

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Erivedge (vismodegib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial and Continuation: 1 year

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

APPROVAL CRITERIA

Initial 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
- V. Individual has locally advanced disease and is NOT a candidate for surgery and radiation.

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

- I. Individual does not show evidence of progressive disease while on Erivedge 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.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 26, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4534527/>. Accessed on October 3, 2019.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 26, 2019.
 - a. Basal Cell Skin Cancer. V1.2029. Revised August 31, 2018
 - b. Central Nervous System Cancers. V2.2019. Revised September 16, 2019.

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