Retifanlimab-dlwr (Zynyz[™])

<u>Place of Service</u> Office Administration Outpatient Facility Administration Infusion Center Administration

HCPCS: J3590

NDC:

50881-006-03: 500 mg/20 mL (25 mg/mL) single-dose vial

Condition(s) listed in policy (see criteria for details)

<u>Merkel cell carcinoma</u>

AHFS therapeutic class: Antineoplastic agents

Mechanism of action: programmed death receptor-1 (PD-1)–blocking monoclonal antibody

(1) Special Instructions and pertinent Information Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Zynyz[™] (retifanlimab-dlwr) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

<u>Merkel cell carcinoma</u>

- 1. Disease is recurrent locally advanced or metastatic, AND
- 2. Being used as a single agent

Covered Doses Up to 500 mg given by IV infusion every 4 weeks

Coverage Period

2 years

ICD-10: C4A.0, C4A.10, C4A.111, C4A.112, C4A.121, C4A.122, C4A.20-C4A.22, C4A.30, C4A.31, C4A.39, C4A.4, C4A.51, C4A.52, C4A.59-C4A.62, C4A.70-C4A.72, C4A.8, C4A.9, C7B.1, Z85.821

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Zynyz[™] (retifanlimab-dlwr) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety</u> <u>Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.</u>

Please refer to the Provider Manual and User Guide for more information.

PHP Medi-Cal

Retifanlimab-dlwr (Zynyz[™])

Effective: 05/31/2023

(5) Additional Information

How supplied: 500 mg/20 mL (25 mg/mL) solution in a single-dose vial

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Zynyz[™] (retifanlimab-dlwr) [Prescribing information]. Wilmington, DE: Incyte Corporation, Inc.; 3/2023.

(7) Policy Update

Date of initial review: 2Q2023 Date of next review: 2Q2024 Changes from previous policy version:

New policy

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee