

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Odomzo Prior Authorization Policy

- Odomzo® (sonidegib capsules – Novartis)

REVIEW DATE: 01/17/2024

OVERVIEW

Odomzo, a hedgehog pathway inhibitor, is indicated for the treatment of locally advanced **basal cell carcinoma** in adults whose disease has recurred following surgery or radiation therapy, or who are not candidates for surgery or radiation therapy.¹

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for basal cell skin cancer (version 2.2024 – September 14, 2023) 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 Odomzo is recommended for locally advanced (extensive) disease where surgery and/or radiation therapy may not result in a cure or would possibly produce a significant functional limitation (category 2A). Odomzo is recommended for diffuse basal cell carcinoma formation (e.g. basal cell nevus syndrome [Gorlin syndrome]) or other genetic forms of multiple basal cell carcinoma (category 2A). Odomzo is also recommended for nodal disease if surgery is not feasible (category 2B).

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 patient meets ONE of the following (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 metastases 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, another hedgehog pathway inhibitor.⁵ 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 2.2024 – September 14, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 11, 2024.
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.