Authorization & Appeals Kit

Supporting Patient Access to ODOMZO® (sonidegib)

Sun Pharmaceutical Industries, Inc. cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

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.

SELECT 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 or a female partner of reproductive potential during treatment with ODOMZO and for at least 8 months after the last dose**

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Resource Overview

This kit has been created to provide information and sample letters that can be used to help you communicate with health plans about prior authorization (PA) or appeal issues related to ODOMZO® (sonidegib).

This kit includes:

Checklists to help ensure you have provided all necessary information

Sample letters with information that will usually be required

Table of Contents

Clinical Considerations for ODOMZO® (sonidegib)

The pivotal BOLT* trial evaluated the long-term efficacy and safety of ODOMZO[1,2]

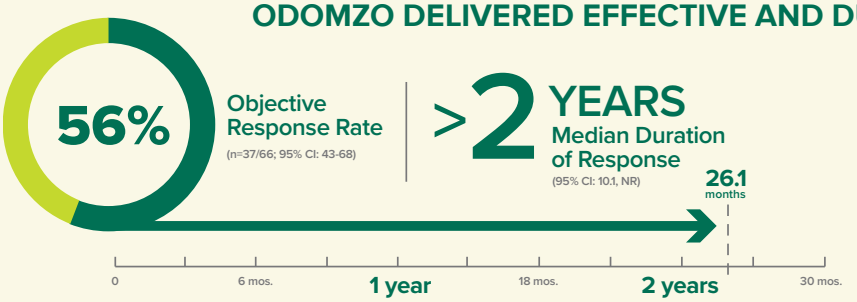
A multicenter (58 centers, 12 countries), randomized, double-blind, phase 2 study evaluating once-daily dosing of ODOMZO in 194 patients with locally advanced basal cell carcinoma (laBCC). Patients were randomized 1:2 to the 200 mg or 800 mg dose once daily, until disease progression or intolerable toxicity. Patients were treated with ODOMZO for a median duration of 11 months (range 1.3 to 33.5 months).[1,2]

Primary end point: Objective Response Rate (ORR), defined as best overall confirmed response of Complete Response (CR) or Partial Response (PR) per central review according to mRECIST criteria[1,2]

Key secondary end point: duration of response (DoR), defined as the time from tumor response to disease progression[1,2]

ODOMZO is the only hedgehog pathway inhibitor (HHI) proven to provide more than 2 years of tumor response in patients with laBCC[1,2]

ODOMZO DELIVERED EFFECTIVE AND DURABLE RESULTS[1,2]



The only HHI with **42 MONTHS** of centrally reviewed data[3]

ORR: CR of 5%, n=3 + PR of 52%, n=34. CR is defined as ≥2 negative biopsies (fresh tumor biopsy specimens were required to confirm a CR) and complete disappearance of target lesions by photography assessment and per MRI. PR is defined as ≥50% decrease in the sum of the product of perpendicular diameters (SPD) of the lesions by photography assessment and 30% decrease in the sum of diameters of lesions per MRI[1,2,4]

DoR: At the 30-month data analysis, the median DoR was 26.1 months[1]

Greater than 90% of the most common adverse reactions (ARs) were mild (Grade 1) or moderate (Grade 2)[1,2†]

The most common ARs occurring in ≥10% of patients receiving ODOMZO 200 mg (n=79) are muscle spasms, alopecia, dysgeusia, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight, decreased appetite, myalgia, abdominal pain, headache, pain, vomiting, and pruritus

*BOLT=Basal Cell Carcinoma Outcomes with LDE225 Treatment. LDE225 was the investigative term for sonidegib.[2]
†No Grade 4 ARs were reported.[1]
CI=confidence interval; mRECIST=modified Response Evaluation Criteria In Solid Tumors; MRI=magnetic resonance imaging; NR=not reached.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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. Based on animal studies, female fertility may be compromised. Report pregnancies to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Clinical Considerations for ODOMZO® (sonidegib) (cont'd)

ICD-10-CM Diagnosis Codes[5]

Code	Description
C44.01	Basal cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.112	Basal cell carcinoma of skin of right eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.119	Basal cell carcinoma of skin of left eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

