

Clinical Policy: Sonidegib (Odomzo)

Reference Number: PA.CP.PHAR.272

Effective Date: 01/18

Last Review Date: 04/19

[Revision Log](#)

Description

Sonidegib (Odomzo[®]) is a hedgehog pathway inhibitor.

FDA Approved Indication(s)

Odomzo is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness[®] that Odomzo is **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

A. Basal Cell Carcinoma (must meet all):

1. Diagnosis of basal cell carcinoma (BCC);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 200 mg/day (one tablet);
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Basal Cell Carcinoma (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has responded positively to therapy;
 - a. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 200 mg/day (one tablet);
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCC: basal cell carcinoma

FDA: Food and Drug Administration

NCCN: National Comprehensive Care Network

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindication/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BCC	200 mg PO QD	200 mg/day

V. Product Availability

Capsules: 200 mg

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13 .18	
2Q 2019 annual review: references reviewed and updated.	04.17 .19	

References

1. Odomzo Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2017. Available at <https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf>. Accessed February 4, 2019.
2. Sonidegib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 4, 2019.
3. Basal cell skin cancer (Version 1.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 4, 2019.