Evolent Clinical Guideline 3060 for Odomzo™ (sonidegib)

Guideline Number:	Applicable Codes	
Evolent_CG_3060		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
April 2017	April 2026	April 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Odomzo (sonidegib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Basal Cell Skin Cancer (BCC)

- Odomzo (sonidegib) may be used as monotherapy in a member with locally advanced or locally recurrent BCC not amenable to or a candidate for curative surgery and/or radiation therapy.

CONTRAINDICATIONS/WARNINGS

- Contraindications
    - Sonidegib can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Sonidegib is embryotoxic, fetotoxic, and teratogenic in animals. Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females of reproductive potential to use effective contraception during treatment with sonidegib and for at least 20 months after the last dose. Advise males of the potential risk of exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with sonidegib and for at least 8 months after the last dose.

EXCLUSION CRITERIA

- Odomzo (sonidegib) use after disease progression with the same regimen or after failure of Erivedge (vismodegib).
- Concurrent use with other anticancer therapies.
- Use of Odomzo (sonidegib) for metastatic BCC.
- Dosing exceeds single dose limit of Odomzo (sonidegib) 200 mg.
- Treatment exceeds the maximum limit of 30 (200 mg) capsules/month.
- Investigational use of Odomzo (sonidegib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - sonidegib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
April 2026	• Updated contraindications/warnings section • Updated references
April 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1312 Odomzo (sonidegib) • Updated references
April 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or

drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Lear JT, 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.
2. Odomzo prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ 2023.
3. Clinical Pharmacology Elsevier Gold Standard 2026.
4. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
7. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
8. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
9. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.