VERSION 1, JULY 2020

# ODOMZO SUPPORT™
## Patient Assistance Program (PAP)

Odomzo® (sonidegib) capsules 200mg

## APPLICATION

ODOMZO SUPPORT™ will initiate a benefits investigation (BI) of your patient's insurance coverage for ODOMZO®. If applicable, ODOMZO SUPPORT™ will research eligibility for the ODOMZO SUPPORT™ PAP for non-insured, functionally uninsured, and underinsured patients. If eligible, ODOMZO SUPPORT™ will help with this PAP application.

To get your patients started, prescribers are required to complete this form in its entirety with their patient, as well as **sign** and **fax** the form and any supporting documents to the ODOMZO SUPPORT™ PAP at **1-877-872-6575** or mail to **PO Box 29051, Phoenix, AZ 85038-9051**.

***Please see page 3 for eligibility guidelines.***

**For more information about the ODOMZO SUPPORT™ PAP, call 1-844-5-ODOMZO (1-844-563-6696) Monday - Friday, 8 AM - 8 PM EST.**

### INDICATION

ODOMZO® (sonidegib) is indicated for the 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.

### IMPORTANT SAFETY INFORMATION

**WARNING: EMBRYO-FETAL TOXICITY**

- ODOMZO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. ODOMZO is embryotoxic, fetotoxic, and teratogenic in animals
- Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females of reproductive potential to use effective contraception during treatment with ODOMZO and for at least 20 months after the last dose
- Advise males of the potential risk of exposure through semen and to use condoms with a pregnant partner ora female partner of reproductive potential during treatment with ODOMZO and for at least 8 months after the last dose

**Embryo-fetal Toxicity:** ODOMZO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Females of Reproductive Potential: Verify pregnancy status prior to initiating ODOMZO. Advise females to use effective contraception and not to breastfeed, due to the potential for serious adverse reactions in breastfed infants, during treatment and for at least 20 months after the last dose. Report pregnancies to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

Males: Advise males to use condoms, even after a vasectomy, and to not donate semen during treatment and for at least 8 months after the last dose to avoid potential drug exposure in pregnant females or females of reproductive potential.

Blood Donation: Advise patients not to donate blood or blood products while taking ODOMZO, and for at least 20 months after the last dose because their blood or blood products might be given to a female of reproductive potential.

**Please see additional Important Safety Information on pages 2 and 3 and click for full Prescribing Information, including BOXED WARNING.**

VERSION 1, JULY 2020

# How to apply for the ODOMZO SUPPORT™ PAP

Odomzo® (sonidegib) capsules 200mg

**1 Complete** this form in its entirety with your patient.

**2 Sign and date** the form.

*IMPORTANT:*
*Wet signatures are required from both the patient and the prescriber. Once you've completed the digital form, please print to complete the wet signature portion (1 from patient, 2 from prescriber).*

**3 Fax the completed, signed form** with the appropriate supporting information to 1-877-872-6575, or mail to PO Box 29051, Phoenix, AZ 85038-9051, based on the following patient insurer status:

**NO INSURANCE:** Fax the completed, signed form and proof of income.

**FINANCIAL HARDSHIPS:** Fax the completed, signed form, proof of income, and supporting documentation explaining changes in circumstances (eg, loss of employment, change in marital status).

**PREVIOUS APPROVAL OR DENIAL:** If there is already a prior authorization (PA) or insurance appeals approval or denial, please include in the fax. If a PA is required for the Sun Pharma product requested, you will need to provide the PA number and date of approval or attach a copy of the denial letter. If this is a renewal, you will need to process and submit a new PA. If this information is not received with the healthcare provider section of this application, there may be a delay in processing for your patient.

*IMPORTANT: Proof of income should be in the form of 1) the previous year's federal income tax returns for the patient, spouse, and dependents; 2) all income statements from the patient's employer (W2 or 1099); or 3) the patient's Social Security Income Yearly Benefits Statement.*

## What to expect after applying

Once the application is received, an ODOMZO SUPPORT™ customer service representative will conduct a BI to help better understand your patient's coverage and the costs associated with ODOMZO® treatment. Providing complete and accurate information will ensure a timely response to your request.

**Once the BI is completed, ODOMZO SUPPORT™ will:**

- **FOLLOW UP** with the provider and payer to make sure that the PA is submitted and approved

  **NOTE:** If the PA is denied, the customer service representative will send the appeal requirements to the provider and follow up at a later time
- **PROCESS** the outcome of the BI and evaluate your patient's eligibility
- **RESEARCH ELIGIBILITY** for the ODOMZO SUPPORT™ PAP, if applicable, for non-insured, functionally uninsured, and underinsured patients. If eligible, ODOMZO SUPPORT™ will help with this PAP application

## IMPORTANT SAFETY INFORMATION (cont'd)

**Musculoskeletal Adverse Reactions:** Musculoskeletal adverse reactions, which may be accompanied by serum creatine kinase (CK) elevations, occur with ODOMZO and other drugs which inhibit the hedgehog (Hh) pathway. Obtain serum CK and creatinine levels prior to initiating therapy, periodically during treatment, and as clinically indicated. Temporary dose interruption or discontinuation of ODOMZO may be required based on the severity of musculoskeletal adverse reactions.

**Premature Fusion of the Epiphyses:** ODOMZO is not indicated for use in pediatric patients. Premature fusion of the epiphyses has been reported in pediatric patients exposed to ODOMZO and other Hh pathway inhibitors. In some cases, fusion progressed after discontinuation.

**Drug Interactions:** Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, administer for less than 14 days and monitor closely for adverse reactions, particularly musculoskeletal. Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inducers.

**Please see additional Important Safety Information on pages 1 and 3 and click for full Prescribing Information, including BOXED WARNING.**

# Eligibility guidelines

Odomzo® (sonidegib) capsules 200mg

Eligibility is subject to each patient's current status. Eligibility reverification will be completed on a case-by-case basis, based on each patient's insurance. For patients with government insurance, eligibility reverification occurs at the start of the calendar year (January 1). Uninsured patients and commercially insured patients must have eligibility reverified 12 months after the original date of the application. Eligibility guidelines are subject to change. Sun Pharma reserves the right to change, rescind, or revoke its Patient Assistance Program at any time.

**Patients may qualify for the ODOMZO SUPPORT™ PAP if the following guidelines are met:**

## Non-insured patients

- Residency in the United States, Puerto Rico, Guam, or Virgin Islands
- Insurance coverage is terminated, or the patient has no insurance (commercial or government insurance such as Medicare/ Medicaid)
- Income at or below 400% of the federal poverty level (FPL), or a hardship exception (between 400% and 425%) and cost of drug that is greater than 10% of the patient's annual household income
- Diagnosis is an on-label ICD-10-CM code
- At least 18 years of age

## Underinsured patients

- Residency in the United States, Puerto Rico, Guam, or Virgin Islands
- Commercial insurance coverage identified, but the patient cannot afford out-of-pocket costs
- Income at or below 400% of the FPL, or a hardship exception (between 400% and 425%) and cost of drug that is greater than 10% of the patient's annual household income
- Diagnosis is an on-label ICD-10-CM code
- At least 18 years of age

## Functionally uninsured patients

- Residency in the United States, Puerto Rico, Guam, or Virgin Islands
- Insurance does not cover ODOMZO®, no prescription coverage, emergency only, discount card only, exceeded yearly cap, generic coverage only, product not on formulary (no non-formulary exception available or non-formulary exception not approved)
- Income at or below 400% of the FPL, or a hardship exception (between 400% and 425%) and cost of drug that is greater than 10% of the patient's annual household income
- Diagnosis is an on-label ICD-10-CM code
- At least 18 years of age

To start the application process for your patient, please **complete, sign, and fax** pages 4 and 5 of this form to **1-877-872-6575**

OR

**Mail to:**
PO Box 29051
Phoenix, AZ 85038-9051

**For more information about the ODOMZO SUPPORT™ PAP, call 1-844-5-ODOMZO (1-844-563-6696) Monday - Friday, 8 AM - 8 PM EST.**

## IMPORTANT SAFETY INFORMATION (cont'd)

**Geriatric Use:** There was a higher incidence of serious adverse events, Grade 3 and 4, and events requiring dose interruption or discontinuation in patients ≥65 years compared with younger patients; this was not attributable to an increase in any specific adverse event.

**Most Common Adverse Reactions:** The most common adverse reactions occurring in ≥10% of patients were muscle spasms (54%), alopecia (53%), dysgeusia (46%), fatigue (41%), nausea (39%), musculoskeletal pain (32%), diarrhea (32%), decreased weight (30%), decreased appetite (23%), myalgia (19%), abdominal pain (18%), headache (15%), pain (14%), vomiting (11%), and pruritus (10%).

**Please see additional Important Safety Information on pages 1 and 2 and click for full Prescribing Information, including BOXED WARNING.**

# ODOMZO SUPPORT™
## Patient Assistance Program

Please complete this form in its entirety. Once completed, please print, sign, and fax to the ODOMZO SUPPORT™ Patient Assistance Program at 1-877-872-6575 or mail to PO Box 29051, Phoenix, AZ 85038-9051. If you have any questions on the application process, please call 1-844-5-ODOMZO (1-844-563-6696) Monday - Friday, 8 AM - 8 PM EST.

Odomzo® (sonidegib) capsules 200mg

## PATIENT INFORMATION

○ NEW PATIENT APPLICATION ○ PATIENT REAPPLICATION

First name | Middle initial | Last name | Date of birth (MM/DD/YYYY)

Address | City/State | ZIP code

Phone number

**GENDER:** ○ Male ○ Female ○ Prefer not to say

Previous treatment history, if any

## INCOME

**NOTE:** You (the patient) will need to provide proof of household income. Please be sure to fax proof of income with this form.

Number of people in the household (yourself, your spouse, and any dependents)

Total combined **monthly** household income (yourself, your spouse, and any dependents)

Total combined **annual** household income (yourself, your spouse, and any dependents)

## INSURANCE INFORMATION

**PLEASE CHECK ONE:**

○ No insurance coverage

○ **PREFERRED:** Copy of the policyholder's insurance card(s) (front and back) is attached (include all insurance cards: commercial, Medicare, and/or secondary insurance and prescription card)

○ Complete the insurance information below (if you cannot copy the policyholder's insurance card[s])

Primary insurance | Policy holder

Insurance phone # | Policy ID

Group # | Rx BIN | PCN

## PATIENT ATTESTATION AND HIPAA AUTHORIZATION FOR RELEASE OF INFORMATION

By signing this form, I give permission for my health care providers (HCPs), my pharmacies, my health insurer(s), and third-party contractors or service providers acting on their behalf ("Health Care Entities") to disclose my personal information, including information about my insurance, prescriptions, medical condition, and health ("Personal Information") to Sun Pharmaceutical Industries, Inc., its affiliates, business partners, service providers, third-party contractors, and agents (together, "Sun Pharma") so that Sun Pharma can (1) help to verify or coordinate insurance coverage or otherwise obtain payment for my treatment with the Sun Pharma Oncology medication prescribed by the HCP on the Service Request Form; (2) coordinate my receipt of and payment for the Sun Pharma Oncology medication prescribed by the HCP on this Service Request Form; (3) facilitate my access to the Sun Pharma Oncology medication prescribed by the HCP on this Service Request Form; (4) provide me with information about the Sun Pharma Oncology medication prescribed by the HCP on this Service Request Form, disease awareness and management programs, and educational materials; and (5) manage the Patient Assistance Program.

I understand that once my Personal Information is disclosed to Sun Pharma, it may no longer be protected by federal privacy law. I understand that I may refuse to sign this Authorization. I also may revoke (withdraw) this Authorization at any time in the future by calling 1-844-5-ODOMZO (1-844-563-6696). My refusal or future revocation will not affect the commencement or continuation of my treatment by my doctor(s), my eligibility for, enrollment in, or payment of benefits from my health plan(s); however, if I revoke this Authorization, I may no longer be eligible to participate in the Patient Assistance Program. If I revoke this Authorization, my Health Care Entities will stop using or sharing my information as authorized in this Authorization once they receive notification of my revocation; but my revocation will not affect uses and disclosures of my Personal Information previously disclosed in reliance upon this Authorization by them before they receive notification of my revocation. I understand that this Authorization will remain valid for one (1) year after the date of my signature, unless I revoke it earlier or it ends earlier under applicable law. I understand I am entitled to receive a copy of this Authorization after I sign it.

Patient signature | Printed name | Date (MM/DD/YYYY) | Personal rep signature | Printed name | Date (MM/DD/YYYY)

**I ACKNOWLEDGE THAT I HAVE READ AND AGREE TO THE PATIENT HIPAA AUTHORIZATION ABOVE.**

Patient signature | Printed name | Date (MM/DD/YYYY) | Personal rep signature | Printed name | Date (MM/DD/YYYY)

## PRESCRIBER INFORMATION

Prescriber's name | NPI #

Phone number | Fax

Address

City | State | ZIP code

## ODOMZO® PRESCRIPTION INFORMATION

| | *Basal cell carcinoma of skin of nose* | *Basal cell carcinoma of skin, unspecified* | *Basal cell carcinoma of skin of scalp and neck* | *Basal cell carcinoma of skin of other parts of face* | |
|---|---|---|---|---|---|
| **PRIMARY ICD-10-CM DIAGNOSIS CODE(S)** (check all that apply) | ☐ C44.311 | ☐ C44.91 | ☐ C44.41 | ☐ C44.319 | ☐ Other |
| **SECONDARY ICD-10-CM DIAGNOSIS CODE(S)** (check all that apply) | ☐ C44.311 | ☐ C44.91 | ☐ C44.41 | ☐ C44.319 | ☐ Other |

### PRESCRIBED DOSE

◯ ODOMZO® (sonidegib) 200 mg tablet

Please attach your prescription if this form does not comply with your state laws.

### DIRECTIONS

One dose of ODOMZO® 200 mg daily, on an empty stomach, at least 1 hour before or 2 hours after a meal.

Quantity | Days' supply | Refills

**Has the patient previously been treated with Erivedge® (vismodegib):** ◯ Yes ◯ No

Prescriber signature (wet signature required) | Print prescriber name | Date (MM/DD/YYYY)

◯ **DISPENSE AS WRITTEN**

## PRESCRIBER ATTESTATION AND SIGNATURE

Sun Pharmaceutical Industries, Inc., its affiliates, business partners, service providers, third-party contractors, and agents (together, "Sun Pharma") will use the information you provide to administer and improve the ODOMZO SUPPORT™ Patient Assistance Program (the "Program"). By signing this form, I (the prescriber) understand and agree that:

- I certify that the patient and physician information obtained in this application is complete and accurate to the best of my knowledge
- I have prescribed ODOMZO® based on my professional judgment of medical necessity
- Any medications supplied by Sun Pharma as a result of this form are for use by the named patient only and shall not be sold, traded, bartered, transferred, returned for credit, or submitted to any third-party payer (private or government) for reimbursement
- Sun Pharma may modify or terminate the Program at any time without notice
- I have received the necessary legal authorization from the patient to transmit the patient's personal health information, for the purposes provided on this form, to Sun Pharma
- I authorize the Program to transmit prescribing information to a third party(ies) to dispense the drug above to this patient
- My patient has provided a signed HIPAA Authorization that allows me to share protected health information with Sun Pharma for purposes of this Program
- The Program may contact me for additional information relating to the Program, including but not limited to via email, fax, telephone, and text

I understand that the Program is designed to support patients who are experiencing a delay in obtaining insurance coverage for ODOMZO® for up to 2 years or until such coverage is secured. I confirm that I will support the above-identified patient in seeking to secure such coverage as I deem appropriate. I understand that neither I nor the patient may seek reimbursement for free product received under the Program.

Prescriber signature (wet signature required) | Print prescriber name | Date (MM/DD/YYYY)

**Please click for full Prescribing Information, including BOXED WARNING.**

SUN PHARMA


PM-US-ODZ-0303 08/2020

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