



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/1/2016
LAST REVIEW DATE: 11/18/2021
LAST CRITERIA REVISION DATE: 11/18/2021
ARCHIVE DATE:

ODOMZO® (sonidegib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



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Criteria:

- **Criteria for initial therapy:** Odomzo (sonidegib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Dermatologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. Locally advanced basal cell carcinoma (laBCC) that has recurred following surgery **OR** radiation therapy **OR** the individual is not a candidate for surgery or radiation
 - b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Negative pregnancy testing in a woman of childbearing age
 - b. Serum creatine kinase (CK)
 - c. Serum creatinine
 - d. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1
 5. Will not be used with strong or moderate CYP3A inducers such as carbamazepine, efavirenz, modafinil, phenobarbital, phenytoin, rifabutin, rifampin, and St. John's wort
 6. Will not be used with strong CYP3A inhibitors such as saquinavir, ketoconazole, itraconazole, voriconazole, posaconazole, and nefazodone

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Odomzo (sonidegib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Dermatologist
 2. Individual's condition has not worsened while on therapy
 - a. Worsening is defined as:
 - i. Disease progression
 - ii. There is no evidence of efficacy, disease stability and/or improvement



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3. Individual has been adherent with the medication
4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
 - a. Significant adverse effect such as:
 - i. Musculoskeletal toxicity
 - ii. Rhabdomyolysis
 - iii. Will not be used with serum CK elevation greater than 2.5 times upper limit of normal with worsening renal function
 - iv. Will not be used with serum CK elevation greater than 10 times upper limit of normal
 - v. Will not be used with recurrent serum CK elevation greater than 5 times upper limit of normal
 - vi. Will not be used with recurrent severe or intolerable musculoskeletal adverse reactions
5. There are no significant interacting drugs

Renewal duration: 12 months

➤ Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Odomzo (sonidegib) is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

Odomzo (sonidegib) is a Smoothened (SMO) antagonist which inhibits the hedgehog (Hh) signaling pathway. Sonidegib binds to and inhibits Smoothened, a transmembrane protein involved in Hh signal transduction and activation of the cascade. Hh plays an important role in embryonic growth and has been implicated as a growth stimulus for various cancers, where activation of the pathway significantly accelerates tumor growth. Activation of Hh has been implicated in the development of basal cell carcinoma.

Basal cell carcinoma (BCC):

- Skin cancer is the most common cancer and basal cell carcinoma (BCC) accounts for approximately 80 percent of non-melanoma skin cancers
- BCC starts in the top layer of the skin (the epidermis) and usually develops in areas that have been regularly exposed to the sun and other forms of ultraviolet radiation

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- Approximately 70-80% of BCC occurs on the head, face, and neck
 - Between 1-10% of BCC becomes locally advanced (laBCC) or metastatic (mBCC)
 - Metastasis is very rare and occurs in less than 1% of all BCC cases
- The selection of a treatment for BCC depends on factors such as the location, depth, stage, and size of the tumor
- The goal of treatment of BCC is to cure the tumor and to preserve function and cosmesis
 - Surgical approaches are typically the most effective means of treatment
 - Various surgical techniques used for the majority of BCCs are generally curative
 - Superficial lesions may be treated with topical therapies
 - The care for BCC that has not progressed is surgical resection, radiation therapy, topical imiquimod, and topical fluorouracil
 - The vast majority of patients can be successfully managed with cryotherapy, curettage and electrodesiccation, topical treatments (5-fluorouracil, imiquimod), or simple surgical excision
- Locally advanced basal cell skin cancer refers to basal cancers that have not spread to other parts of the body
- With more advanced lesions, Mohs micrographic surgery, more extensive surgical resection, or radiation therapy may be required for locoregional disease
- When BCC advances, systemic therapy may be needed
- The use of systemic therapy is limited to patients with distant metastases or locally advanced disease that cannot be adequately managed with surgical or radiotherapeutic techniques
- In patients with laBCC or mBCC, systemic therapies, such as Hedgehog pathway inhibitors [sonidegib (Odomzo) and vismodegib (Erivedge)], may be therapeutic options
- Hedgehog pathway inhibitors, include Odomzo (sonidegib) and Erivedge (vismodegib)
 - Patients that experienced treatment resistance to Erivedge (vismodegib) have been shown to have the same resistance to Odomzo (sonidegib)

Resources:

Odomzo (sonidegib) product information, revised by Sun Pharmaceutical Industries, Inc. 05-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed August 27, 2021

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Basal Cell Skin Cancer Version 2.2021 – February 25, 2021. Available at <https://www.nccn.org>. Accessed August 27, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.



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Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.
