

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Odomzo (sonidegib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Odomzo (sonidegib)	May be subject to quantity limit

### APPROVAL CRITERIA

Initial requests for Odomzo (sonidegib) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older;

**AND**

- II. Individual has a diagnosis of basal cell carcinoma (BCC); **AND**
- III. Individual has locally advanced recurrent disease following surgery or radiation;  
**OR**
- IV. Individual has locally advanced disease and is not a candidate for surgery or radiation therapy;  
**OR**
- V. Individual has a diagnosis of advanced BCC with nodal or distant metastases disease involvement (NCCN 2A).

Requests for continuation of therapy with Odomzo (sonidegib) may be approved if the following criteria are met:

- I. Individual does not show evidence of progressive disease while on Odomzo therapy.

**Note:**

Odomzo (sonidegib) has black box warnings related to embryo-fetal toxicity. Odomzo can cause embryo-fetal death or severe birth defects when administered to a pregnant woman and is embryotoxic, fetotoxic, and teratogenic in animals.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 26, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 26, 2019.
  - a. Basal Cell Skin Cancer. V1.2029. Revised August 31, 2018

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