Novartis Patient Support™

Prior Authorization and Appeals Guide

Information and sample letters to help you navigate health plan coverage for your patients on SCEMBLIX® (asciminib) tablets

Phone:
866-433-8000

Fax:
800-368-5564

Online:
www.scemblix-startform.com

For questions or support, reach out to your dedicated Associate Director, Access & Reimbursement (ADAR) or contact Novartis Patient Support.

Please see Important Safety Information on pages 12-14 and full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

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Not actual patients.

Table of Contents

This guide is a resource for you to use if your patient is faced with insurance restrictions such as prior authorization (PA), step edit, or a plan not having a policy in place for SCEMBLIX. Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this guide are designed to help you and your patients gather relevant documentation for complete communications with your patient's health plan.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Select a tab on the bottom of each page to go to the section that interests you. Press the home icon button to return to this page. This guide is interactive—keep an eye out for callouts to see where you can click.

Please see Important Safety Information on pages 12-14 and full Prescribing Information.

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Overview of the **Reimbursement Process**

Various health insurance providers may manage access to SCEMBLIX differently. Use this page to review the health plan coverage process and identify which steps apply to your patient.

Based on a patient's medical circumstances and the provider's clinical expertise, SCEMBLIX has been determined as an appropriate treatment option for them.

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Submit your patient's prescription

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Conduct a benefits verification for your patient

A benefits verification helps your practice determine a patient's health plan coverage.

If you need assistance with this step, your dedicated **Novartis Patient Support team can help**. Simply complete the SCEMBLIX Start Form to enroll your patients in **Novartis Patient Support**.

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Address the health plan's coverage policies

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Prior authorization (PA) required

See tips and a checklist if the plan requires a PA to confirm that certain criteria have been met to cover SCEMBLIX for your patient.

Select each key word (**Prior authorization**, **Exception**, or **Appeal**) to jump to that section of the guide.

Exception appropriate

See tips and checklist for an exception request if SCEMBLIX is excluded from the formulary or NDC blocks are in place.

If denied, submit an Appeal

See tips and checklist for submitting a formal appeal to the health plan if the PA request is denied.

SCEMBLIX is approved

Once your patient's health plan approves coverage, SCEMBLIX may be delivered to your patient if filled through a specialty pharmacy, or your patient may receive the medication at an in-office dispensing pharmacy or health system pharmacy.

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Tips for Completing a PA Request

If a patient's health plan requires a PA for SCEMBLIX, review the specific forms and information required by the health plan to ensure that the PA request is as complete as possible.

Tips

Conduct (or review) a benefits verification of your patient's health plan to help determine the specific health plan coverage criteria for SCEMBLIX.

Ensure that you understand and satisfy all plan-specific requirements:

- The patient's health plan will have a unique PA form that can be located on its website or by contacting their customer service
- In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
- Some health plans encourage the use of electronic PA submission platforms (eg, CoverMyMeds®)

Start a request

- Visit covermymeds.health
- Log in to your account
- Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

covermymeds®

- Complete PA requests in minutes and get a response as quickly as a few hours
- No paper, no fax, no duplicate services
- Electronic paper signatures

Visit covermymeds.health and create an account to get started

90% SCEMBLIX PAs are approved

Turnaround time **<1 Day** for a majority of PAs to be approved

Consider including a personalized letter with PA documentation. Your patient's health plan may require you to submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for SCEMBLIX.

Click here to view sample Letter(s) of Medical Necessity for your office.

A PA may be denied for SCEMBLIX based on various reasons. Common causes of a PA denial are shown below.

Administrative Errors	Medical Necessity	Step Therapy
Spelling, coding, or other administrative inaccuracies can result in a denied PA request.	Health plans may deny coverage if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.	Depending on a health plan's formulary, patients are often required to receive a preferred treatment before another treatment can be prescribed.

Health plans take time to formulate their PA policies and coverage decisions and they often include criteria for use. If SCEMBLIX is not listed on formulary, is NDC blocked, or has criteria for use, such as a step through another agent, you may be able to submit an exception for these scenarios.

See the following page for a helpful PA request checklist.

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Preparing a PA Submission

Submission checklist

Consider the following points when preparing to submit a PA for your patient. The checklist below is provided to help ensure your PA Request Letter is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The list below is intended to provide examples of what information is usually required.

