



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erivedge Prior Authorization Policy

- Erivedge® (vismodegib capsules – Genentech/Roche)

REVIEW DATE: 01/15/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Erivedge, an inhibitor of the hedgehog signaling pathway, is indicated for adults for the treatment of metastatic **basal cell carcinoma**, or locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.¹

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines address Erivedge.

- **Basal Cell Skin Cancer:** NCCN guidelines (version 3.2024 – March 1, 2024) note that surgical approaches offer the most effective and efficient means for accomplishing a cure; radiation therapy may be chosen as the primary treatment in order to achieve optimal overall results.² Erivedge is recommended for locally advanced (extensive) disease where surgery and/or radiation therapy may not result in a cure or would possibly produce a significant functional limitation, nodal disease if surgery is not feasible, metastatic disease, and diffuse basal cell carcinoma formation (e.g. basal cell nevus syndrome [Gorlin syndrome] or other genetic forms of multiple basal cell carcinoma) as “other recommended regimens” (all category 2A). Erivedge is also recommended as neoadjuvant therapy for locally advanced (extensive) disease where surgery and/or radiation therapy may not result in a cure or

would possibly produce a significant functional limitation as “other recommended regimens” (category 2B).

- **Central Nervous System Cancers:** NCCN guidelines (version 1.2023 – March 24, 2023) list Erivedge as a treatment option for patients with recurrent medulloblastoma who have received prior systemic therapy and have mutations in the sonic hedgehog pathway as “useful in certain circumstances” (category 2A).³

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Erivedge. All approvals are provided for the duration noted below.

- **Erivedge® (vismodegib capsules - Genentech/Roche)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Basal Cell Carcinoma, Locally Advanced.** Approve for 1 year if the patients meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):

- i.** Patient is ≥ 18 years of age; AND
- ii.** Patient meets ONE of the following (a or b):
 - a)** Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
 - b)** Patient meets BOTH of the following [(1) and (2)]:
 - (1)** Patient is not a candidate for surgery; AND
 - (2)** According to the prescriber, the patient is not a candidate for radiation therapy; OR

B) Patient is Currently Receiving Erivedge. Approve.

- 2. Basal Cell Carcinoma, Metastatic.** Approve for 1 year if the patient is ≥ 18 years of age.

Note: This includes primary or recurrent nodal metastases and distant metastatic disease.

Other Uses with Supportive Evidence

- 3. Diffuse Basal Cell Carcinoma Formation.** Approve for 1 year if the patient is ≥ 18 years of age.

Note: This includes basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma.

4. Central Nervous System Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Note: This includes brain and spinal cord tumors.

A) Patient is ≥ 18 years of age; AND

B) Patient has medulloblastoma; AND

C) Patient has tried at least one chemotherapy agent; AND

Note: Examples of chemotherapy include etoposide, carboplatin, cisplatin.

D) According to the prescriber, the patient has a mutation of the sonic hedgehog pathway.

CONDITIONS NOT COVERED

- **Erivedge® (vismodegib capsules - Genentech/Roche)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Odomzo (sonidegib capsules).** Note: This does not apply to a patient already started on Erivedge. Refer to criteria for basal cell carcinoma, Locally Advanced for a Patient Currently Receiving Erivedge. There are no data to support the use of Erivedge in patients who have experienced disease progression on Odomzo, another hedgehog signaling pathway inhibitor. Previous use of a hedgehog inhibitor was not allowed in the pivotal study for Odomzo.¹ Patients who develop resistance to one of the hedgehog pathway inhibitors are not expected to respond to another hedgehog pathway inhibitor. There is an open-label study which evaluated patients (n = 9) with advanced basal cell carcinoma; patients with resistance to Odomzo also progressed on Erivedge.⁴

REFERENCES

1. Erivedge® capsules [prescribing information]. South San Francisco, CA: Genentech/Roche; March 2023.
2. NCCN Basal Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – March 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 13, 2025.
3. NCCN Central Nervous System Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – September 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 13, 2025.
4. Danial C, Sarin KY, Oro AE, Chang AL. An investigator-initiated open-label trial of sonidegib in advanced basal cell carcinoma patients resistant to vismodegib. *Clin Cancer Res.* 2016;22(6):1325-1329.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/17/2024
Annual Revision	Diffuse Basal Cell Carcinoma Formation: New condition of approval was added to Other Uses with Supportive Evidence. Metastatic colorectal cancer and ovarian cancer were removed from the Conditions Not Covered.	01/15/2025

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