sonidegib (Odomzo®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO153

Description

Sonidegib (Odomzo) is an orally administered Hedgehog pathway inhibitor.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
sonidegib (Odomzo)	200 mg capsule	Basal cell carcinoma of the skin, locally advanced	30 capsules/30 days

Initial Evaluation

I. Sonidegib (Odomzo) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, an oncologist or dermatologist; **AND**
   C. Sonidegib (Odomzo) will not be used in combination with any other oncologic medication; **AND**
   D. A diagnosis of **locally advanced basal cell carcinoma (BCC)** when the following are met:
      1. Basal cell carcinoma has recurred or progressed after radiation or surgery, unless both are contraindicated; **AND**
      2. The member has not progressed on any other oncologic medication (e.g., has not progressed on vismodegib [Erivedge]); **AND**
      3. Provider attestation that the member, either male or female, has been counseled on the teratogenicity and embryo-fetal toxicity risks with sonidegib (Odomzo).

II. Sonidegib (Odomzo) is considered investigational when used for all other conditions, including but not limited to:
   A. Metastatic basal cell carcinoma
   B. Acute leukemia
   C. Breast cancer
   D. Medulloblastoma
   E. Multiple myeloma
   F. Myelofibrosis
   G. Prostate cancer
   H. Breast cancer
   I. Ovarian cancer

J. Graft versus host disease
K. Pancreatic cancer
L. Lung cancer
M. Hepatocellular carcinoma

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Sonidegib (Odomzo) is prescribed by, or in consultation with, an oncologist or dermatologist; **AND**
IV. A diagnosis of **locally advanced basal cell carcinoma**; **AND**
    A. Clinical response to therapy, such as improvement or stabilization of disease, or decrease or stabilization of tumor size or spread; **AND**
    B. Provider attestation that the member, either male or female, has been counseled on the teratogenicity and embryo-fetal toxicity risks with sonidegib (Odomzo).

Supporting Evidence

I. The safety and efficacy of sonidegib (Odomzo) was evaluated in a single, double-blind, single-drug trial. Those included had a diagnosis of locally advanced basal cell carcinoma (laBCC), and 144 adult subjects were randomized (2:1) to receive sonidegib (Odomzo) 800 mg or 200 mg daily. To be included in the trial, subjects were required to have lesions for which radiotherapy was contraindicated or inappropriate (e.g., limitations due to tumor location), that had recurred after radiotherapy, had unresectable disease in which surgical resection would result in substantial deformity, or that had recurred after prior surgical resection. The primary outcome was objective response rate (ORR) which was determined by a blinded central review committee according to the modified Response Evaluation Criteria in Solid Tumors (mRECIST). A secondary measure was duration of response (DoR). The ORR was 56% (CI 43-68), and consisted of three (5%) complete responders, and 34 (52%) partial responders. The median duration of response was 26.1%; however, due to the single-drug nature of the trial, these results should be interpreted with caution.
II. There were 128 subjects randomized to sonidegib (Odomzo) 800 mg daily. There was a lack of further benefit over the 200 mg dose relative to the safety profile.
III. Sonidegib (Odomzo) carries a black box warning for embryo-fetal death or severe birth defects when administered to a pregnant woman. It is noted in the medication label that pregnancy be ruled out prior to initiating therapy. Those of reproductive potential should use contraception during treatment and for at least 20 months following the last dose. Males carry of risk of exposure through semen; thus, the package label recommends use of condoms with female partners during medication exposure and for at least eight months after the last dose.

IV. Vismodegib (Erivedge) is FDA-approved for adults with metastatic and locally advanced basal cell carcinoma. Erivedge has an overlapping indication with sonidegib (Odomzo), and if disease progression has occurred on or after one of these therapies, there is currently insufficient evidence regarding safety and/or efficacy of the other. One published piece of literature evaluated sonidegib (Odomzo) in those that were resistant to vismodegib (Erivedge); however, this trial included only nine subjects all of which showed no response to sonidegib (Odomzo) or were not evaluable for safety and/or efficacy. Available evidence disfavors use of sequential Hedgehog pathway inhibitors.

Investigational or Not Medically Necessary Uses

I. There is currently insufficient evidence to support safety and/or efficacy of sonidegib (Odomzo) in the following settings:
   A. Metastatic basal cell carcinoma
   B. Acute leukemia
   C. Breast cancer
   D. Medulloblastoma
   E. Multiple myeloma
   F. Myelofibrosis
   G. Prostate cancer
   H. Breast cancer
   I. Ovarian cancer
   J. Graft versus host disease
   K. Pancreatic cancer
   L. Lung cancer
   M. Hepatocellular carcinoma

References

1. Odomzo [Package Insert]. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. 2017.
2. Burness CB, Scott LJ. Sonidegib: A Review in Locally Advanced Basal Cell Carcinoma. Target Oncol. 2016;11(2):239-46.
3. Danial C., Sarin K. Oro A., et al. An investigator-initiated open-label trial of sonidegib in advanced basal cell carcinoma patients resistant to vismodegib. Clin Cancer Res. 2016;22: 1325-1329.

Policy Implementation/Update:

Date Created	October 2015
Date Effective	November 2015
Last Updated	November 2019
Last Reviewed	November 2019

Action and Summary of Changes	Date

Prior authorization transitioned to policy. Addition of age edit, clarification and addition of requirements regarding previous therapies and use of sonidegib (Odomzo) monotherapy. Renewal duration increased for six to 12 months.	11/2019