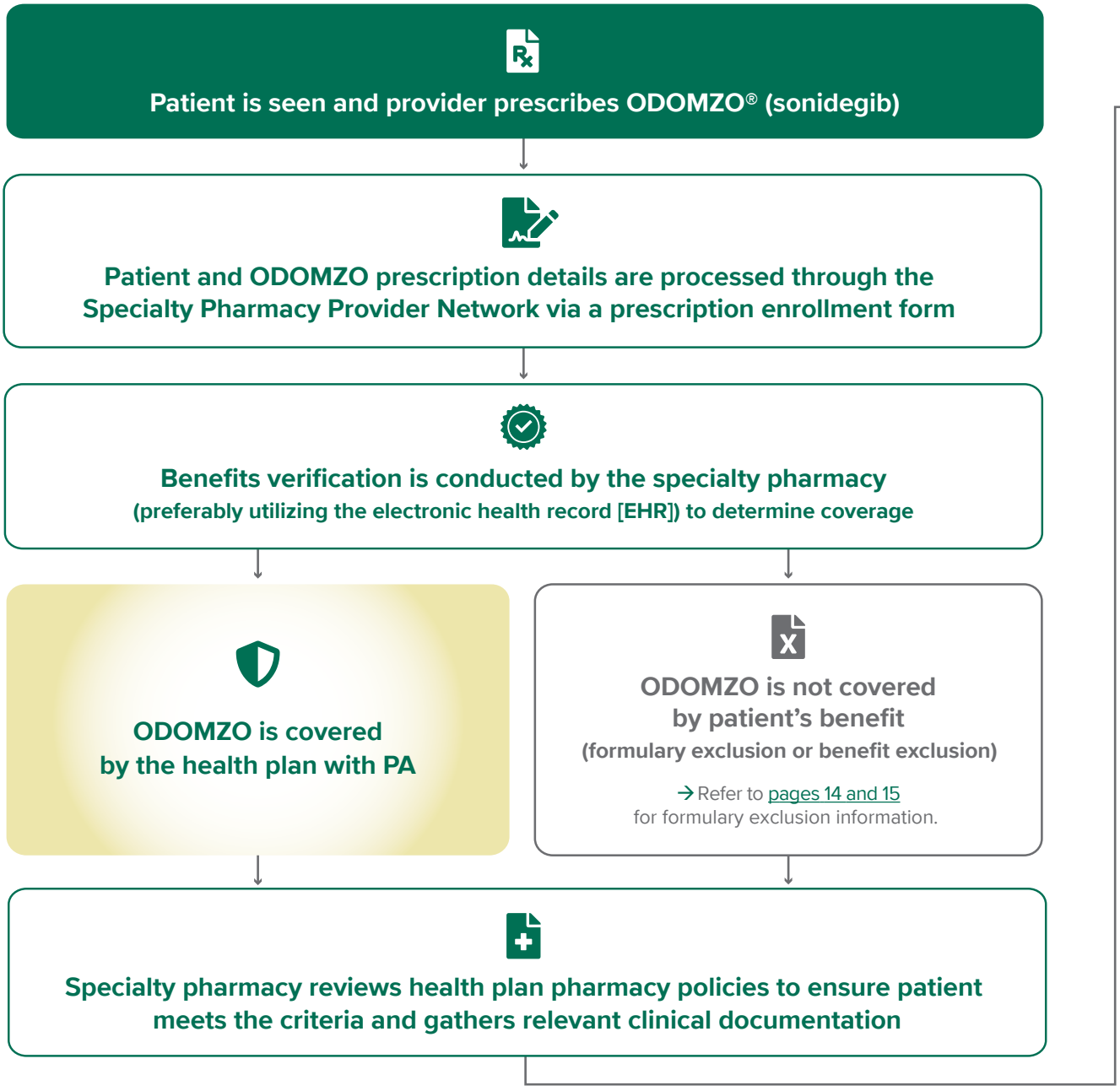
Embryo-fetal Toxicity (continued):

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.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Prior Authorization Process Overview



SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

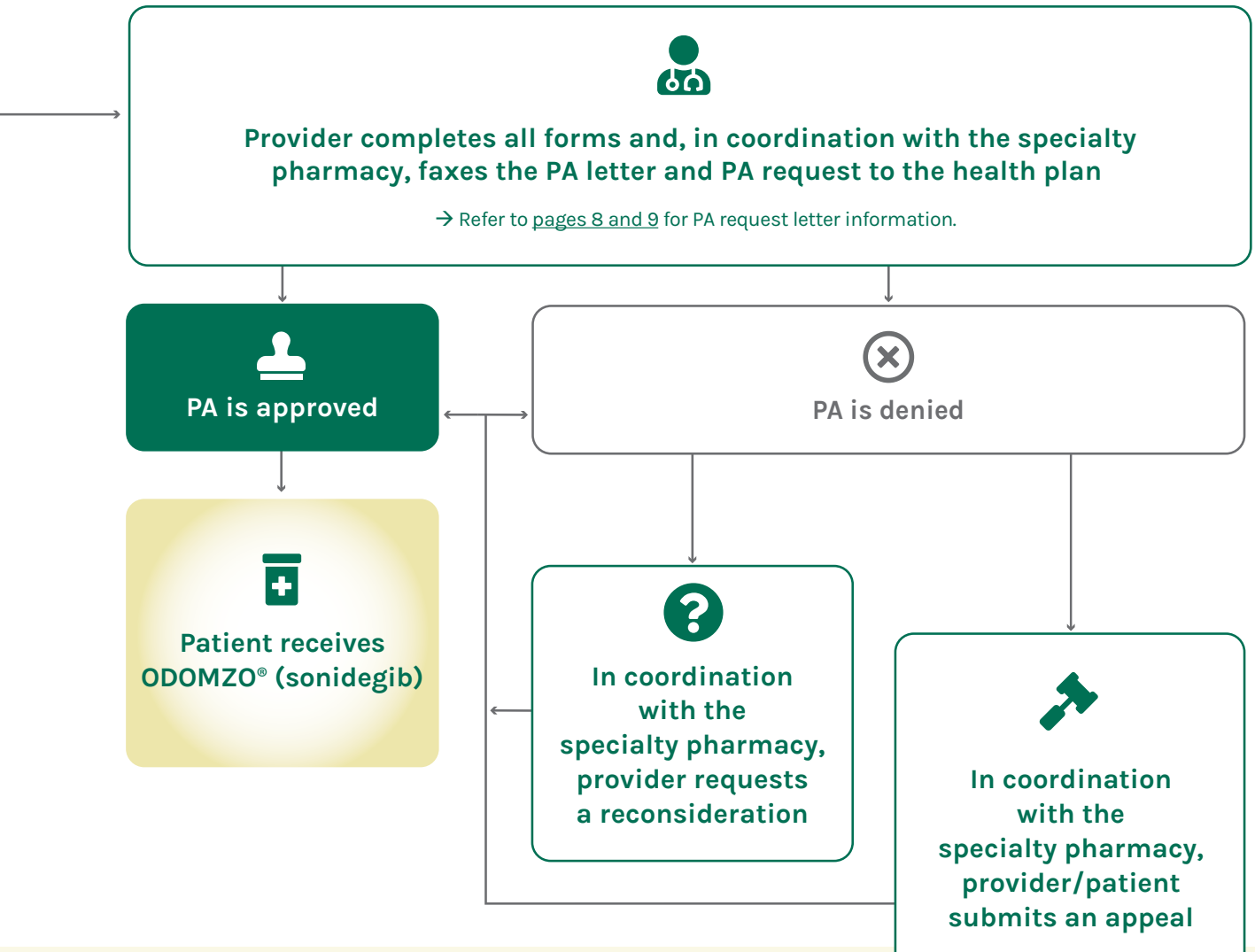
Embryo-fetal Toxicity (continued):

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 throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Prior Authorization Process Overview (cont'd)



Claims may be rejected for PA, step therapy, or non-formulary reasons. Some plans may exclude coverage for acne treatments for patients over a certain age (eg, 25 years).

Many payers will allow up to 3 levels of appeals for PA denials. A third level of appeal may include an external review.*

Formulary exclusions may be appealed while appeals for benefit exclusions are generally not available.

*An external review can also be requested at any point when there are extenuating circumstances.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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 pathway. In a pooled safety analysis of 12 clinical studies involving 571 patients with various advanced cancers treated with ODOMZO, at doses ranging from 100 mg to 3000 mg, rhabdomyolysis (defined as serum CK increase of more than ten times the baseline value with a concurrent 1.5-fold or greater increase in serum creatinine above baseline value) occurred in 1 patient (0.2%) treated with ODOMZO 800 mg.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Suggestions for a PA Request Letter

All PA forms should be completed and submitted to the plan by your office. Benefits verifications performed by the customer service center of the patient's plan can identify PA requirements, step therapies, and form requirements.

