



PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Hedgehog Pathway Inhibitor) – Odomzo Prior Authorization Policy

- Odomzo® (sonidegib capsules – Novartis)

REVIEW DATE: 01/21/2026; selected revision 01/28/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 1.2026 – September 2, 2025) 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.

- **Odomzo® (sonidegib capsules – Novartis)**
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

- 1. Basal Cell Carcinoma, Locally Advanced.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets ONE of the following (i or ii):
 - i.** Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
 - ii.** According to the prescriber, the patient is not a candidate for surgery or radiation therapy.

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.
- 3. Diffuse Basal Cell Carcinoma Formation.** Approve for 1 year if the patient is ≥ 18 years of age.
Note: This includes basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma.

CONDITIONS NOT COVERED

- **Odomzo® (sonidegib capsules – Novartis)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Erivedge (vismodegib capsules).** 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.

REFERENCES

1. Odomzo® capsules [prescribing information]. East Hanover, NJ: Novartis; August 2023.
2. The NCCN Basal Cell Skin Cancers Clinical Practice Guidelines in Oncology (version 1.2026 – September 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 16 2026.
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; March 2023
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/17/2024
Annual Revision	Diffuse Basal Cell Carcinoma Formation: New condition of approval was added to Other Uses with Supportive Evidence.	01/15/2025
Update	04/08/2025: The policy name was changed from "Oncology – Odomzo PA Policy" to "Oncology (Oral – Hedgehog Pathway Inhibitor) – Odomzo PA Policy".	N/A
Annual Revision	Basal Cell Carcinoma, Locally Advanced: The requirement that the "patient is not a candidate for surgery and according to the prescriber, the patient is not a candidate for radiation therapy" was changed to "according to the prescriber, patient is not a candidate for surgery or radiation therapy." An option for approval for a patient currently receiving Odomzo was removed.	01/21/2026
Selected Revision	Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Erivedge (vismodegib capsules). The following was Note removed, " <u>Note:</u> This does not apply to a patient already started on Odomzo."	01/28/2026

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