

Clinical Policy: Sonidegib (Odomzo)

Reference Number: ERX.SPA.125

Effective Date: 10.01.16

Last Review Date: 05.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Odomzo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Basal Cell Carcinoma (must meet all):

1. Diagnosis of 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 (1 tablet) per day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Basal Cell Carcinoma (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Odomzo for BCC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 200 mg (1 tablet) per day;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

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

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCC: basal cell carcinoma

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindication/Boxed Warnings

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

V. Dosage and Administration

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

VI. Product Availability

Capsules: 200 mg

VII. References

1. Odomzo Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2019. Available at <https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf>. Accessed February 7, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 7, 2020.
3. National Comprehensive Cancer Network Guidelines. Basal Cell Skin Cancer Version 1.2020. Available at www.nccn.org. Accessed February 7, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.16	09.16
Converted to new template. Age, maximum dose, pregnancy precaution added. Dosing guidance for off-label use added. Approval periods increased from 3/6 to 6/12 months. References updated.	07.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: added prescriber requirement; updated NCCN Compendium supported use in BCC with nodal or distant metastases; added continuity of care language to section II; approval duration changed to length of benefit; references reviewed and updated.	02.08.18	05.18
2Q 2019 annual review: no significant changes; summarized NCCN and FDA approved uses for improved clarity by removing specific requirements for locally advanced, nodal, or distant metastasis; references reviewed and updated.	02.04.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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