A PA letter comes from the patient and/or the physician. Fax the PA request to the health plan. Many payers will allow up to 3 levels of appeals for PA denials. Refer to pages 10 and 11 for PA Appeal Letter information.

Checklist

- ☐ Use the health plan's website to locate their PA form
- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ List previous therapies, if applicable
  - Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ Document that all PA requirements of the plan have been met, if applicable
- ☐ Provide evidence that the patient is an appropriate candidate for ODOMZO® (sonidegib), including, but not limited to:
  - Diagnosis of laBCC
  - Lesions for which radiotherapy was contraindicated or inappropriate:
    - that had recurred after radiotherapy
    - that were unresectable or for which surgical resection would result in substantial deformity, or
    - that had recurred after prior surgical resection
  - Patient is ≥18 years of age
- ☐ Information can include:
  - Efficacy and safety data for ODOMZO
  - Adverse events/contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
- ☐ Review sample letter format on the next page for additional information

PA Process Overview

DOB=date of birth; NCCN=National Comprehensive Cancer Network®.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

Musculoskeletal Adverse Reactions (Continued): In Study 1, musculoskeletal adverse reactions occurred in 68% of patients treated with ODOMZO 200 mg daily, with 9% reported as Grade 3 or 4 serum CK elevations. The most frequent musculoskeletal manifestations reported were muscle spasms (54%), musculoskeletal pain (32%), and myalgia (19%). Increased serum CK laboratory values occurred in 61% of patients, with 8% having Grade 3 or 4. Musculoskeletal pain and myalgia usually preceded serum CK elevation. ODOMZO was temporarily interrupted in 8% of patients or permanently discontinued in 8% of patients for musculoskeletal adverse reactions. The incidence of musculoskeletal adverse reactions requiring medical intervention (magnesium supplementation, muscle relaxants, analgesics or narcotics) was 29%, including four patients (5%) who received intravenous hydration or were hospitalized.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Sample PA Request Letter for ODOMZO® (sonidegib)

[Date]
[Payer Name]
[Payer Representative]
[Payer Address]
[City, State, ZIP Code]
[Payer Fax Number]

Attention: [Payer Representative]
Attention: [Department Name]

Re: Coverage request for ODOMZO® (sonidegib) capsules
Subscriber: [Subscriber's First and Last Name]
Patient Name: [Patient's First and Last Name]
Policy Number/Patient ID: [Policy Number/Patient ID]
Group Number: [Group Number]
Patient Date of Birth: [Patient Date of Birth]
Patient: [Patient Age]
Patient Sex: [Patient Sex]

Dear Medical or Pharmacy Director Name:

I am writing on behalf of [Patient's First and Last Name], [Policy Number/Patient's ID], to request coverage for ODOMZO®.

[Mr./Mrs./Ms. Patient's First and Last Name] meets your prior authorization criteria of: [List coverage criteria met]

[Mr./Mrs./Ms. Patient's First and Last Name] was provided with ODOMZO®. The full Prescribing Information for ODOMZO® can be accessed at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf.

Summary of Patient's Medical History and Diagnosis

[Patient's First and Last Name] is [Patient Age] years old and was initially diagnosed with [Diagnosis] on [Date]. [Patient's First and Last Name] has been in my care since [Date].

[Provide a discussion of the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant biopsy or laboratory test results, highlighting the factors leading you to recommend use of ODOMZO®].

Rationale for treatment

In my clinical opinion, [Mr./Mrs./Ms. Patient's First and Last Name] should receive ODOMZO® for the following reasons:

- [Please provide patient-specific reasons for treatment]

Please do not hesitate to contact me at [Phone Number] if any additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician Name]

Suggestions for a PA Appeal Letter

This type of letter can be used when a PA request for ODOMZO® (sonidegib) has been denied. There can be multiple levels of appeals. Please refer to the plan's specific appeal guidelines.

This letter comes from the patient and the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 12 and 13). Many payers will allow up to 3 levels of appeals for PA denials.

