

5.21.061

Section:	Prescription Drugs	Effective Date:	July 1, 2026
Subsection:	Antineoplastic Agents	Original Policy Date:	August 14, 2015
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Last Review Date: June 11, 2026

Odomzo

Description

Odomzo (sonidegib)

Background

Odomzo is used in the treatment of locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or in patients who are not candidates for surgery or radiation therapy. It works by inhibiting a molecular pathway, called the Hedgehog pathway, which is active in basal cell cancers. By suppressing this pathway, Odomzo may stop or reduce the growth of cancerous lesions (1).

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. Basal cell carcinoma starts in the top layer of the skin called the epidermis and usually develops in areas that have been regularly exposed to the sun and other forms of ultraviolet radiation. Locally advanced basal cell skin cancer refers to basal cancers that have not spread to other parts of the body, but cannot be curatively treated with local treatments, specifically surgery and radiation (2).

Regulatory Status

FDA-approved indication: Odomzo is a hedgehog pathway inhibitor 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 (1).

Odomzo carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Pregnancy status must be determined prior to initiation of treatment in females of

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reproductive potential. Females should be advised of the need to use effective contraception during treatment with Odomzo and for at least 20 months after the last dose. Males should be advised of the potential risk of Odomzo exposure through semen (1).

Patients should be instructed not to donate blood or blood products while receiving Odomzo and for at least 20 months after the last dose of Odomzo (1).

Patients that experienced treatment resistance to vismodegib have been shown to have the same resistance to Odomzo (sonidegib) (3).

Safety and effectiveness of Odomzo have not been established in pediatric patients (1).

Related policies

Erivedge

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Odomzo may be considered **medically necessary** if the conditions indicated below are met.

Odomzo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced basal cell carcinoma

AND ONE of the following:

- Reoccurrence following surgery
- NOT** a candidate for surgery or radiation

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AND ALL of the following:

1. Has **NOT** been previously treated with vismodegib
2. Females of reproductive potential **only**: patient is **NOT** pregnant and will be advised to use effective contraception during treatment with Odomzo and for 20 months after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use condoms, even after a vasectomy, during treatment with Odomzo and for 8 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced basal cell carcinoma

AND NONE of the following:

1. Disease progression
2. Signs or symptoms of toxicity

Policy Guidelines**Pre - PA Allowance**

None

Prior - Approval Limits

Quantity 90 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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Summary

Odomzo is a hedgehog pathway inhibitor indicated for the treatment of adults with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, who are not candidates for radiation and have not been previously treated with vismodegib. Odomzo carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Females should be advised of the need for contraception, males should be advised of the potential risk of Odomzo exposure through semen. Patients should be instructed to not donate blood or blood products while receiving Odomzo and for at least 20 months after the last dose of Odomzo. Patients may continue Odomzo until disease progression or unacceptable toxicity has occurred. Safety and effectiveness have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Odomzo while maintaining optimal therapeutic outcomes.

References

1. Odomzo [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; August 2023.
2. Peggy A Wu. Epidemiology, pathogenesis, and clinical features of basal cell carcinoma. UpToDate. Updated on March 10, 2021.
3. Danial C, Sarin K, Oro A, et al. An Investigator-Initiated Open-Label Trial of Sonidegib in Advanced Basal Cell Carcinoma Patients Resistant to Vismodegib. *Clin Cancer Res*. 2016; 22: 1325-1329.
4. NCCN Drugs & Biologics Compendium® Sonidegib 2026. National Comprehensive Cancer Network, Inc. Accessed on April 20, 2026.

Policy History

Date	Action
August 2015	Addition to PA
September 2015	Annual review
June 2016	Annual editorial review and reference update Policy code changed from 5.04.61 to 5.21.61 Addition of age to renewal section. Addition of no previous therapy with vismodegib
September 2016	Annual review
June 2017	Annual review and reference update
June 2018	Annual review and reference update

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March 2019	Annual review and reference update
June 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual editorial review and reference update. Revised contraception requirements for consistency
June 2023	Annual review and reference update
June 2024	Annual review and reference update
June 2025	Annual review and reference update
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.