

# Clinical Policy: Vismodegib (Erivedge)

Reference Number: PA.CP.PHAR.273

Effective Date: 01/18

Last Review Date: 04/19

[Revision Log](#)

## Description

Vismodegib (Erivedge®) is a hedgehog pathway inhibitor.

## FDA Approved Indication(s)

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma (BCC), or with locally advanced BCC that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

## Policy/Criteria

It is the policy of Pennsylvania Health and Wellness® that Erivedge 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
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 150 mg/day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

#### B. Other diagnoses/indications: Refer to PA.CP.PMN.53

### 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 Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 150 mg/day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**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 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.PMN.53.

### III. 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: Contraindications/Boxed Warnings*

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

### IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BCC	150 mg PO QD	150 mg/day

### V. Product Availability

Capsules: 150 mg

### 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: added prescriber and age requirement; updated NCCN Compendium supported use in BCC with nodal or distant metastases; removed pregnancy as not an absolute CI per PI; references reviewed and updated.	02.08 .18	
2Q 2019 annual review: summarized NCCN and FDA approved uses for improved clarity by removing specific requirements for locally advanced,	04.17 .19	

Reviews, Revisions, and Approvals	Date	Approval Date
nodal, or distant metastasis (approach aligns with previously approved corporate policy for Odomzo); references reviewed and updated.		

**References**

1. Erivedge Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; January 2019. Available at [https://www.gene.com/download/pdf/erivedge\\_prescribing.pdf](https://www.gene.com/download/pdf/erivedge_prescribing.pdf). Accessed February 4, 2019.
2. Vismodegib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed February 4, 2019.
3. Basal cell skin cancer (Version 1.2019). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed February 4, 2019.