

Medical Policy:

Zynyz (retifanlimab-dlwr) intravenous injection

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare and Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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.