SPECIALTY GUIDELINE MANAGEMENT

ZOLINZA (vorinostat)

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.

A. FDA-Approved Indication

Zolinza is indicated for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent, or recurrent disease on or following two systemic therapies

B. <u>Compendial Uses</u> Mycosis fungoides (MF)/Sézary syndrome (SS)

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

II. CRITERIA FOR INITIAL APPROVAL

Cutaneous T-cell Lymphoma (CTCL)

Authorization of 12 months may be granted for the treatment of CTCL (e.g., MF, SS).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

- 1. Zolinza [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2022.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 9, 2024.

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