

**ZYNYZ
(retifanlimab-dlwr)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Zynyz (retifanlimab-dlwr) is a programmed death receptor-1 (PD-1) blocking antibody. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Zynyz binds to the PD-1 receptor, blocks interaction with its ligands PD-L1 and PD-L2, and potentiates T-cell activity (1).

Regulatory Status

FDA-approved indication: Zynyz is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (1).

Zynyz contains warnings for the following: immune-mediated adverse reactions, infusion-related reactions, and complications of allogeneic hematopoietic stem cell transplantation (HSCT) (1).

Zynyz can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Zynyz and for 4 months after the last dose (1).

The safety and effectiveness of Zynyz have not been established in pediatric patients less than 18 years of age (1).

Summary

Zynyz is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma. Patients taking Zynyz should be monitored for immune-mediated adverse reactions. The safety and effectiveness of Zynyz have not been established in pediatric patients less than 18 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zynyz while maintaining optimal therapeutic outcomes.



**BlueCross
BlueShield**

Federal Employee Program.

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References

1. Zynyz [package insert]. Wilmington, DE: Incyte Corporation; April 2024.
2. NCCN Drugs & Biologics Compendium® Retifanlimab-dlwr 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.