Checklist

- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ Acknowledge that you are familiar with the company's policy and state the reason for the denial
- ☐ Document that all PA requirements of the plan have been met, if applicable
  - Diagnosis of laBCC
  - Lesions for which radiotherapy was contraindicated or inappropriate:
    - that had recurred after radiotherapy
    - that were unresectable or for which surgical resection would result in substantial deformity, or
    - that had recurred after prior surgical resection
  - Patient is ≥18 years of age
- ☐ List previous therapies, if applicable
- ☐ Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ If other agents/treatments are not appropriate for this patient, explain why not (if they have not already been listed as previous therapies)
- ☐ Provide rationale and clinical support for your recommendation. Information can include:
  - Efficacy and safety data for ODOMZO
  - Adverse events or contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology, NCCN Guidelines®)
- ☐ Attach a Letter of Medical Necessity (see pages 12 and 13)

For second- and third-level appeals, it may be helpful to include:

- ☐ The original letter of denial
- ☐ Specific medical notes in response to the denial
  - A third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing

PA Process Overview

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

Musculoskeletal Adverse Reactions (Continued): Obtain baseline serum CK and creatinine levels prior to initiating ODOMZO, periodically during treatment, and as clinically indicated (eg, if muscle symptoms are reported). Obtain serum creatinine and CK levels at least weekly in patients with musculoskeletal adverse reactions with concurrent serum CK elevation greater than 2.5 times ULN until resolution of clinical signs and symptoms. Temporary dose interruption or discontinuation may be required. Advise patients starting ODOMZO of the risk of muscle-related adverse reactions and to promptly report any new unexplained muscle pain, tenderness, or weakness occurring during treatment or that persists after discontinuing ODOMZO.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Sample Letter of Appeal for ODOMZO® (sonidegib)

[Date]
[Payer Name]
[Payer Representative]
[Payer Address]
[City, State, ZIP Code]
[Payer Fax Number]

Attention: [Payer Representative]
Attention: [Department Name]

Re: Appeal of denial for ODOMZO® (sonidegib) capsules
Subscriber: [Subscriber's First and Last Name]
Patient Name: [Patient's First and Last Name]
Policy Number/Patient ID: [Policy Number/Patient ID]
Group Number: [Group Number]
Patient Date of Birth: [Patient Date of Birth]
Patient: [Patient Age]
Patient Sex: [Patient Sex]

Dear Medical or Pharmacy Director Name:

I am writing on behalf of [Patient's First and Last Name], [Policy Number/Patient's ID], to request an appeal of a denied prior authorization for ODOMZO®.

According to your denial letter, [Name of health plan] denied this prior authorization because [Reason from denial letter]. I am asking you reconsider your denial of coverage for ODOMZO® for this patient.

[Mr./Mrs./Ms. Patient's First and Last Name] was provided with ODOMZO®. The full Prescribing Information for ODOMZO® can be accessed at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf.

Rationale for appeal

In my clinical opinion, [Mr./Mrs./Ms. Patient's First and Last Name] should receive ODOMZO® for the following reasons:

- [Please provide patient-specific reasons for treatment]

Please do not hesitate to contact me at [Phone Number] if any additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician Name]

Suggestions for a Letter of Medical Necessity

Some plans require that a Letter of Medical Necessity be submitted along with a PA Appeal Letter (see pages 10 and 11) to support the choice of ODOMZO® (sonidegib) over agents that are on formulary.

The information provided below and the sample letter on the next page may be helpful to consider as you prepare the letter.

A Letter of Medical Necessity should also accompany a Formulary Exception Request Letter (see pages 14 and 15).

Checklist

- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ Include specific diagnosis codes for locally laBCC where appropriate
- ☐ Clearly state the rationale for treatment with ODOMZO and why it is appropriate for your patient
- ☐ Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider
- ☐ List previous therapies, if applicable
- ☐ Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ Explain why formulary-preferred agents are not appropriate if they have not already been listed as previous therapy
- ☐ Provide rationale and clinical support for your recommendation. Information can include:
  - Efficacy and safety data for ODOMZO
  - Adverse events/contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology, NCCN Guidelines®)
- ☐ To close the letter, summarize your recommendation, and provide a phone number should any additional information be required

◀ PA Process Overview

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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 throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Sample Letter of Medical Necessity for ODOMZO® (sonidegib)

