

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Odomzo Prior Authorization Policy

- Odomzo® (sonidegib capsules – Novartis)

REVIEW DATE: 12/21/2022

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.¹

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for basal cell carcinoma (version 2.2022 – March 24, 2022) 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.² For locally advanced disease in which curative radiation therapy and curative surgery are not feasible, a hedgehog pathway inhibitor such as Odomzo is among the treatment options (category 2A). For primary or recurrent nodal metastases, Odomzo (category 2B) is among the alternatives when surgery is not feasible.

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 one of the following criteria:

FDA-Approved Indication

- 1. Basal Cell Carcinoma, Locally Advanced.** Approve for 1 year if the patients meets ONE of the following conditions (A or B):
 - A) Initial Therapy.** Approve if the patient meets BOTH of the following (i and ii):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient meets one of the following (a or b):
 - a)** Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
 - b)** Patient meets BOTH of the following [(1) and (2)]:
 - (1)** Patient is not a candidate for surgery; AND
 - (2)** 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 1 year if the patient meets both of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Disease is limited to nodal metastases.
Note: This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Odomzo is not recommended in the following situations:

1. **Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Erivedge (vismodegib capsules).** Note: This does not apply to a patient already started on Odomzo. Refer to criteria for Basal Cell Carcinoma, Locally Advanced for a Patient Currently Receiving Odomzo. Results from an open-label study (n = 9) showed resistance to Odomzo in patients with advanced basal cell carcinoma who had progressed while taking Erivedge.⁶ 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.³ 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[®] capsules [prescribing information]. East Hanover, NJ: Novartis; May 2019.
2. The NCCN Basal Cell Skin Cancers Clinical Practice Guidelines in Oncology (version 2.2022 – March 24, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 13, 2022.
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[®] 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.