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5.21.035

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 22, 2013
Subject:	Erivedge	**Page:**	1 of 4

Last Review Date: March 7, 2025

Erivedge

Description

Erivedge (vismodegib)

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).

Related policies
Odomzo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Erivedge may be considered **medically necessary** if the conditions indicated below are met.

Erivedge may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic basal cell carcinoma
2. Locally advanced basal cell carcinoma that has recurred following surgery
3. Locally advanced basal cell carcinoma and the member is not a candidate for surgery or radiation.

AND ALL of the following:

a. Females of reproductive potential **only**: patient is **NOT** pregnant and will be advised to use effective contraception during treatment with Erivedge and for 24 months after the last dose
b. Males with female partners of reproductive potential **only**: patient will be advised to use condoms, even after a vasectomy, during treatment with Erivedge and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Metastatic or locally advanced basal cell carcinoma
   a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 84 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

Policy History

Date	Action
April 2013	Addition to PA
September 2014	Annual criteria review and reference update
December 2015	Annual review and reference update
March 2016	Annual editorial review Policy number was changed from 5.04.35
June 2016	Annual review
June 2017	Annual editorial review and reference update Addition of age limit to renewal criteria
June 2018	Annual review and reference update
March 2019	Annual review and reference update
June 2020	Annual review and reference update
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.035
June 2023	Annual review and reference update. Per SME, revised contraception requirements for consistency
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.