[Date]
[Payer Name]
[Payer Representative]
[Payer Address]
[City, State, ZIP Code]
[Payer Fax Number]

Attention: [Payer Representative]
Attention: [Department Name]

Re: Coverage of ODOMZO® (sonidegib) capsules
Subscriber: [Subscriber's First and Last Name]
Patient Name: [Patient's First and Last Name]
Policy Number/Patient ID: [Policy Number/Patient ID]
Group Number: [Group Number]
Patient Date of Birth: [Patient Date of Birth]
Patient: [Patient Age]
Patient Sex: [Patient Sex]

Dear Medical or Pharmacy Director Name:

I am writing on behalf of [Patient's First and Last Name], [Policy Number/Patient's ID], to document the medical necessity of ODOMZO®.

This letter serves to document my patient's medical history and diagnosis and to summarize my treatment rationale.

[Mr./Mrs./Ms. Patient's First and Last Name] was provided with ODOMZO®. The full Prescribing Information for ODOMZO® can be accessed at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf.

Summary of Patient's Medical History and Diagnosis

[Patient's First and Last Name] is [Patient Age] years old and was initially diagnosed with [Diagnosis] on [Date]. [Patient's First and Last Name] has been in my care since [Date].

[Provide a discussion of the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant biopsy or laboratory test results, highlighting the factors leading you to recommend use of ODOMZO®].

Rationale for treatment

In my clinical opinion, [Mr./Mrs./Ms. Patient's First and Last Name] should receive ODOMZO® for the following reasons:

- [Please provide patient-specific reasons for treatment]

In summary, ODOMZO® is medically necessary and reasonable for [Mr./Mrs./Ms. Patient's First and Last Name's Diagnosis]. Please do not hesitate to contact me at [Phone Number] if any additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician Name]

Suggestions for a Formulary Exception Request Letter

This type of letter can be used when ODOMZO® (sonidegib) is not listed on a formulary or if it has an NDC block. While the plan may provide a form on its website that can be used to apply for an exception, you can refer to the information in this kit to see what is typically required.

This letter is written and sent by the patient, with the help of their physician. The letter should also be signed by the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 12 and 13).

Checklist

- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ Note the patient is requesting an exception to your formulary to fill their prescription for ODOMZO
- ☐ Include diagnosis and specific diagnosis code for laBCC where appropriate
- ☐ List previous therapies, if applicable. Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ Provide rationale and clinical support for your reasons for requesting this formulary exception
- ☐ Provide a phone number should any additional information be required to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of ODOMZO for this patient
- ☐ Include physician and patient signature at the bottom of the letter
- ☐ If this is a second- or third-level appeal for formulary exception, include level of appeal, letter of denial, and medical notes in response to denial

PA Process Overview

NDC=National Drug Code.

SELECT IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Sample Formulary Exception Request Letter for ODOMZO® (sonidegib)

[Date]
[Payer Name]
[Payer Representative]
[Payer Address]
[City, State, ZIP Code]
[Payer Fax Number]

Attention: [Payer Representative]
Attention: [Department Name]

Re: Exception request for coverage of ODOMZO® (sonidegib) capsules
Subscriber: [Subscriber's First and Last Name]
Patient Name: [Patient's First and Last Name]
Policy Number/Patient ID: [Policy Number/Patient ID]
Group Number: [Group Number]
Patient Date of Birth: [Patient Date of Birth]
Patient: [Patient Age]
Patient Sex: [Patient Sex]

Dear [Medical or Pharmacy Director Name]:

I am writing on behalf of [Patient's First and Last Name], [Policy Number/Patient's ID], to request an exception to your formulary for ODOMZO®.

This letter serves to document my patient's medical history and diagnosis and to summarize my treatment rationale.

[Mr./Mrs./Ms. Patient's First and Last Name] was provided with ODOMZO®. The full Prescribing Information for ODOMZO® can be accessed at https://www.odomzo.com/themes/custom/odomzo/global/pdfs/pi.pdf.

Summary of Patient's Medical History and Diagnosis

[Patient's First and Last Name] is [Patient Age] years old and was initially diagnosed with [Diagnosis] on [Date]. [Patient's First and Last Name] has been in my care since [Date].

[Provide a discussion of the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant biopsy or laboratory test results, highlighting the factors leading you to recommend use of ODOMZO®].

Rationale for treatment

In my clinical opinion, [Mr./Mrs./Ms. Patient's First and Last Name] should receive ODOMZO® for the following reasons:

- [Please provide patient-specific reasons for treatment]

In summary, ODOMZO® is medically necessary and reasonable for [Mr./Mrs./Ms. Patient's First and Last Name's Diagnosis]. Please do not hesitate to contact me at [Phone Number] if any additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician Name]

covermymeds®

PA Determinations, Faster.

PA SUPPORT IS AVAILABLE FOR ODOMZO® (SONIDEGIB) THROUGH COVERMYMEDS.

Through an online platform and integrations with 75% of EHRs, more than 750,000 providers use CoverMyMeds® to electronically submit PA requests to every health plan.

- Submit requests for any medication and all plans
- Receive faster PA determinations, often in real time
- Automatically renew previously submitted PA requests
- Use the solution at no cost

HOW TO INITIATE A PA REQUEST AT THE PROVIDER OFFICE:

01 **Create an account with CoverMyMeds**, or log into your existing account at covermymeds.com.

02 **Shorten time to therapy by creating a PA request** required for treatment.

03 Fill in medical details and then **click one button to electronically submit the request** to any plan for determination.

HOW TO COMPLETE A PHARMACY INITIATED REQUEST:

01 **Create an account with CoverMyMeds**, or log into your existing account at covermymeds.com.

02 On your CoverMyMeds dashboard, click **"Enter Key."**

03 Enter the access key, as well as **your patient's last name and DOB,** as indicated on the fax. You'll see that most of the request is already completed.

04 Fill in any remaining fields and click **"Send to Plan."**

05 **Mark determinations directly** in your CoverMyMeds account. Once it's determined by the plan, the pharmacy will be notified of the outcome.

Questions? CoverMyMeds can help.

Live support: call 1-866-452-5017 or chat at covermymeds.com
FAQ and webinar registration: go.covermymeds.com/help

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

Co-Pay Program for Eligible Commercially Insured Patients

Insured Patients:

Pay as little as $10*

Patients can activate this card by calling 1-877-ODOMZO-1 (1-877-636-6961) or visiting www.activatethecard.com/7436

Patients who are members of health plans (often termed "maximizer" plans) that claim to reduce their patients' out-of-pocket costs will have a reduced maximum program benefit of $6,000 per calendar year. Out-of-pocket costs may be co-pay, co-insurance, or deductible. Limitations apply. See full terms and conditions below. This offer is not valid under Medicare, Medicaid, or any other federal or state program. We reserve the right to rescind, revoke, or amend this program without notice

Terms and Conditions

To participate in the ODOMZO® (sonidegib) Co-Pay Program ("Program"), you must present this card, along with a valid prescription for ODOMZO, to your pharmacist. Patients with commercial health insurance who qualify to participate can pay as little as $10 per month for ODOMZO. Enrollment is subject to the Eligibility Rules and Terms and Conditions, stated below. If you have any questions regarding Eligibility, the Terms and Conditions, or to discontinue participation, please call 1-877-ODOMZO-1 (1-877-636-6961) (8:00 AM-8:00 PM EST, Monday-Friday).

Eligibility Rules

- To participate in this Program, you must have commercial health insurance and be a resident of the United States, Puerto Rico, Guam, or the Virgin Islands
- Patients who are members of health plans (often termed "maximizer" plans) that claim to reduce their patients' out-of-pocket costs may have a reduced maximum program benefit of $6,000 per calendar year. Out-of-pocket costs may be co-pay, co-insurance, or deductible
- The following patients are *ineligible* for this Program:
  - Patients covered under Medicaid (including Medicaid patients enrolled in a Medicaid Managed Care Plan or a qualified health plan purchased through a health insurance exchange marketplace established by a state government or the federal government)
  - Patients covered by Medicare or a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered)
  - Patients covered by TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program
  - Patients who are members of health plans that claim to eliminate their out-of-pocket costs are not eligible for cost support. If you are a member of one of these plans, please call 1-877-264-2440
  - Patients with no insurance