- **Fill out the plan- and/or state-specific PA form**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for SCEMBLIX
- **Check that the following information is accurate and complete:**
  - Patient and insurance information (name, address, date of birth, insurance information, etc)
  - Prescriber information (name, address, specialty, office contact, NPI, etc)
- **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC code**
- **Attach relevant clinical documentation supporting treatment with SCEMBLIX, such as:**
  - A clear summary statement citing the rationale for treatment with SCEMBLIX and reasons why other treatment may not be appropriate
  - Relevant medical records and clinical notes that support treatment with SCEMBLIX
    - Documented Ph+ CML-CP diagnosis, including the appropriate ICD-10-CM code and date of diagnosis (consider attaching the SCEMBLIX PI to support appropriate use for the indication)
    - Sokal risk score
    - For second-line or later patients, intolerance of and/or resistance to other TKIs
    - For second-line or later patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I
  - Appropriate clinical information from the Prescribing Information for SCEMBLIX
  - Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for PH+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia*)
  - Efficacy and safety trial data from ASC4FIRST, ASCEMBL, and/or X2101 clinical trials

Click here to download a customizable PA letter for your office in Word doc format.

Click here for a list of ICD-10 codes.

For support throughout the health plan coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support.

Reach out to your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and health plan coverage criteria.

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*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed October 1, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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Submitting an Exception

If the patient's health plan has placed restrictions on SCEMBLIX, such as formulary exclusion, higher tier placement, or step therapy requirements, you will need to submit an exception request to ensure health plan coverage.

Step Therapy Exception Request

Use this type of exception request to support patients seeking approval for SCEMBLIX to provide rationale and support as to why the patient should not have to step through a plan-preferred agent first.

Tiering Exception Request

Use this type of exception request to support patients seeking approval for SCEMBLIX as a preferred drug that has a lower co-payment than its assigned tier.

Formulary Exception Request

Use this type of exception request to support patients seeking approval for SCEMBLIX or to remove any applicable National Drug Code (NDC) blocks if SCEMBLIX is excluded from the formulary of your patient's health plan.

Tips

Conduct a benefits verification of your patient's health plan to help determine the specific health plan coverage criteria for SCEMBLIX.

Check to see if the patient's health plan has its own **Exception Request Form**—it can be located on its website or by contacting their customer service.

You may also submit a **Step Therapy Exception Request/Tiering Exception Request** or **Formulary Exception Request** if your patient's health plan previously approved SCEMBLIX but has since changed its formulary to exclude or move SCEMBLIX to a higher tier without grandfathering in current patients.

Consider asking your patient to write their own exception request letter that is signed by the physician.

Click here to view a checklist with helpful tips for your patient when writing to their insurance provider.

If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform.

See the following page for a helpful exception request checklist.

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Exception Request Checklist

Consider the following points when preparing to submit an exception request. The checklist below is provided to help ensure your exception request is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- **Fill out the health plan's exception request form, if required**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
- **Complete a Letter of Medical Necessity with relevant patient information and clinical support, which can include information such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - A statement of the exception you are requesting for the patient and the reason for the request
  - Diagnosis and corresponding ICD-10 code(s)
    - **Click here** for a list of ICD-10 codes
  - Rationale for choosing SCEMBLIX
  - Summary of the patient's current condition and relevant treatment history
  - If appropriate, a statement of the patient's financial hardship
- **Attach relevant clinical documentation:**
  - A clear summary statement citing the rationale for treatment with SCEMBLIX and reasons why other treatment may not be appropriate
  - Relevant medical records and clinical notes that support treatment with SCEMBLIX
  - Appropriate clinical information from the Prescribing Information for SCEMBLIX
  - Efficacy and safety trial data from ASC4FIRST, ASCEMBL, and/or X2101 clinical trials
  - For second-line or later patients, intolerance and/or resistance to other TKIs
  - For second-line or later patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I/C
  - Disease-specific criteria, including information such as the following:
    - Documented Ph+ CML-CP diagnosis including the appropriate ICD-10-CM code and date of diagnosis (consider attaching the SCEMBLIX PI to support appropriate use for the indication)
    - Sokal risk score
    - List of previously administered treatments (eg, TKI therapies), if relevant
      - Note: Document response to the treatments, reason for discontinuation, and treatment duration
  - Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for PH+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)

Click here to view sample Letter(s) of Medical Necessity for your office.

For support throughout the health plan coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support.

Reach out to your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and health plan coverage criteria.

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Submitting an Appeal

If the patient's PA or exception request for SCEMBLIX has been denied, you can consider an appeal. Your patient's health plan will provide a written explanation and include information about how to request an appeal. Review the health plan's guidelines on the appeals process to ensure the appeal is as complete as possible.

Tips

Conduct a benefits verification of your patient's health plan to help determine the specific health plan coverage criteria for SCEMBLIX.

