BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

ODOMZO® (sonidegib)
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Odomzo (sonidegib) and/or generic equivalent (if available) 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. Individual has 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

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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. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual 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. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual is not currently taking any other drugs which cause severe adverse reactions or any drug interactions requiring discontinuation such as:
   a. Strong or moderate CYP3A inducers (e.g., carbamazepine, efavirenz, modafinil, phenobarbital, phenytoin, rifabutin, rifampin, and St. John's wort, others)
   b. Strong CYP3A inhibitors (e.g., saquinavir, ketoconazole, itraconazole, voriconazole, posaconazole, and nefazodone, others)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Odomzo (sonidegib) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

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 responded while on therapy with response defined as there is documented evidence of efficacy, disease stability and/or improvement

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
   a. Musculoskeletal toxicity such as muscle pain or spasm, tenderness or weakness
   b. Rhabdomyolysis (defined as serum CK increase of more than 10 times the baseline value) with a concurrent 1.5-fold or greater increase in serum creatinine above baseline value
   c. Will not be used with serum CK elevation greater than 2.5 times upper limit of normal with worsening renal function

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d. Will not be used with serum CK elevation greater than 10 times upper limit of normal
e. Will not be used with recurrent serum CK elevation greater than 5 times upper limit of normal
f. Will not be used with recurrent severe or intolerable musculoskeletal adverse reactions

6. Individual is not currently taking any other drugs which cause severe adverse reactions or any drug interactions requiring discontinuation such as:
   a. Strong or moderate CYP3A inducers (e.g., carbamazepine, efavirenz, modafinil, phenobarbital, phenytoin, rifabutin, rifampin, and St. John's wort, others)
   b. Strong CYP3A inhibitors (e.g., saquinavir, ketoconazole, itraconazole, voriconazole, posaconazole, and nefazodone, others)

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 Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

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.

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. 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 cure of 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-

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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. Patients that experienced treatment resistance to Erivedge (vismodegib) have been shown to have the same resistance to Odomzo (sonidegib).

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:

Category 1:
Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:
Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:
Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:
Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

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Resources:

Odomzo (sonidegib) product information, revised by Sun Pharmaceutical Industries, Inc. 08-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 15, 2024.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Basal Cell Skin Cancer Version 3.2024 – Updated March 01, 2024. Available at https://www.nccn.org. Accessed October 15, 2024.

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

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

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