

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Odomzo® (sonidegib capsules – Novartis)

TAC APPROVAL DATE: 10/10/2018

OVERVIEW

Odomzo, a hedgehog pathway inhibitor, is indicated for the treatment of adults 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.¹ Efficacy was established in a single trial conducted in patients with either metastatic BCC or locally advanced BCC. The study enrolled adults with histologically confirmed metastatic basal cell carcinoma for which all existing treatment options had been exhausted, or locally advanced basal cell carcinoma not amenable to curative surgery or radiation.

Disease Overview

Localized BCC is most commonly treated with surgery or radiation therapy and is usually cured by local therapy.² Few options exist in the scenario of disease progression; however, hedgehog pathway inhibitors have provided another option for patients with advanced disease and in those who are not amenable to local therapy. The sonic hedgehog signaling pathway has emerged as playing a pivotal role in the parthenogenesis of BCC.² Mutations in the patched (PTCH) gene on chromosome 9q, which codes for the sonic hedgehog receptor, are the underlying cause of nevoid BCC syndrome, and are frequently present in sporadic BCC.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for BCC (version 1.2019 –) 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.² For residual disease when surgery and radiation therapy are contraindicated and for recurrent disease with distant metastases, a hedgehog pathway inhibitor] or clinical trials should be considered.

Safety

Odomzo has a Boxed Warning stating that it may cause fetal harm when administered to a pregnant woman.¹ Pregnancy status should be verified prior to initiation of therapy. Female patients should use contraception during and for 24 months after the final dose. Male patients should use contraception to avoid exposure to a partner of childbearing potential during and for 8 months after the final dose.

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 (BCC), 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. The patient's basal cell carcinoma has recurred following surgery or radiation therapy; OR
 - ii. The patient meets BOTH of the following (a and b):
 - a) The patient is not a candidate for surgery; AND
 - b) According to the prescribing physician, the patient is not a candidate for radiation therapy.
 - B) **Patients Currently Receiving Odomzo.** Approve.

Other Uses with Supportive Evidence

2. **Basal Cell Carcinoma (BCC), Metastatic.** Approve for 3 years.

Although Odomzo is not indicated in metastatic BCC, the pivotal study enrolled adults with histologically confirmed metastatic basal cell carcinoma for which all existing treatment options had been exhausted.¹ In this study, an objective response was obtained by 15% of patients (n = 2/13) patients who were treated with Odomzo 200 mg.³ 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 BCC list hedgehog pathway inhibitors (i.e., Erivedge, Odomzo) as treatment options for patients with metastatic BCC.²

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Odomzo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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.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 Pharmaceuticals Corporation; September 2017.
2. The NCCN Basal Cell Skin Cancers Clinical Practice Guidelines in Oncology (Version 1.2019 – August 31, 2018). © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 10, 2018.
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; September 2017.
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.

HISTORY

| Type of Revision | Summary of Changes* | TAC Approval Date |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| New Policy | -- | 09/09/2015 |
| Annual revision | No changes to the criteria. | 09/14/2016 |
| Annual revision | No changes to the criteria. | 09/13/2017 |
| Annual revision | Patients Already Started on Odomzo: This criterion only applies to BCC, locally advanced disease; reformat to address in the criteria section for this condition. Conditions Not Recommended for Coverage: Remove Solid Tumors Other than Basal Cell Carcinoma from this section of the policy. This indication remains a denial but is not specifically listed in the policy. | 10/10/2018 |

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee.