BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 1/01/16**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE: 11/16/17
	ARCHIVE DATE:

ODOMZO® (sonidegib) oral capsule

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.

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.**

ODOMZO® (sonidegib) oral capsule (cont.)

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
- 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

ODOMZO® (sonidegib) oral capsule (cont.)

- 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)

Odomzo (sonidegib)

Medication class:
Antineoplastic agent, hedgehog pathway inhibitor

FDA-approved indication(s):
- Treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy

Recommended Dose:
- 200 mg once daily

Maximum dosage
- Not stated

Available Dosage Forms:
- 200 mg capsules

Warnings, Precautions, and other Clinical Information:
- Interrupt Odomzo for severe or intolerable musculoskeletal adverse reactions, restart upon resolution of signs and symptoms
- Permanently discontinue for recurrence of severe or intolerable musculoskeletal adverse reactions
- Interrupt for first occurrence of serum CK elevation between 2.5-10x ULN, restart upon resolution of signs and symptoms
- Interrupt for recurrent serum CK elevation between 2.5-5x ULN, restart upon resolution of signs and symptoms
- Permanently discontinue for serum CK elevation > 2.5x ULN with worsening renal function
- Permanently discontinue for serum CK elevation > 10x ULN
- Permanently discontinue with recurrent serum CK > 5x ULN
- Less than 10% of an oral dose is absorbed
- Avoid strong and moderate CYP3A inducers such as carbamazepine, efavirenz, modafinil, phenobarbital, phenytoin, rifabutin, rifampin, and St. John's wort
- Avoid strong CYP3A inhibitors such as saquinavir, ketoconazole, itraconaxole, voriconazole, posaconazole, and nefazodone
- Avoid long term (> 14 days) use of moderate CYP3A inhibitors
- Verify pregnancy status of a woman of child bearing potential prior to starting Odomzo
- Woman of child bearing age should use effective contraception
- Woman who is breast feeding an infant or child should stop breast feeding

ODOMZO® (sonidegib) oral capsule (cont.)

- Male, even if vasectomized, on Odomzo should use condoms with female partners of reproductive potential

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 an Oncologist or Dermatologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of locally advanced basal cell carcinoma (laBCC) **and ONE** of the following:
     - laBCC has recurred following surgery or radiation therapy
     - Individual is not a candidate for surgery or radiation therapy

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Pregnancy testing in a woman of child bearing age
     - Serum creatinine kinase (CK)

  5. There are **NO** contraindications:
     - Contraindications include:
       - Serum CK elevation greater than 2.5 times upper limit of normal with worsening renal function
       - Serum CK elevation greater than 10 times upper limit of normal
       - Recurrent serum CK elevation greater than 5 times upper limit of normal
       - Recurrent severe or intolerable musculoskeletal adverse reactions

  Initial approval duration: 6 months with initial fills of 14 days per fill for first 3 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 an Oncologist or Dermatologist

  2. Individual's condition has not worsened while on therapy
     - Worsening is defined as:
       - Progressive disease while on Odomzo

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use such as:
     - Musculoskeletal toxicity

ODOMZO® (sonidegib) oral capsule (cont.)

- Signs and symptoms may include:
  - Muscle spasms, musculoskeletal pain, myalgia, increased serum CK, dark urine, decreased amount of urine, rhabdomyolysis

5. There are no significant interacting drugs

Renewal duration: 12 months

Resources:

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.

Odomzo. Package Insert. Revised by manufacturer 07/2015. Accessed 10-02-2015.

Odomzo. Package Insert. Revised by manufacturer 05/2016. Accessed 10-20-2016

NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer. Version 1.2018, Sep 18, 2017. https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

UpToDate: Epidemiology, pathogenesis, and clinical features of basal cell carcinoma. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/epidemiology-pathogenesis-and-clinical-features-of-basal-cell-carcinoma?source=search_result&search=basal%20cell%20carcinoma&selectedTitle=1~150

UpToDate: Treatment and prognosis of basal cell carcinoma at low risk for recurrence. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-and-prognosis-of-basal-cell-carcinoma-at-low-risk-of-recurrence?source=search_result&search=basal%20cell%20carcinoma&selectedTitle=2~150

UpToDate: Treatment of basal cell carcinoma at high risk for recurrence. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-basal-cell-carcinomas-at-high-risk-for-recurrence?source=search_result&search=basal%20cell%20carcinoma&selectedTitle=3~150

UpToDate: Systemic treatment of advanced cutaneous squamous and basal cell carcinoma. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/systemic-treatment-of-advanced-cutaneous-squamous-and-basal-cell-carcinomas?source=see_link

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.