Terms and Conditions

- You agree not to seek any reimbursement for all or any part of the co-pay assistance received through the Program. By using this card, you are certifying that you understand the Eligibility Rules and Terms and Conditions, that you have responded truthfully to questions when activating the card, and that you will disclose and report your receipt of any Program benefits to your insurer, health plan, or any third party that pays or reimburses you for the cost of medications, if required
- This offer may be rescinded, revoked, or cancelled at any time, without further notice, and the rules may be amended at any time, without further notice

Disclosures

- This Program is not insurance
- The Program is void where prohibited by law, taxed, or restricted. Any benefit provided is not transferable and cannot be combined with any other program, free trial, discount, prescription savings card, or other offer. No purchase other than for an ODOMZO prescription, is required to participate
- Personal data that you provide to the Program may be collected, analyzed, and shared with the program sponsor for market research and other lawful purposes, but only in aggregated and de-identified form

Please see additional Important Safety Information throughout, and full Prescribing Information, including Boxed WARNING.

Odomzo® (sonidegib) capsules 200mg

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 or a 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. Based on animal studies, female fertility may be compromised. 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.

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 pathway. In a pooled safety analysis of 12 clinical studies involving 571 patients with various advanced cancers treated with ODOMZO, at doses ranging from 100 mg to 3000 mg, rhabdomyolysis (defined as serum CK increase of more than ten times the baseline value with a concurrent 1.5-fold or greater increase in serum creatinine above baseline value) occurred in 1 patient (0.2%) treated with ODOMZO 800 mg.

In Study 1, musculoskeletal adverse reactions occurred in 68% of patients treated with ODOMZO 200 mg daily, with 9% reported as Grade 3 or 4 serum CK elevations. The most frequent musculoskeletal manifestations reported were muscle spasms (54%), musculoskeletal pain (32%), and myalgia (19%). Increased serum CK laboratory values occurred in 61% of patients, with 8% having Grade 3 or 4. Musculoskeletal pain and myalgia usually preceded serum CK elevation. ODOMZO was temporarily interrupted in 8% of patients or permanently discontinued in 8% of patients for musculoskeletal adverse reactions. The incidence of musculoskeletal adverse reactions requiring medical intervention (magnesium supplementation, muscle relaxants, analgesics or narcotics) was 29%, including four patients (5%) who received intravenous hydration or were hospitalized.

Obtain baseline serum CK and creatinine levels prior to initiating ODOMZO, periodically during treatment, and as clinically indicated (eg, if muscle symptoms are reported). Obtain serum creatinine and CK levels at least weekly in patients with musculoskeletal adverse reactions with concurrent serum CK elevation greater than 2.5 times ULN until resolution of clinical signs and symptoms. Temporary dose interruption or discontinuation may be required. Advise patients starting ODOMZO of the risk of muscle-related adverse reactions and to promptly report any new unexplained muscle pain, tenderness, or weakness occurring during treatment or that persists after discontinuing ODOMZO.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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%).

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see accompanying full Prescribing Information for ODOMZO, including **Boxed Warning**.

References: 1. ODOMZO [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; August 2022. **2.** Lear JT, Migden MR, Lewis KD, et al. Long-term efficacy and safety of sonidegib in patients with locally advanced and metastatic basal cell carcinoma: 30-month analysis of the randomized phase 2 BOLT study. *J Eur Acad Dermatol Venereol*. 2018;32(3):372-381. doi:10.1111/jdv.14542 **3.** Data on file. Sun Pharmaceutical Industries, Inc. Princeton, NJ. **4.** Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer.* 2009;45(2):228-247. **5.** Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. Accessed April 7, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm

From: <name@email.com>
To: <insert email of customer>
Cc:
Subject: Prior Authorization and Appeals Toolkit for Your Practice

Odomzo® (sonidegib) capsules 200mg

<Insert greeting>,

You are receiving this communication based on your interest in prescribing ODOMZO® to treat adult patients with locally advanced basal cell carcinoma.

The attached toolkit is intended to support patient access to ODOMZO and contains information and sample letters you may use to communicate with health plans to gain prior authorization (PA) for ODOMZO or appeal unfavorable coverage decisions on behalf of your patients. The four sample letters and full Prescribing Information are also attached.

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Click here to see the full Prescribing Information for ODOMZO, including **Boxed WARNING.**

I look forward to providing you with more information regarding ODOMZO for the treatment of locally advanced basal cell carcinoma.

Sincerely,

<Sender Name>
<Sender Number>
<Sender Email>

SUN PHARMA