Erivedge (vismodegib) Prior Approval Criteria
September 2016

OVERVIEW:
Erivedge, an inhibitor of the hedgehog (Hh) signaling pathway, is indicated for the treatment of adults with metastatic basal cell carcinoma (mBCC), or with locally advanced basal cell carcinoma (LaBCC) that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. Efficacy was established in a single trial conducted in patients with either mBCC or LaBCC. Patients with LaBCC were required to have lesions that had recurred after radiotherapy, unless radiotherapy was contraindicated or inappropriate (e.g., patients with Gorlin syndrome; limitations because of location of tumor or cumulative prior radiotherapy dose), and where the lesions were either unresectable or surgical resection would result in substantial deformity.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Erivedge. All approvals are provided for 1 year in duration unless otherwise noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

Please Note: In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, oncologist, or dermatologist.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Erivedge is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Metastatic Basal Cell Carcinoma (mBCC). Approve.
   Erivedge is indicated for the treatment of adults with metastatic BCC, or with locally advanced BCC that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2. Locally Advanced Basal Cell Carcinoma (LaBCC). Approve if the patient meets ONE of the following conditions (a or b):
   a) The patient’s basal cell carcinoma has recurred following surgery or radiation therapy; OR
b) The patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician.

3. **Patient has been started on Erivedge.** Approve for an indication or condition addressed as an approval in this document.

**Other Uses with Supportive Evidence**

4. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.** Prescriber will provide specific diagnosis for documentation. Approve.

**Approval Duration**
Initial Approval = Approve for 1 year
Re-authorization = Approve for 1 year

**REFERENCES**