

Odomzo® (sonidegib)

Document Number: IC-0253

Last Review Date: 07/1/2019

Date of Origin: 08/25/2015

Dates Reviewed: 07/2016, 08/2015, 07/2016, 08/2017, 07/2018, 07/2019

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 200 mg capsule: 1 capsule per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 200 mg daily

III. Initial Approval Criteria

Basal Cell Carcinoma †

- Patient is 18 years or older; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Must be used as a single agent; **AND**
- Patient has locally advanced or metastatic disease; **AND**
 - Disease has recurred following surgery or radiation therapy; **OR**
 - Patient is not a candidate for surgery or radiation therapy

† FDA approved indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in Section III; **AND**
- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe musculoskeletal reactions including creatine kinase elevations, premature fusion of the epiphyses, etc.

V. Dosage/Administration

| Indication | Dose |
|----------------------------|--|
| Basal cell carcinoma (BCC) | 200 mg orally once daily on an empty stomach administered until disease progression or unacceptable toxicity |

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – prescription drug, oral, chemotherapeutic, nos

NDC:

- 200 mg capsules: 47335-0303-xx

VII. References

1. ODOMZO [package insert]. Cranbury, NJ; Sun Pharmaceutical Industries, Inc.; May 2019. Accessed May 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sonidegib. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|----------|--|
| C44.01 | Basal cell carcinoma of skin of lip |
| C44.111 | Basal cell carcinoma of skin of unspecified eyelid, including canthus |
| C44.1121 | Basal cell carcinoma of skin of right upper eyelid, including canthus |
| C44.1122 | Basal cell carcinoma of skin of right lower eyelid, including canthus |
| C44.1191 | Basal cell carcinoma of skin of left upper eyelid, including canthus |
| C44.1192 | Basal cell carcinoma of skin of left lower eyelid, including canthus |
| C44.211 | Basal cell carcinoma of skin of unspecified ear and external auricular canal |
| C44.212 | Basal cell carcinoma of skin of right ear and external auricular canal |
| C44.219 | Basal cell carcinoma of skin of left ear and external auricular canal |
| C44.310 | Basal cell carcinoma of skin of unspecified parts of face |
| C44.311 | Basal cell carcinoma of skin of nose |
| C44.319 | Basal cell carcinoma of skin of other parts of face |

ODOMZO® (sonidegib) Prior Auth Criteria

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| ICD-10 | ICD-10 Description |
|---------|--|
| C44.41 | Basal cell carcinoma of skin of scalp and neck |
| C44.510 | Basal cell carcinoma of anal skin |
| C44.511 | Basal cell carcinoma of skin of breast |
| C44.519 | Basal cell carcinoma of skin of other part of trunk |
| C44.611 | Basal cell carcinoma of skin of unspecified upper limb, including shoulder |
| C44.612 | Basal cell carcinoma of skin of right upper limb, including shoulder |
| C44.619 | Basal cell carcinoma of skin of left upper limb, including shoulder |
| C44.711 | Basal cell carcinoma of skin of unspecified lower limb, including hip |
| C44.712 | Basal cell carcinoma of skin of right lower limb, including hip |
| C44.719 | Basal cell carcinoma of skin of left lower limb, including hip |
| C44.81 | Basal cell carcinoma of overlapping sites of skin |
| C44.91 | Basal cell carcinoma of skin, unspecified |
| Z85.828 | Personal history of other malignant neoplasm of skin |

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| Jurisdiction | Applicable State/US Territory | Contractor |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|--------------------------------------|-------------------------|
| 15 | KY, OH | CGS Administrators, LLC |