VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erivedge Prior Authorization Policy
- Erivedge® (vismodegib capsules – Genentech/Roche)

REVIEW DATE: 12/01/2021

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.[1]

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines address Erivedge.

- **Basal Cell Carcinoma:** Guidelines (version 1.2022 – November 17, 2021) 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] When surgery and radiation therapy are contraindicated and for recurrent disease with nodal or distant metastases, a hedgehog pathway inhibitor is among the treatment options.
- **Central Nervous System Cancers:** Guidelines (version 2.2021 – September 8, 2021) list Erivedge as a treatment option for ceratin patients with recurrent disease, if chemotherapy has been tried and if there is a mutation of the sonic hedgehog pathway.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Basal Cell Carcinoma, Locally Advanced.** Approve for 3 years if the patients meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets one of the following (a or b):
       - **a)** Patient has recurrent basal cell carcinoma following surgery or radiation therapy; OR
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient is not a candidate for surgery; AND
         - **(2)** According to the prescriber, the patient is not a candidate for radiation therapy.
   - **B)** Patient is Currently Receiving Erivedge. Approve.

2. **Basal Cell Carcinoma, Metastatic.** Approve for 3 years if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

3. **Central Nervous System Cancer.** Approve for 3 years if the patient meets ALL of the following (A, B, and C):
   Note: This includes brain and spinal cord tumors.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one chemotherapy agent; AND
   Note: Examples of chemotherapy include etoposide, carboplatin, cisplatin.
   C) According to the prescriber, the patient has a mutation of the sonic hedgehog pathway.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Erivedge is not recommended in the following situations:

1. **Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Odomzo® (sonidegib capsules).** Note: This does not apply to a patient already started on Erivedge. Refer to criteria for basal cell carcinoma, Locally Advanced for a Patient Currently Receiving Erivedge. There are no data to support the use of Erivedge in patients who have experienced disease progression on Odomzo. Previous use of a hedgehog inhibitor was not allowed in the pivotal study for Odomzo.[3] Patients 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 patients (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.[7]

2. **Metastatic Colorectal Cancer.** Erivedge is not recognized in the treatment recommendations for colon cancer from the NCCN (version 3.2021 – September 10, 2021).[4] 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 patients requiring first-line treatment for metastatic colorectal cancer.[3] Adults with histologically confirmed disease were randomized 1:1 to Erivedge or placebo (n = 199). There was not a significant difference is median PFS or 12-month survival with Erivedge vs. placebo.

3. **Ovarian Cancer.** The NCCN guidelines for Ovarian Cancer (version 3.2021 – September 9, 2021) do not address the use of Erivedge for the management of ovarian cancer.[6] 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.[5] Eligible patients 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.
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Erivedge® capsules [prescribing information]. South San Francisco, CA: Genentech/Roche; July 2020.

2. The NCCN Basal Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – November 17, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 24, 2021.
3. Berlin JD, Bendell JC, Hart LL, et al. A randomized Phase II trial of vismodegib versus placebo with FOLFOX or FOLFIRI and bevacizumab in patients with previously untreated metastatic colorectal cancer. *Clin Cancer Res*. 2013;19(1):258-267.
4. NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2021 – September 10, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on Novmeber 26, 2021.
5. Kaye SB, Fehrenbacher L, Holloway R, et al. A Phase II, randomized, placebo-controlled study of vismodegib as maintenance therapy in patients with ovarian cancer in second or third complete remission. *Clin Cancer Res*. 2012;18(23):6509-6518.
6. NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 3.2021 – September 9, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 26, 2021.
7. Danial C, Sarin KY, Oro AE, Chang AL. An investigator-initiated open-label trial of sonidegib in advanced basal cell carcinoma patients resistant to vismodegib. *Clin Cancer Res*. 2016;22(6):1325-1329.
8. NCCN Central Nervous System Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 24, 2021.