VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

ERIVEDGE (vismodegib)

Effective Date: 4/24/12

Date Developed: 3/1/12 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

ERIVEDGE is an Antineoplastic Agent, Hedgehog Pathway Inhibitor.

Pre-Authorization Criteria:

VCHCP will authorize ERIVEDGE for FDA indicated treatment of metastatic basal cell carcinoma, or locally-advanced basal cell carcinoma that has recurred following surgery or in patients who are not candidates for surgery or radiation therapy.

VCHCP requires that ERIVEDGE be prescribed by an Oncologist.

Dosing: Adult
The recommended dose is 150 mg orally once daily until disease progression or until unacceptable toxicity.

Dosing: Hepatic Impairment: For patients with moderate hepatic impairment, decrease the starting dose by approximately half. A starting dose decrease is recommended when administering ERIVEDGE to patients with moderate hepatic impairment.

Dosing: Geriatric
See adult dosing. No dosage adjustment is required in elderly patients.

Dosage Forms: U.S.
ERIVEDGE is available in capsule form, in 150 mg strength.

Administration
ERIVEDGE may be taken with out without food. Swallow capsules whole. Do not open or crush capsules. If a dose of ERIVEDGE is missed, do not make up that dose; resume dosing with the next scheduled dose.

WARNINGS / PRECAUTIONS

- Advise patients that Erivedge exposure during pregnancy can cause

embryo-fetal death or severe birth defects.

- Instruct female patients of reproductive potential to use a highly effective form of contraception (failure rate of less than 1%) while taking Erivedge and for at least 7 months after the last dose of Erivedge.

- Instruct all male patients, even those with prior vasectomy, to use condoms with spermicide, during sexual intercourse with female partners while taking Erivedge and for at least 2 months after the last dose of Erivedge.

- Instruct patients to immediately contact their healthcare provider if they (or, for males, their female partner) become pregnant or if pregnancy is suspected following exposure to Erivedge.

- Instruct patients to immediately report any pregnancy exposure to Erivedge and encourage participation in the Erivedge pregnancy pharmacovigilance program by calling the Genentech Adverse Event Line at 1-888-835-2555.

- Inform female patients of the potential for serious adverse reactions in nursing infants from Erivedge, taking into account the importance of the drug to the mother.

- Advise patients not to donate blood or blood products while taking Erivedge and for at least 7 months after the last dose of Erivedge.

- Advise patients to swallow Erivedge capsules whole and not to crush or open the capsules.

ADVERSE REACTIONS

- The most common adverse reactions (incidence of $\geq$ 10%) are muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting and ageusia.

REFERENCES

Genentech pharmacy/drug insert, issued January 2012

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