

## PHARMACY COVERAGE GUIDELINE

### ERIVEDGE® (vismodegib) Generic Equivalent (if available)

#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).

#### **Criteria:**

- **Criteria for initial therapy:** Erivedge (vismodegib) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
  1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with an Oncologist or Dermatologist
  2. Individual is 18 years of age or older
  3. Individual has a confirmed diagnosis of **ONE** of the following:
    - a. Metastatic basal cell carcinoma (mBCC) or locally advanced basal cell carcinoma (laBCC) that has recurred following surgery **OR** the individual is not a candidate for surgery **AND** the individual is not a candidate for radiation

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- b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
4. Individual has completed **ALL** the following **baseline tests** before initiation of treatment and will have continued monitoring clinically appropriate:
  - a. There is documentation of a negative pregnancy in a woman of childbearing age
  - b. Serum creatine phosphokinase (CPK)
  - c. Serum creatinine
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Erivedge (vismodegib) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Dermatologist
2. Individual has documentation of positive clinical response to therapy defined as there is evidence of efficacy, disease stability and/or improvement
3. Individual has been adherent with the medication
4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
  - a. Stevens-Johnson syndrome
  - b. Toxic epidermal necrolysis
  - c. Drug reaction with eosinophilia and systemic symptoms
  - d. Severe or intolerable musculoskeletal and connective tissue reactions such as muscle spasms, arthralgias, severe elevations in serum creatine phosphokinase (CPK)

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

#### 1. Off-Label Use of Non-Cancer Medications

ORIGINAL EFFECTIVE DATE: 11/19/2021 | ARCHIVE DATE: | LAST REVIEW DATE: 11/20/2025 | LAST CRITERIA REVISION DATE: 11/16/2023

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#### 2. Off-Label Use of Cancer Medications

##### Description:

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

Basal cell carcinoma and squamous cell carcinoma of the skin are collectively referred to as non-melanoma skin cancer (NMSC). They are the most commonly diagnosed malignant neoplasms in Caucasians, yet they are rarely fatal. Squamous cell carcinomas are more aggressive, and neglected lesions can be life-threatening due to local extension or metastasis. By contrast, basal cell carcinoma (BCC) is rarely life-threatening. While BCC tumors have low metastatic potential, they are locally invasive and can be destructive to the skin and to the surrounding tissues. The majority of BCC involve the face and head. The presentation of BCC is divided into three groups based on lesion histopathology: nodular, superficial, and morpheaform.

According to the National Comprehensive Cancer Network (NCCN) Clinical practice 2024 Guideline in Oncology for basal cell skin cancer, surgical approaches are the most effective & efficient means of accomplishing cure but considerations of function, cosmesis, and patient preferences may lead to choosing radiation therapy as primary treatment.

Primary treatments for low-risk basal cell carcinoma include curettage and electrodesiccation or standard excision or radiation therapy for non-surgical candidates. In patients with low-risk, superficial basal cell skin cancer, where surgery and radiation are contraindicated or impractical topical therapies such as 5-fluorouracil, topical imiquimod, photodynamic therapy (aminolevulinic acid, porfimer sodium), or vigorous cryotherapy may be considered.

Primary treatments for high-risk basal cell carcinoma include Mohs micrographic surgery (MMS) or resection or standard excision or radiation therapy for non-surgical candidates. For high-risk basal cell carcinoma individuals with positive Mohs margins adjuvant therapy may include radiation or hedgehog pathway inhibitor may be considered. If residual disease is still present after adjuvant therapy and further surgery and radiation treatments are contraindicated, other systemic treatment with hedgehog pathway inhibitor may be considered.

The hedgehog signaling pathway is involved in basal cell proliferation and tumor growth. Signaling in this pathway is initiated by the cell surface receptor smoothed homolog (SMO). This pathway normally is inhibited by another cell surface receptor, called the patched homolog 1 (PTCH1). Binding of the hedgehog ligand to PTCH1 prevents this inhibition. Two mechanisms have been identified by which the hedgehog pathway may be involved in the pathogenesis of basal cell carcinoma. Mutations of PTCH1 may prevent inhibition of SMO activation of the hedgehog pathway or mutations of SMO may result in constitutive activation of the pathway.

Two inhibitors, vismodegib and sonidegib, have clinically useful activity in patients with locally advanced or metastatic basal cell carcinoma.

Erivedge (vismodegib) is an inhibitor of the hedgehog (Hh) signaling pathway. Vismodegib binds to and inhibits Smoothed, a transmembrane protein involved in Hh signal transduction and activation of the cascade. Hh plays an important role in embryonic growth and has been implicated as a growth stimulus for various cancers, where

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activation of the pathway significantly accelerates tumor growth. Activation of Hh has been implicated in the development of basal cell carcinoma.

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#### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

#### **NCCN recommendation definitions:**

Category 1:

Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:

Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:

Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:

Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

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#### **Resources:**

Erivedge (vismodegib) product information, revised by Genentech, Inc. 03-2023. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed July 24, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Basal Cell Skin Cancer Version 1.2026 – Updated September 02, 2025. Available at <https://www.nccn.org>. Accessed October 07, 2025.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.