

Odomzo® (sonidegib) (Oral)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Odomzo 200 mg capsule: 1 capsule per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 200 mg daily

III. Initial Approval Criteria ¹

- Patient is at least 18 years of age; **AND**
- Women of child-bearing age must have a negative pregnancy test prior to initiation of therapy (*females of reproductive potential should use effective contraception during and for at least 20 months after the last dose and males of reproductive potential should also do so during and for at least 8 months after the last dose*); **AND**

Universal Criteria ¹

- Patient's serum creatine kinase (CK) will be obtained at baseline and periodically monitored during therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
 - Coadministration with strong CYP3A4 inhibitors (e.g., nefazadone, itraconazole, etc.); **AND**
 - Long-term (≥ 14 days) coadministration with moderate CYP3A4 inhibitors (e.g., aprepitant, ciprofloxacin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
 - Coadministration with moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.); **AND**

Basal Cell Carcinoma (BCC) † 1-5

- Patient has locally advanced disease; **AND**
 - Used as a single agent; **AND**
 - Disease has recurred following surgery or radiation therapy; **OR**
 - Patient is not a candidate for surgery or radiation therapy; **OR**
 - Residual disease is present post-surgery; **OR**
- Patient has diffuse BCC formation (e.g., Gorlin syndrome or other genetic form of multiple BCC)

† FDA approved indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as 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: severe musculoskeletal reactions including creatine kinase elevations, premature fusion of the epiphyses, etc.; **AND**
- Patient does not have any of the following:
 - Serum CK elevation greater than 2.5 times ULN with worsening renal function
 - Serum CK elevation greater than 10 times ULN
 - Recurrent serum CK elevation greater than 5 times ULN
 - Recurrent severe or intolerable musculoskeletal adverse reactions

V. Dosage/Administration ¹

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, not otherwise specified

NDC:

- Odomzo 200 mg capsules: 47335-0303-xx

VII. References

1. Odomzo [package insert]. Cranbury, NJ; Sun Pharmaceutical Industries, Inc.; May 2019. Accessed May 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sonidegib. National Comprehensive Cancer Network, 2022. 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 2022.
3. Lear JT, Migden MR, Lewis KD, et al. Long-term efficacy and safety of sonidegib in patients with locally advanced and metastatic basal cell carcinoma: 30-month analysis of the randomized phase 2 BOLT study. *J Eur Acad Dermatol Venereol*. 2018 Mar;32(3):372-381. doi: 10.1111/jdv.14542. Epub 2017 Nov 6.
4. Migden MR, Guminski A, Gutzmer R, et al. Treatment with two different doses of sonidegib in patients with locally advanced or metastatic basal cell carcinoma (BOLT): a multicentre, randomised, double-blind phase 2 trial. *Lancet Oncol*. 2015 Jun;16(6):716-28. doi: 10.1016/S1470-2045(15)70100-2. Epub 2015 May 14.
5. Gailani MR, Bale SJ, Leffell DJ, et al. Developmental defects in Gorlin syndrome related to a putative tumor suppressor gene on chromosome 9. *Cell* 1992;69:111-117. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/1348213>.

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

ICD-10	ICD-10 Description
C44.319	Basal cell carcinoma of skin of other parts of face
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
Q87.89	Other specified congenital malformation syndromes, not elsewhere classified

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), Local Coverage Article (LCAs) 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.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC