

Evolut Clinical Guideline 3209 for Erivedge™ (vismodegib)

Guideline Number: Evolut_CG_3209	<u>Applicable Codes</u>	
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Original Date: October 2012	Last Revised Date: November 2025	Implementation Date: November 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Erivedge (vismodegib) 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 Carcinoma (BCC)

- Erivedge (vismodegib) may be used as a single agent in adult members with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

CONTRAINDICATIONS/WARNINGS

- US Boxed Warning
 - Embryofetal toxicity
 - Vismodegib can cause embryofetal death or severe birth defects when administered to a pregnant woman. Vismodegib is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations.
 - Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating vismodegib. Advise pregnant women of the potential risks to a fetus. Advise females of reproductive potential to use effective contraception during and after vismodegib. Advise males of the potential risk of vismodegib exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential.

EXCLUSION CRITERIA

- Member has disease progression while taking Erivedge (vismodegib) or another Hedgehog inhibitor (i.e., sonidegib).
- Erivedge (vismodegib) is being used concurrently with other chemotherapy.
- Dosing exceeds single dose limit of Erivedge (vismodegib) 150 mg.
- Treatment exceeds the maximum limit of Erivedge (vismodegib) 28 (150 mg) capsules/month.
- Investigational use of Erivedge (vismodegib) 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 definition 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, in light of 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 - vismodegib

Applicable Lines of Business

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

POLICY HISTORY

Date	Summary
November 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1222 Erivedge (vismodegib) • Updated indication section • Updated references
November 2024	• Updated NCH verbiage to Evolent • Added new reference • Updated maximum dosage form quantities in exclusion criteria

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

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6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
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