

Erivedge® (vismodegib) (Oral)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 150 mg capsule: 1 capsule per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 150 mg daily

III. Initial Approval Criteria ^{1,2}

Coverage is provided for the following conditions:

- Patient is at least 18 years or older; **AND**
- Negative pregnancy test for women of child-bearing potential (*Note: Females of reproductive potential should use effective contraception during and for at least 24 months after the last dose and males of reproductive potential should also do so during and for at least 3 months after the last dose*); **AND**

Basal Cell Carcinoma † ¹⁻³

- Patient has nodal or metastatic disease; **OR**
- Patient has locally advanced disease; **AND**
 - Disease has recurred following surgery or radiation therapy; **OR**
 - Patient is not a candidate for surgery and radiation therapy

CNS Cancer – Medulloblastoma ‡ ²

- Used as a single agent; **AND**

- Patient has recurrent disease; **AND**
- Patient has received prior chemotherapy; **AND**
- Patient has mutations in the sonic hedgehog pathway

† FDA approved indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria ^{1,2}

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN]), drug reaction with eosinophilia and systemic symptoms (DRESS), premature fusion of the epiphyses, etc.

V. Dosage/Administration

Indication	Dose
All Indications	150 mg by mouth daily

VI. Billing Code/Availability Information

HCPCS:

J8999 – Prescription drug oral, chemotherapeutic, Not Otherwise Specified

NDC:

Erivedge 150 mg capsules: 50242-0140-xx

VII. References

1. Erivedge [package insert]. South San Francisco, CA; Genentech; July 2020. Accessed October 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vismodegib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2020.

3. Sekulic A, Migden M, Seguin N, et al. Long-term safety and efficacy of vismodegib in patients with advanced basal cell carcinoma: final update of the pivotal ERIVANCE BCC study. BMC Cancer 2017 May 16;17(1):332.doi: 10.1186/s12885-017-3286-5.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C44.01	Basal cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.9	Malignant neoplasm of brain, unspecified
Z85.828	Personal history of other malignant neoplasm of skin

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC