Erivedge (vismodegib) capsule | ACCESS SOLUTIONS®

Erivedge Sample Coding

Advanced Basal Cell Carcinoma

TYPE	CODE	DESCRIPTION
Diagnosis: ICD-10-CM	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
		Basal cell carcinoma of skin of left lower limb,

Please see the full Prescribing Information for a complete discussion of the risks associated with Erivedge, including the BOXED WARNING and the Medication Guide.

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	C44.719		including hip
	C44.81		Basal cell carcinoma of overlapping sites of skin
	C44.91		Basal cell carcinoma of skin, unspecified
Drug: NDC Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	**10-digit**	**11-digit**	
	50242-140-01	50242-0140-01	150 mg (28 capsules)

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.
NDC=National Drug Code.

Important Safety Information & Indication

Indication

ERIVEDGE® (vismodegib) capsule 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 and Additional Important Safety Information

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 pregnancy status of females of reproductive potential within 7 days prior to initiating Erivedge therapy. Advise females of reproductive potential to use effective contraception during and after Erivedge therapy. 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. Advise pregnant women of the potential risks to a fetus**
- 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

Female Patients

- Advise females of reproductive potential to use effective contraception during therapy with Erivedge and for 24 months after the final dose

Male Patients

- Advise males of the potential risk to an embryo or fetus if a female partner of reproductive potential is exposed to Erivedge. Advise male patients to use condoms with a pregnant partner or a female partner of reproductive potential, even after a vasectomy, during therapy 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

Semen Donation

- Vismodegib is present in semen. It is not known if the amount of vismodegib in semen can cause embryo-fetal harm. Advise male patients not to donate semen during and for 3 months after the final dose of 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

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Adverse Reactions

- The most common adverse reactions (≥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 Reversibility of amenorrhea is unknown. In clinical trials, a total of 3 of 10 pre-menopausal women developed amenorrhea while receiving Erivedge
- Treatment-emergent grade 3 laboratory abnormalities observed in clinical trials were hyponatremia in 6 patients (4%), hypokalemia in 2 patients (1%), and azotemia in 3 patients (2%)
- 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 CPK reported. Within the subset of patients, 38% had a shift from baseline, and one of the patients had a Grade 3 value. The prevalence of Grade 3/4 CPK elevation across the entire study population with any CPK measurement was 2.4% (11 out of 453 patients)

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 infant, or the effects of the drug on milk production. Because of the potential for serious adverse reactions in breastfed infants from Erivedge, advise a nursing woman 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.

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