



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Oral – Hedgehog Pathway Inhibitor) – Erivedge Prior Authorization Policy
- Erivedge® (vismodegib capsules – Genentech/Roche)

REVIEW DATE: 01/21/2026; selected revision 01/28/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Erivedge, a hedgehog pathway inhibitor, 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 1.2026 – September 2, 2025) 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 in combination with radiation therapy, 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, 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 a “Preferred” treatment for metastatic disease (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 3.2025 – December 5, 2025) 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 BOTH of the following (A and B):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets ONE of the following (i, ii, iii, or iv):
 - i.** Erivedge will be used as neoadjuvant therapy before surgery; OR
 - ii.** Erivedge will be used in combination with radiation therapy; OR
 - iii.** Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
 - iv.** According to the prescriber, the patient is not a candidate for radiation therapy or surgery.
- 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 \geq 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 \geq 18 years of age; AND

B) Patient has medulloblastoma; AND

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

Note: Examples of chemotherapy regimens include one of the following drugs: cyclophosphamide, etoposide, carboplatin, cisplatin, vincristine.

D) Patient has a mutation of the sonic hedgehog (SHH) pathway.

CONDITIONS NOT COVERED

• **Erivedge® (vismodegib capsules - Genentech/Roche)** is(are) considered not medically necessary 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). 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 1.2026 – September 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 16, 2026.
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
Update	04/08/2025: The policy name was changed from "Oncology – Erivedge PA Policy" to "Oncology (Oral – Hedgehog Pathway Inhibitor) – Erivedge PA Policy".	N/A
Annual Revision	Basal Cell Carcinoma, Locally Advanced: The following option of approval was added: "Erivedge will be used in combination with radiation therapy." The requirement that the "patient is not a candidate for surgery and according to the prescriber, the patient is not a candidate for radiation therapy" was changed to "according to the prescriber, patient is not a candidate for surgery or radiation therapy." An option for approval for a patient currently receiving Erivedge was removed. Central Nervous System Cancer: The word "agent" was changed to "regimen" for the requirement which previously stated that "patient has tried at least one chemotherapy agent." Cyclophosphamide and vincristine were added to the Note of examples of a chemotherapy regimen. The wording "according to the prescriber" was removed from "patient has a mutation in the sonic hedgehog (SHH) pathway."	01/21/2026
Selected Revision	Basal Cell Carcinoma, Locally Advanced: The following option for approval was added: Erivedge will be used as neoadjuvant therapy before surgery. Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Odomzo (sonidegib capsules): The following was Note removed, " <u>Note:</u> This does not apply to a patient already started on Erivedge."	01/28/2026

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