and external auricular canal)
C4A.20	Ear, unspecified
C4A.21	Ear, right
C4A.22	Ear, left
C4A.3	Face, unspecified
C4A.30	Face, other part
C4A.31	Nose
C4A.4	Scalp and Neck
C4A.6	Upper limb (including shoulder)
C4A.60	Upper limb, unspecified
C4A.61	Upper limb, right
C4A.62	Upper limb, left
C4A.7	Lower limb (including hip)
C4A.70	Lower limb, unspecified
C4A.71	Lower limb, right
C4A.5	Trunk, unspecified
C4A.51	Anal or perianal skin
C4A.52	Skin of breast
C4A.59	Trunk, other part
C4A.8	Overlapping sites (eg, junction of neck and trunk)

C7B.1	Metastatic MCC or nodal presentation without known primary
C4A.9	unspecified site
Z85.821	History of MCC of the skin

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review; No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Updated JCode, No criteria changes
EmblemHealth & ConnectiCare	05/11/2023	New Policy

References

1. Product Information: ZYNYZ™ intravenous injection, retifanlimab-dlwr intravenous injection. Incyte Corporation (per FDA), Wilmington, DE, 2023.