Erivedge (vismodegib)

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	-

Medications	Quantity Limit
Erivedge (vismodegib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Erivedge (vismodegib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Basal Cell Skin Cancer; AND
- II. Individual is 18 years or older; **AND**
- III. Individual has Metastatic disease;

OR

IV. Individual has locally advanced or recurrent disease following surgery and/or radiation:

OR

 Individual has locally advanced or nodal disease and is NOT a candidate for surgery and/or radiation;

OR

- VI. Individual has a diagnosis of diffuse BCC formation, as Gorlin syndrome or other genetic forms of multiple BCC (NCCN 2A); **AND**
- VII. Individual is 18 years or older;

OR

- VIII. Individual has a diagnosis of recurrent medulloblastoma (NCCN 2A); AND
- IX. Individual is 18 years or older; **AND**
- X. Individual has received prior chemotherapy; **AND**
- XI. Individual has sonic hedgehog (SHH)-activated disease (i.e. mutations in the sonic hedgehog pathway).

Requests for Erivedge (vismodegib) may not be approved for the following:

 Individual has shown evidence of progressive disease while on Erivedge (vismodegib) or Odomzo (sonidegib) therapy.

Note:

Erivedge has a black box warning for embryo-fetal toxicity. Erivedge can result in embryo-fetal death or severe birth defects when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge. Advise pregnant women of the potential risks to a fetus.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 11, 2023.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 5. Robinson GW, Orr BA, Wu G, et al. Vismodegib exerts targeted efficacy against recurrent sonic hedgehog-subgroup medulloblastoma: results from phase II pediatric brain tumor consortium studies PBTC-025B and PBTC-032. *J Clin Oncol* 2015;33(24):2646-54.
- 6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 11, 2023.
 - a. Basal Cell Skin Cancer. V2.2024. Revised September 14, 2023.
 - b. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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