Promptly submit the appeal upon receipt of the denial before the health plan's deadline.

Clearly address the plan's specific reason(s) for denial when writing the appeal letter:

- Refer to the PA denial letter for information to include in the appeal and to evaluate if a Letter of Medical Necessity should be included

Review the appeals process for your patient's health plan.

Always refer to the health plan's website to locate its appeal form or information for submitting your own document:

- Many health plans will allow **up to 3 levels of appeal of PA denials**; the third level of appeal may include a review by an independent, noninsurance-affiliated external review board or hearing
- Your patient's appeals rights and the appeals process are covered in health plan documents and on each Explanation of Benefits (EOB) form

If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform.

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Appeal Submission Checklist

Consider the following points when preparing to submit an appeal. The checklist below is provided to help ensure your appeal submission is as complete as possible when communicating with insurance providers. The checklist is intended to provide examples of what information is usually required.

- **Fill out an Appeal Form in response to the denial, if required by the health plan**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
  - Make sure that you review and attach the denial letter
- **Complete an Appeal Letter with relevant patient information and clinical support, such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - Denial date and denial reference number
  - Summary of patient's diagnosis and corresponding ICD-10 code(s)
    - **Click here** for a list of ICD-10 codes
  - Summary of patient's treatment history
  - Detail why each of the health plan's suggested alternative therapies are not appropriate for your patient
  - Rationale for choosing SCEMBLIX
- **Attach relevant clinical documentation, such as:**
  - A clear summary statement citing the rationale for treatment with SCEMBLIX and reasons why other treatment may not be appropriate
  - Relevant medical records and clinical notes that support treatment with SCEMBLIX
  - Appropriate clinical information from the Prescribing Information for SCEMBLIX
  - Efficacy and safety trial data from ASC4FIRST, ASCEMBL, and/or X2101 clinical trials
  - For second-line or later patients, intolerance and/or resistance to other TKIs
  - For second-line or later patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I/C
  - Disease-specific criteria, including information such as the following:
    - Documented Ph+ CML-CP diagnosis including the appropriate ICD-10-CM code and date of diagnosis (consider attaching the SCEMBLIX PI to support appropriate use for the indication)
    - Sokal risk score
    - List of previously administered treatments (eg, TKI therapies), if relevant
      - Note: Document response to the treatments, reason for discontinuation, and treatment duration
- Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for PH+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)

Click here to view sample Letter(s) of Appeal for your office.

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Reach out to your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and health plan coverage criteria.

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Sample Letters

The sample letter links below are available for you to reference when crafting your own letter to the patient's health plan. The sample letters are intended to provide examples of the types of information that are often required.

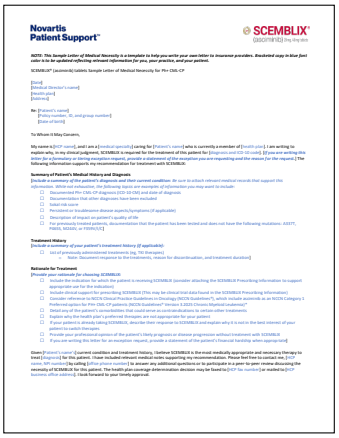
Click the links below to view sample letters for your office:

Sample PA Request Letter

Sample Letter of Medical Necessity

Sample Appeal Letter

Sample Appeal Letter for Specialty Exclusions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NOTE: This Sample Letter of Medical Necessity is a template to help you write your own letter to insurance providers. Bracketed copy in blue font color is to be updated reflecting relevant information for you, your practice, and your patient.

SCEMBLIX® (asciminib) tablets Sample Letter of Medical Necessity for Ph+ CML-CP

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [NCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, SCEMBLIX is required for the treatment of this patient for [diagnosis and ICD-10 code]. [If you are writing this letter for a formulary or timing exception request, provide a statement of the exception you are requesting and the reason for the request.] The following information supports my recommendation for treatment with SCEMBLIX:

Summary of Patient's Medical History and Diagnosis

[Include a summary of the patient's diagnosis and their current condition. Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:

- Documented Ph+ CML-CP diagnosis (ICD-10-CM) and date of diagnosis
- Documentation that other diagnoses have been excluded
- Salient risk score
- Persistent or troublesome disease aspects/symptoms (if applicable)
- Description of impact on patient's quality of life
- For previously treated patients, documentation that the patient has been tested and does not have the following mutations: A337T, F359I, M244V, or F359C/V/I]

Treatment History

[Include a summary of your patient's treatment history (if applicable):

