

Erivedge[®] (vismodegib) (Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

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

- Erivedge 150 mg capsules: 1 capsule per day

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

- 150 mg daily

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Negative pregnancy test for women of child-bearing potential within the preceding 7 days
(*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**

Universal Criteria ^{1,2}

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

Basal Cell Carcinoma † ‡ ¹⁻⁴

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

- Patient has diffuse basal cell carcinoma (BCC) formation (e.g., basal cell nevus syndrome [Gorlin syndrome] or other genetic forms of multiple BCC) ‡

CNS Cancer – Medulloblastoma ‡²

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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria^{1,2}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant 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]), musculoskeletal adverse reactions, premature fusion of the epiphyses, etc.

V. Dosage/Administration^{1,5}

Indication	Dose
All Indications	Administer 150 mg orally once 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; March 2023. Accessed October 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) vismodegib. National Comprehensive Cancer Network, 2023. 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 2023.

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.
4. Sekulic A, Migden MR, Oro AE, et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. *N Engl J Med*. 2012 Jun 7;366(23):2171-9. doi: 10.1056/NEJMoa1113713.
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 Aug 20;33(24):2646-54. doi: 10.1200/JCO.2014.60.1591.

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

ICD-10	ICD-10 Description
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
Q87.89	Other specified congenital malformation syndromes, not elsewhere classified

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: <https://www.cms.gov/medicare-coverage-database/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