

Erivedge[®]

(vismodegib) capsule



Not actual patients. Images used for illustrative purposes only.

Access. Assistance. Support.

Discover all the resources available to you
and your patients taking Erivedge

Indication

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

Boxed Warning

EMBRYO-FETAL TOXICITY

- Erivedge can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Erivedge is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations
- 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. Advise females of reproductive potential to use effective contraception during and after Erivedge
- Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential

Please see full [Prescribing Information](#), including the **BOXED WARNING** and the [Medication Guide](#), for a complete discussion of the risks associated with Erivedge.

Connecting patients to their Genentech medicine

We believe every person should get the Genentech medicine they have been prescribed, and we offer programs to help make this happen

- **Genentech Access Solutions:** Provides helpful access and reimbursement support to assist your patients and practice after a Genentech medicine is prescribed
- **Co-pay Assistance:** Genentech can help your patients and practice address each patient's coverage scenario
 - **The Oncology Co-pay Assistance Program** provides financial assistance to eligible commercially insured patients to help with their co-pays, co-insurance, or other out-of-pocket (OOP) costs*
 - An independent **co-pay assistance foundation** is a charitable organization providing financial assistance to patients with specific disease states†
- **Genentech Patient Foundation:** Provides free Genentech medicine to people who don't have insurance coverage or who have financial concerns and meet eligibility criteria. Learn more and download the Enrollment Form at GenentechPatientFoundation.com‡

*Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications and/or administration of their Genentech medication. Patient must be taking the Genentech medication for an FDA-approved indication. See full Terms and Conditions at copayassistancenow.com.

†Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from Genentech Access Solutions. This information is provided as a resource to patients. Please note that this list is not indicative of Genentech's endorsement or financial support of any particular disease area and/or foundation, nor is it exhaustive. There may be other foundations to support the patient's disease state.

‡To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine must have pursued all other forms of financial assistance and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet different income requirements.

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Genentech Access Solutions is your resource for helpful access and reimbursement support

We can help your patients and practice by providing:

- Benefits investigations to verify coverage and benefits reverification support
- Prior authorization resources
- Information about authorized specialty pharmacies and specialty distributors
- Sample billing and coding information
- Resources for denials and appeals
- Referrals to co-pay assistance that may help eligible insured patients with OOP costs
- Referrals to the Genentech Patient Foundation, which provides qualified patients with free Genentech medicine

To enroll in Genentech Access Solutions, complete and submit the:

Prescriber Service Form — filled out by the healthcare provider and used to collect the patient's health insurance and treatment information

Patient Consent Form — completed by the patient and gives permission for Genentech Access Solutions to work with you and the patient's health insurance plan





The Prescriber Service Form can now be completed via Quick Enroll at go.gene.com/quickenroll.

Patients can access the Patient Consent Form for download or online completion at Genentech-Access.com/PatientConsent.

Both forms must be received before Genentech can begin helping your patient. Only the information requested on these forms is required. Providing additional documents or information will delay processing.

Oncology Co-pay Assistance Program

The Oncology Co-pay Assistance Program can help eligible patients with the OOP costs associated with Erivedge

	 Eligible patients pay as little as a \$5 co-pay for Erivedge
	No income requirements
	Annual benefit limit of co-pay card is \$25,000

This Oncology Co-pay Assistance Program is valid ONLY for patients with commercial insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medication. Patients using Medicare, Medicaid, or any other federal or state government program to pay for their medications are not eligible. Under the program, the patient will pay a co-pay. After reaching the maximum program benefit, the patient will be responsible for all OOP expenses.

All participants are responsible for reporting the receipt of all program benefits as required by any insurer or by law. No party may seek reimbursement for all or any part of the benefit received through this Program. The program is only valid in the United States and US Territories. This program is void where prohibited by law and shall follow state restrictions in relation to AB-rated generic equivalents (eg, MA, CA) where applicable. The patient, guardian, prescriber, hospital, and any other person using the program agree not to seek reimbursement for all or any part of the benefit received by the patient through the offer of this program. Genentech reserves the right to rescind, revoke, or amend the program without notice at any time. Additional terms and conditions apply. Please visit copayassistancenow.com for the full list of Terms and Conditions.

To enroll, eligible patients can:	<ul style="list-style-type: none">• Visit copayassistancenow.com• Call (855) MY-COPAY or (855) 692-6729 Monday through Friday, 9 AM–8 PM ET
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Additional Patient Support

Sample Program—help patients start treatment



Patients can receive a month of free medicine

Erivedge is a 150-mg capsule dosed once daily.

To participate:	Contact your representative for more details about our sample program
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Erivedge Patient Support Line—help patients throughout treatment



One-on-one phone support with Patient Support Specialists is available*

Patients can:	Call (855) 7-ERIVEDGE or (855) 737-4833 Monday through Friday, 9 AM–8 PM ET
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*The Erivedge Patient Support Line is for educational purposes only; it is not intended to provide medical advice or to be a substitute for the guidance you provide to your patients.



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- **Advise males of the potential risk of Erivedge exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential**
- **Females of Reproductive Potential:** Use contraception during therapy with Erivedge and for 24 months after the final dose
- **Males:** Use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female partners of reproductive potential during and for 3 months after the final dose of Erivedge. Do not donate semen during and for 3 months after the final dose of Erivedge
- **Blood Donation:** Advise patients not to donate blood or blood products while receiving Erivedge and for 24 months after the final dose of Erivedge
- Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at (888) 835-2555

Additional Important Safety Information

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported during treatment with Erivedge. Permanently discontinue Erivedge in patients with these reactions

Please see full [Prescribing Information](#), including the **BOXED WARNING** and the [Medication Guide](#), for a complete discussion of the risks associated with Erivedge.

Premature Fusion of the Epiphyses

- Premature fusion of the epiphyses has been reported in pediatric patients exposed to Erivedge. In some cases, fusion progressed after drug discontinuation. Erivedge is not indicated for pediatric patients

Adverse Reactions

- The most common adverse reactions ($\geq 10\%$) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia
- Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown. In clinical trials, 30% of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia (4%), azotemia (2%), and hypokalemia (1%)
- Additionally, in a post-approval clinical trial conducted in 1232 patients with locally advanced or metastatic BCC treated with Erivedge, a subset of 29 patients had baseline values for blood creatine phosphokinase (CPK) reported. Within the subset of patients, 38% had a shift from baseline, including Grade 3 (3%) increased CPK. Grade 3 or 4 increased CPK occurred in 2.4% of the 453 patients across the entire study population with any CPK measurement
- Adverse reactions identified during post-approval use: drug-induced liver injury, Stevens-Johnson syndrome/toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms

Use in Specific Populations

Lactation

- No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. Advise women that breastfeeding is not recommended during therapy with Erivedge and for 24 months after the final dose

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Erivedge
(vismodegib) capsule

Committed to Helping Patients—Regardless of Their Ability to Pay

	COMMERCIAL Insurance	PUBLIC Insurance	NO Insurance
Genentech Co-pay Programs*	✓		
Referrals to Independent Co-pay Assistance Foundations†	✓	✓	
Genentech Patient Foundation‡	✓	✓	✓

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To learn more about our programs and services:

- Visit Genentech-Access.com/Erivedge
- Call (888) 249-4918 Monday through Friday, 9 AM–8 PM ET

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