SPECIALTY GUIDELINE MANAGEMENT

ODOMZO (sonidegib)

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

Odomzo is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

B. <u>Compendial Use</u> Basal cell carcinoma

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

II. CRITERIA FOR INITIAL APPROVAL

Basal Cell Carcinoma

Authorization of 12 months may be granted as a single agent for treatment of locally advanced or diffuse (e.g., Gorlin syndrome) basal cell carcinoma.

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. Odomzo [package insert]. Cranberry, NJ: Sun Pharmaceutical Industries, Inc.; August 2023.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2023 National Comprehensive Cancer Network Drugs, Inc. Available at https://www.nccn.org. Accessed November 1, 2023.

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