UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Odomzo

Program	Prior Authorization
Medication	Odomzo® (sonidegib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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.

Odomzo has a black box warning for intrauterine fetal death, risk in pregnancy, and other reproductive risks. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. Basal Cell Carcinoma

1. Initial Authorization

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

(1) Diagnosis of metastatic basal cell carcinoma (BCC)

-OR-

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

(a) Diagnosis of locally advanced basal cell carcinoma

-AND-

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

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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.

B. NCCN Recommended Regimens

1. **Initial Authorization**

a. **Odomzo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Odomzo therapy

Authorization will be issued for 12 months.

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]. Novartis Pharmaceuticals Corporation: East Hanover, NJ; May 2019.

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2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 1, 2019.

Program	Prior Authorization - Odomzo (sonidegib)
Change Control	
Date	Change
12/2015	New program
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual Review. Updated References.
9/2018	Annual review. Added NCCN Recommended Regimen criteria. Updated references.
9/2019	Added metastatic basal cell carcinoma diagnosis to criteria. Updated background and references.
9/2020	Annual review. No changes to coverage criteria. Added Additional Clinical Rules section.

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