

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

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 or nodal disease and is not a candidate for surgery or radiation therapy;

OR

- V. Individual is 18 years of age or older; **AND**
- VI. Individual has a diagnosis of diffuse BCC formation, as Gorlin syndrome or other genetic forms of multiple BCC.

Requests for Odomzo (sonidegib) may not be approved for the following:

- I. Individual has shown evidence of progressive disease while on Odomzo (sonidegib) or Erivedge (vismodegib) 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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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: October 11, 2023.

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 11, 2023.
 - a. Basal Cell Skin Cancer. V2.2024. Revised September 14, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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