CENTENE Corporation

Clinical Policy: Vismodegib (Erivedge)

Reference Number: CP.PHAR.273
Effective Date: 08.16
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Vismodegib (Erivedge®) is a hedgehog pathway inhibitor.

FDA Approved Indication(s)

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma (BCC), or with locally advanced BCC that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Erivedge is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Basal Cell Carcinoma (must meet all):

1. Diagnosis of one of the following (a, b, c, or d):
   a. Metastatic BCC;
   b. Locally advanced or recurrent BCC that meets one of the following (i, ii, or iii):
      i. Member has disease that recurred following surgery;
      ii. Member had disease that recurred following radiation;
      iii. Member is not a candidate for surgery or radiation;
   c. Nodal BCC if surgery is not feasible;
   d. Diffuse BCC formation (e.g., Gorlin syndrome or other genetic forms of multiple BCC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Erivedge is prescribed as a single agent;
5. For Erivedge requests, member must use generic vismodegib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 150 mg (one capsule) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA– 12 months
Commercial – 12 months or duration of request, whichever is less

B. **Medulloblastoma (off-label)** (must meet all)**:**
   1. Diagnosis of recurrent medulloblastoma;
   2. Prescribed by or in consultation with an oncologist;
   3. Age ≥ 18 years;
   4. Member has received prior chemotherapy (*see Appendix B for examples*);
   5. Tumor is positive for a sonic hedgehog mutation;
   6. Erivedge is prescribed as a single agent;
   7. For Erivedge requests, member must use generic vismodegib, if available, unless contraindicated or clinically significant adverse effects are experienced;
   8. Request meets one of the following (a or b):*
      a. Dose does not exceed 150 mg (one capsule) per day;
      b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN* (in italics)

Approval duration:
Medicaid/HIM/ICHRA– 12 months
Commercial – 12 months or duration of request, whichever is less

C. **Other diagnoses/indications** (must meet 1 or 2)**:**
   1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
      a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
      b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
   2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. **All Indications in Section I** (must meet all)**:**
   1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Erivedge for a covered indication and has received this medication for at least 30 days;
   2. Member has responded positively to therapy;

3. For Erivedge requests, member must use generic vismodegib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 150 mg (one capsule) day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA– 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BCC: basal cell carcinoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of prior chemotherapy for medulloblastoma:	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Cisplatin, cyclophosphamide, and vincristine • Cisplatin, lomustine (Gleostine®), and vincristine		

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BCC	150 mg PO QD	150 mg/day

VI. Product Availability
Capsule: 150 mg

VII. References
1. Erivedge Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; March 2023. Available at https://www.erivedge.com/. Accessed January 30, 2026.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 30, 2026.
3. National Comprehensive Cancer Network Guidelines. Basal Cell Skin Cancer Version 1.2026. Available at https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed January 30, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2022 annual review: added indication of diffuse basal cell carcinoma (BCC) formation per NCCN category 2A recommendation; added generic redirection criteria; WCG.CP.PHAR.273 was retired and initial approval duration was consolidated to 6 months; Commercial approval durations revised from “Length of Benefit” to “12 months or duration of request, whichever is less”; references reviewed and updated.	02.14.22	05.22
Template changes applied to other diagnoses/indications.	09.20.22	
2Q 2023 annual review: no significant changes; references reviewed and updated. Template verbiage does not apply to continued therapy section.	01.20.23	05.23
2Q 2024 annual review: for BCC, specified locally advanced BCC, added indication of nodal BCC if surgery is not feasible per NCCN 2A recommendation; references reviewed and updated.	02.08.24	05.24
2Q 2025 annual review: no significant change; references reviewed and updated.	01.30.25	05.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2026 annual review: clarified metastatic BCC does not require additional requirement of disease recurrence following surgery/radiation or that member is not a candidate for surgery or radiation; extended Medicaid and HIM initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. Added ICHRA line of business.	03.31.26	05.26

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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