

## ODOMZO® (sonidegib)

Document Number: IC-0253

Last Review Date: 07/25/2016

Date of Origin: 08/25/2015

Dates Reviewed: 7/2016, 08/2015

### 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: 30 capsules per 30 days (1 capsule per day)

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

- 200mg daily

### III. Initial Approval Criteria

#### Basal Cell Carcinoma†

- Patient is 18 or older; **AND**
- Women of child-bearing age must have a negative pregnancy test; **AND**
- Must be used as a single agent; **AND**
- Cancer is locally advanced or metastatic; **AND**
  - Cancer 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 in Section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples include: muscle spasms, alopecia,

dysgeusia, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight, decreased appetite, myalgia, abdominal pain, headache, pain, vomiting, and pruritis.

## V. Dosage/Administration

Indication	Dose
Basal cell carcinoma (BCC)	200 mg orally once daily on an empty stomach

## VI. Billing Code/Availability Information

Jcode:

J8999 – prescription drug, oral, chemotherapeutic, nos

NDC:

200 mg capsules – 00078-0645-xx (Novartis)

## VII. References

1. ODOMZO [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corp.; May 2016. Accessed June 2016.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sonidegib. National Comprehensive Cancer Network, 2016. 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 June 2016.

## 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
C44.112	Basal cell carcinoma of skin of right eyelid, including canthus
C44.119	Basal cell carcinoma of skin of left 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 Corporation (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 Corporation (WPS)

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, 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)
15	KY, OH	CGS Administrators, LLC