UnitedHealthcare®
Community Plan

Clinical Pharmacy Program Guidelines for Erivedge

Program	Prior Authorization
Medication	Erivedge® (vismodegib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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]

Erivedge has a black box warning for use in pregnancy and other reproductive risks. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. 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:

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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.

B. **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.

C. **NCCN Recommended Regimens**

1. **Initial Authorization**

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a. **Erivedge** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Erivedge therapy

Authorization will be issued for 12 months.

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.;July 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. AccessedJuly 30, 2020.

Program	Prior Authorization- Erivedge (vismodegib)
Change Control	
Date	Change
3/2013	New program
9/2016	Updated clinical criteria to align with Employer and Individual notification policy and updated policy template.
9/2017	Annual review with no change to coverage criteria. Updated references.
9/2018	Annual review. Added NCCN Recommended Regimen review criteria. Updated references.
9/2019	Added coverage for medulloblastoma. Updated background and references.
9/2020	Annual review with no changes to coverage criteria. Updated references. Added Additional Clinical Rules section.

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