

# STANDARD MEDICARE PART B MANAGEMENT

## ZYNYZ (retifanlimab-dlwr)

### POLICY

#### I. 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 Indication

##### 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Merkel Cell Carcinoma (MCC)**

Authorization of 12 months may be granted for treatment of metastatic or recurrent locally advanced MCC.

#### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted (up to 24 months total) when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication
- B. The requested medication is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy. Benefit is defined as:
  - I. No evidence of unacceptable toxicity while on the current regimen AND
  - II. No evidence of disease progression while on the current regimen

#### IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

- 1. The prescribing information for Zynyz.
- 2. The available compendium
  - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - b. Micromedex DrugDex

Reference number(s)
5851-A

- c. American Hospital Formulary Service- Drug Information (AHFS-DI)
  - d. Lexi-Drugs
  - e. Clinical Pharmacology
3. NCCN Guideline: Merkel cell carcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zynyz are covered.

#### V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

#### IV. REFERENCES

1. Zynyz [package insert]. Wilmington, DE: Incyte Corporation; March 2023.