BlueCross BlueShield Federal Employee Program

ERIVEDGE (vismodegib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Erivedge (vismodegib) is an oral antineoplastic agent that is used to treat adult patients with basal cell carcinoma, the most common type of skin cancer. Basal cell carcinoma is generally a slow growing and painless form of skin cancer that starts in the top layer of the skin (epidermis) that is regularly exposed to sunlight or other ultraviolet radiation. Erivedge works by inhibiting the Hedgehog pathway, a pathway that is active in most basal cell cancers and only a few normal tissues, such as hair follicles (1).

Regulatory Status

FDA-approved indication: Erivedge is a hedgehog pathway inhibitor 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 (1).

Erivedge carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Pregnancy status must be determined within 7 days prior to initiation of treatment in females of reproductive potential. Females should be advised of the need for contraception, males should be advised of the potential risk of Erivedge exposure through semen (1).

Patients should be instructed not to donate blood or blood products while receiving Erivedge and for at least 24 months after the last dose of Erivedge (1).

Safety and effectiveness of Erivedge have not been established in pediatric patients (1).

Summary

Erivedge (vismodegib) is a hedgehog pathway inhibitor 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. Erivedge carries a boxed warning that its use can result in embryo-fetal death or severe birth defects. Females should be advised of the need for contraception. Patients may

continue Erivedge until disease progression or unacceptable toxicity has occurred. Safety and effectiveness of Erivedge have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Erivedge while maintaining optimal therapeutic outcomes.

References

1. Erivedge [package insert]. South San Francisco, CA: Genentech USA Inc.; March 2023.
2. NCCN Drugs & Biologics Compendium® Vismodegib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.