

Clinical Policy: Sonidegib (Odomzo)

Reference Number: PA.CP.PHAR.272

Effective Date: 01/18

Last Review Date: 04/18

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for sonidegib (Odomzo[®]).

FDA Approved Indication(s)

Odomzo is indicated for:

- 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. Prescribed dose does not exceed 200 mg/day;

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

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 (e.g., no disease progression or unacceptable toxicity);
3. Prescribed dose does not exceed 200 mg/day.

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.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Sonidegib is an inhibitor of the Hedgehog pathway which binds to and inhibits Smoothed, a transmembrane protein involved in Hedgehog signal transduction.

Formulations:

Odomzo: 200 mg capsules for oral administration

Appendices

Appendix A: Abbreviation Key

BCC: basal cell carcinoma

FDA: Food and Drug Administration

NCCN: National Comprehensive Care Network

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	

References

1. Odomzo Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; February 2017. Available at <https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf>. Accessed January 2018.
2. Sonidegib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 2018.
3. Basal cell skin cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed January 2018.