I. **Medication Description**

Erivedge (vismodegib) is an oral hedgehog pathway inhibitor. The hedgehog (Hh) signaling pathway regulates normal cell development, replication, and differentiation and hair growth. Erivedge works by binding to and inhibiting the transmembrane protein smoothened that is necessary for Hh signal transduction. Dysregulation of the Hh signaling pathway is associated with basal cell carcinoma development.

II. **Position Statement**

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. **Policy**

Coverage of Erivedge can be provided when the following criteria are met:

- The medication is prescribed by an oncologist or a dermatologist/oncologist **AND**
- The patient is at least 18 years of age **AND**
- The patient has been diagnosed with basal cell carcinoma and one of the following apply:
  - The patient has high-risk disease if residual disease is present and further surgery and radiation are contraindicated or if negative margins are unachievable by MOHS surgery or more extensive surgical procedures **OR**
  - The patient has nodal or distant metastases

IV. **Quantity Limitations**

30 capsules per each 30 day period are covered

V. **Coverage Duration**

Coverage is provided for 6 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Available as 150mg capsules

VIII. Summary of Policy Changes

- 6/15/12: new policy
- 6/15/13: residual disease added to covered indications
- 6/15/14: addition of diagnosis codes to policy
- 6/15/15: updated coverage scenarios to comply with current NCCN recommendations
- 7/1/15: formulary distinctions made
- 6/15/16: updated coverage to coincide with current NCCN treatment guidelines
- 4/5/17: No policy changes

XIII. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.