Prior Authorization
Oncology – Erivedge® (vismodegib capsules)

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy

Cigna covers vismodegib capsules (Erivedge®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior authorization is recommended for prescription benefit coverage of Erivedge. All approvals are provided for the duration noted below.

FDA Indication(s)

1. Basal Cell Carcinoma, Metastatic. Approve for 3 years.

2. Basal Cell Carcinoma, Locally Advanced. Approve for 3 years if the individuals meets ONE of the following conditions (A or B):
   A) Initial Therapy. Approve if the individual meets ONE of the following (i or ii):
      i. Individual has recurrent basal cell carcinoma following surgery or radiation therapy; OR
      ii. Individual meets BOTH of the following (a and b):
         a) Individual is not a candidate for surgery; AND
         b) According to the prescriber, the individual is not a candidate for radiation therapy.
   B) Individual is Currently Receiving Erivedge. Approve.

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Other Uses with Supportive Evidence

3. **Central Nervous System Cancer.** (Note: This includes brain and spinal cord tumors.) Approve for 3 years if the individual meets BOTH of the following (A and B):
   - **A)** Individual has tried at least one chemotherapy agent; AND
     - **Note:** Examples of chemotherapy include etoposide, carboplatin, cisplatin.
   - **B)** According to the prescriber, the individual has a mutation of the sonic hedgehog pathway.

**Conditions Not Covered**

**Vismodegib capsules (Erivedge®)** is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. **Basal Cell Carcinoma (Locally Advanced or Metastatic), in Individuals with Disease Progression While on Odomzo® (sonidegib capsules).** [Note: This does not apply to individuals already started on Erivedge. Refer to criteria for basal cell carcinoma, Locally Advanced for Individuals Currently Receiving Erivedge.] There are no data to support the use of Erivedge in individuals who have experienced disease progression on Odomzo. Previous use of a hedgehog inhibitor was not allowed in the pivotal study for Odomzo. Individuals who develop resistance to one of the hedgehog pathway inhibitors are not expected to respond to another hedgehog pathway inhibitor. There is an open-label study which evaluated individuals (n = 9) with advanced basal cell carcinoma who had progressed on Erivedge that showed resistance to Odomzo, another hedgehog signaling pathway used in basal cell carcinoma.

2. **Metastatic Colorectal Cancer.** Erivedge is not recognized in the treatment recommendations for colon cancer from the NCCN (version 4.2020 – June 15, 2020). In combination with standard of care treatment for first-line disease, Erivedge did not confer incremental clinical benefit as measured by progression-free survival (PFS) compared with standard care therapy alone. A Phase II study was designed to assess whether Erivedge would prolong PFS when combined with standard of care therapy (FOLFOX [leucovorin, fluorouracil, oxaliplatin] or FOLFIRI [leucovorin, fluorouracil, irinotecan]) in combination with Avastin® (bevacizumab injection) in individuals requiring first-line treatment for metastatic colorectal cancer. Adults with histologically confirmed disease were randomized 1:1 to Erivedge or placebo (n = 199). There was not a significant difference in median PFS or 12-month survival with Erivedge vs. placebo.

3. **Ovarian Cancer.** The NCCN guidelines for Ovarian Cancer (version 1.2020 – March 11, 2020) do not address the use of Erivedge for the management of ovarian cancer. The prespecified magnitude of PFS was not achieved in a Phase II, randomized, double-blind, placebo-controlled trial in adults with histologically confirmed epithelial ovarian carcinoma, primary peritoneal carcinoma, or fallopian tube carcinoma. The study was conducted to determine an estimate of clinical benefit of maintenance therapy with Erivedge in the setting of second or third complete remission as measured by PFS using radiographic assessment. Eligible individuals had received chemotherapy (platinum based and/or non-platinum based) for recurrent disease and had achieved complete response after their most recent chemotherapy regimen. PFS was not statistically different with Erivedge vs. placebo.

**Background**

**Overview**

Erivedge, an inhibitor of the hedgehog signaling pathway, is 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. It binds to and inhibits Smoothened, a transmembrane protein involved in Hedgehog signal transduction.

**Guidelines**

National Comprehensive Cancer Network (NCCN) guidelines for basal cell carcinoma (version 1.2020 – October 24, 2019) note that surgical approaches offer the most effective and efficient means for accomplishing a cure;
radiation therapy may be chosen as the primary treatment in order to achieve optimal overall results.² For residual disease when surgery and radiation therapy are contraindicated and for recurrent disease with nodal or distant metastases, a hedgehog pathway inhibitor should be considered.

For central nervous system cancers, NCCN guidelines (version 3.2019 – September 11, 2020) list Erivedge as a treatment option for certain patients with recurrent disease, if chemotherapy has been tried and if there is a mutation of the sonic hedgehog pathway.

References


Last Revision Details

| Annual Revision | Basal Cell Carcinoma, Locally Advanced: For the criterion applying to a patient who is not a candidate for radiation therapy, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). | 11/04/2020 |

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