



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1162-9
Program	Prior Authorization/Notification
Medication	Odomzo [®] (sonidegib)
P&T Approval Date	10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

1. Background:

Odomzo[®] (sonidegib) is a hedgehog pathway inhibitor indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC), that has recurred following surgery or radiation therapy, or who are not candidates for surgery or radiation therapy.¹

The National Comprehensive Cancer Network (NCCN) also recommends Odomzo for the recurrence of basal cell carcinoma with nodal or distant metastases and for treatment of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC).

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Odomzo will be approved based on the following criterion:</p> <p>a. Patient is less than 19 years of age</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Basal Cell Carcinoma</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Odomzo will be approved based on <u>one</u> of the following criteria:</p> <p>(1) Diagnosis of metastatic basal cell carcinoma</p> <p style="text-align: center;">-OR-</p> <p>(2) Diagnosis of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin</p>
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syndrome, other genetic forms of multiple BCC)

-OR-

(3) **Both** of the following:

(a) Diagnosis of locally advanced basal cell carcinoma

-AND-

(b) **One** of the following:

- i. Cancer has recurred following surgery
- ii. Cancer has recurred following radiation
- iii. Patient is not a candidate for surgery
- iv. Patient is not a candidate for radiation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Odomzo** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Odomzo therapy

Authorization will be issued for 12 months.

C. **NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Odomzo [package insert]. Sun Pharmaceutical Industries, Inc.: Cranbury, NJ; August 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at <https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia>. Accessed September 1, 2023.

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Change Control	
10/2015	New notification.
9/2016	Annual review. Minor formatting changes to background and updated references.
9/2017	Annual Review. Updated references.
9/2018	Annual Review. Updated references.
9/2019	Annual review. Added metastatic basal cell carcinoma diagnosis. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review. No changes to coverage rationale.
10/2021	Annual review. Added diffuse basal cell carcinoma (BCC) formation per NCCN recommendations. Updated references.
10/2022	Annual review. No changes to coverage rationale. Added state mandate. Updated references.
10/2023	Annual review. No changes to coverage rationale. Updated references.