

Specialty Guideline Management

Zynyz

Products Referenced by this Document

Brand Name	Generic Name
Zynyz	retifanlimab-dlwr

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication¹

Merkel cell carcinoma

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

All other indications are considered experimental/investigational and not medically necessary.

Compendial Uses²

Merkel cell carcinoma

Anal carcinoma

Exclusions

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

Reference number(s)
5850-A

Coverage Criteria

Merkel Cell Carcinoma (MCC)^{1,2}

Authorization of 6 months may be granted as a single agent for treatment of metastatic, primary clinical locally advanced, recurrent locally advanced, or recurrent regional MCC.

Anal Carcinoma²

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma.

Continuation of Therapy

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Zynyz [package insert]. Wilmington, DE: Incyte Corporation; April 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 12, 2024.