

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Odomzo Prior Authorization Policy

- Odomzo® (sonidegib capsules – Novartis)

**REVIEW DATE:** 11/04/2020

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### OVERVIEW

Odomzo, a hedgehog pathway inhibitor, is indicated for the treatment of adults with locally advanced **basal cell carcinoma** that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.<sup>1</sup> It is an inhibitor of the hedgehog signaling pathway, where it binds to and inhibits Smoothened, a transmembrane protein involved in Hedgehog signal transduction.

### Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for basal cell carcinoma (version 1.2020 – October 24, 2019) note that surgical approaches offer the most effective and efficient means for accomplishing a cure; radiation therapy may be chosen as the primary treatment in order to achieve optimal overall results.<sup>2</sup> For residual disease when surgery and radiation therapy are contraindicated and for recurrent disease with distant metastases, a hedgehog pathway inhibitor should be considered.

### Other Uses with Supportive Evidence

Although Odomzo is not indicated in metastatic basal cell carcinoma, the pivotal study enrolled adults with histologically confirmed metastatic basal cell carcinoma for which all existing treatment options had been exhausted.<sup>1</sup> In this study, an objective response was obtained by 15% of patients (n = 2/13) patients who were treated with Odomzo 200 mg.<sup>3</sup> In the 12-month analysis, response rates by central review were 7.7% and 17.4% in the Odomzo 200 mg and 800 mg groups, respectively. Disease control rate was 92% in patients treated with either dose of Odomzo. Guidelines for basal cell carcinoma list hedgehog pathway inhibitors (i.e., Erivedge, Odomzo) as treatment options for patients with metastatic basal cell carcinoma.<sup>2</sup>

### POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Odomzo. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Odomzo is recommended in those who meet the following criteria:

#### FDA-Approved Indications

1. **Basal Cell Carcinoma, Locally Advanced.** Approve for 3 years if the patients meets ONE of the following conditions (A or B):
  - A) **Initial Therapy.** Approve if the patient meets ONE of the following (i or ii):
    - i. Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
    - ii. Patient meets BOTH of the following (a and b):

- a) Patient is not a candidate for surgery; AND
  - b) According to the prescriber, the patient is not a candidate for radiation therapy.
- B) Patient is Currently Receiving Odomzo. Approve.**

### **Other Uses with Supportive Evidence**

- 2. Basal Cell Carcinoma, Metastatic.** Approve for 3 years.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Odomzo is not recommended in the following situations:

- 1. Basal Cell Carcinoma (Locally Advanced or Metastatic), in Patients with Disease Progression While on Erivedge (vismodegib capsules).** [Note: This does not apply to patients already started on Odomzo. Refer to criteria for BCC, Locally Advanced for Patients Currently Receiving Odomzo.] Results from an open-label study (n = 9) showed resistance to Odomzo in patients with advanced BCC who had progressed while taking Erivedge.<sup>6</sup> There are no data to support the use of Odomzo in patients who have experienced disease progression on Erivedge. Previous use of a hedgehog inhibitor was not allowed in the pivotal study for Odomzo.<sup>3</sup> Patients who develop resistance to one of the hedgehog pathway inhibitors are not expected to respond to another hedgehog pathway inhibitor.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### **REFERENCES**

- 1. Odomzo<sup>®</sup> capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.
- 2. The NCCN Basal Cell Skin Cancers Clinical Practice Guidelines in Oncology (version 1.2020 – October 24, 2019). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 28, 2020.
- 3. Migden MR, Guminski A, Gutzmer R, et al. Treatment with two different doses of sonidegib in patients with locally advanced or metastatic basal cell carcinoma (BOLT): a multicentre, randomised, double-blind phase 2 trial. *Lancet Oncol.* 2015;16(6):716-728.
- 4. Erivedge<sup>®</sup> capsules [prescribing information]. South San Francisco, CA: Genentech/Roche; July 2020.
- 5. Danial C, Sarin KY, Oro AE, Chang AL. An investigator-initiated open-label trial of sonidegib in advanced basal cell carcinoma patients resistant to vismodegib. *Clin Cancer Res.* 2016;22(6):1325-1329.
- 6. Dummer R, Guminski A, Gutzmer R, et al. The 12-month analysis from Basal Cell Carcinoma Outcomes with LDE225 Treatment (BOLT): A phase II, randomized, double-blind study of sonidegib in patients with advanced basal cell carcinoma. *J Am Acad Dermatol.* 2016;75(1):113-125.