UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1030-11
Program	Prior Authorization/Notification
Medication	Erivedge® (vismodegib)
P&T Approval Date	4/2012, 8/2012, 7/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

1. Background:

Erivedge® (vismodegib) is a hedgehog pathway inhibitor indicated for the treatment of adults 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.[1]

The National Comprehensive Cancer Network (NCCN) also recommends Erivedge for the treatment of medulloblastoma for recurrence as a single agent in patients who have received prior chemotherapy and have mutations in the sonic hedgehog pathway.[2]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Erivedge** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Basal Cell Carcinoma

1. **Initial Authorization**

   a. **Erivedge** will be approved based on **one** of the following criteria:

      (1) Diagnosis of metastatic basal cell carcinoma

      -OR-

      (2) **Both** of the following:

         (a) Diagnosis of locally advanced basal cell carcinoma

-AND-

(b) **One** of the following:

i. Cancer has recurred following surgery
ii. Patient is not a candidate for surgery
iii. Patient is not a candidate for radiation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Erivedge** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Erivedge therapy

Authorization will be issued for 12 months.

C. Medulloblastoma

1. **Initial Authorization**

a. **Erivedge** will be approved based on **all** of the following criteria:

(1) Diagnosis of medulloblastoma

-AND-

(2) Patient has mutations in the sonic hedgehog pathway

-AND-

(3) Patient has failed prior chemotherapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Erivedge** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Erivedge therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a

Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Erivedge [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/nccn-compendia. Accessed August 31, 2023.

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Change Control	
11/2014	Annual review with no change to coverage criteria.
11/2015	Annual review. Increased authorization from 10 months to 12 months. Updated background & references.
9/2016	Annual review. Verbiage change in coverage criteria from Member to Patient. Formatting changes to criteria with no change to clinical intent. Updated background and references.
9/2017	Annual review with no change to coverage criteria. Updated references.
9/2018	Annual review with no change to coverage criteria. Updated references.
9/2019	Annual review. Added coverage for medulloblastoma. Updated references. Added general NCCN recommended review criteria.
9/2020	Annual review with no changes to coverage criteria.
10/2021	Annual review with no changes to coverage criteria.
10/2022	Annual review with no changes to coverage criteria. Added state mandate. Updated references.
10/2023	Annual review with no changes to coverage criteria. Updated references.