- List of previously administered treatments (eg, TKI therapies)
  - Note: Document response to the treatments, reason for discontinuation, and treatment duration]

Rationale for Treatment

[Provide your rationale for choosing SCEMBLIX:

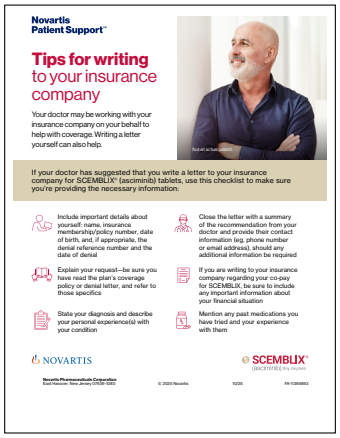
- Include the indication for which the patient is receiving SCEMBLIX (consider attaching the SCEMBLIX Prescribing Information to support medical necessity review)
- Include clinical support for prescribing SCEMBLIX (This may be clinical trial data found in the SCEMBLIX Prescribing Information)
- Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for Ph+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)[1]
- Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- Explain why the health plan's preferred therapies are not appropriate for your patient
- If your patient is already taking SCEMBLIX, describe their response to SCEMBLIX and explain why it is not in the best interest of your patient to switch therapies
- Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with SCEMBLIX
- If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name]'s current condition and treatment history, I believe SCEMBLIX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [NCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the medical necessity of SCEMBLIX for this patient. [If a coverage determination decision may be faxed to [NCP fax number] or mailed to [NCP business office address].] I look forward to your timely approval.

Example of Letter of Medical Necessity

Click the link below to view patient resources for your office:

Patient Letter Checklist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Tips for writing to your insurance company

Your doctor may be working with your insurance company on your behalf to help with coverage. Writing a letter yourself can also help.

Real-life patient

If your doctor has suggested that you write a letter to your insurance company for SCEMBLIX® (asciminib) tablets, use this checklist to make sure you're providing the necessary information:

- Include important details about yourself: name, insurance membership/policy number, date of birth, and, if appropriate, the denial reference number and the date of denial
- Explain your request—be sure you have read the plan's coverage policy or denial letter, and refer to those specifics
- State your diagnosis and describe your personal experience(s) with your condition
- Close the letter with a summary of the recommendation from your doctor and provide their contact information (eg, phone number or email address), should any additional information be required
- If you are writing to your insurance company regarding your co-pay for SCEMBLIX, be sure to include any important information about your financial situation
- Mention any past medications you have tried and your experience with them

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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Example of Patient Letter Checklist

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Glossary

- **Appeal:** A request to a patient's health plan to reconsider their decision to deny health plan coverage
- **Benefits verification:** The process of confirming a patient's health plan coverage to determine what services are covered, what their financial responsibility will be (like co-payments or deductibles), and if any prior authorizations are needed
- **Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—such as doctor visits, prescription medications, and other health care services
- **Exception:** A coverage request made to a patient's health plan to remove a plan restriction placed on a treatment, such as step therapy through preferred treatment(s)
- **Explanation of benefits (EOB):** A statement from the health plan sent to members to track the use of medications and/or health care services, and the associated costs and payments
- **Formulary:** A list of prescription medications covered by an insurer/health plan
- **National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the US
- **Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multi-tier plan, preferred drugs are assigned to a lower tier than nonpreferred drugs
- **Prior authorization (PA):** Also called preauthorization, an administrative tool used by health plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity and plan requirements
- **Step therapy:** A health plan policy requiring patients to follow a stepwise approach to trying a medication before the plan will cover any alternative medications
- **Tiers:** Most health plan formularies are divided into different categories, called tiers, with increasingly scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or nonpreferred medications, and traditional or specialty medications

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INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
    - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

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IMPORTANT SAFETY INFORMATION (cont)

Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

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IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

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NOTE: This Sample Letter of Medical Necessity is a template to help you write your own letter to insurance providers. Bracketed copy in blue font color is to be updated reflecting relevant information for you, your practice, and your patient.

SCEMBLIX® (asciminib) tablets Sample Letter of Medical Necessity for Ph+ CML-CP

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, SCEMBLIX is required for the treatment of this patient for [diagnosis and ICD-10 code]. [***If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request.***] The following information supports my recommendation for treatment with SCEMBLIX:

Summary of Patient's Medical History and Diagnosis
[***Include a summary of the patient's diagnosis and their current condition:*** *Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:*

- ☐ Documented Ph+ CML-CP diagnosis (ICD-10-CM) and date of diagnosis
- ☐ Documentation that other diagnoses have been excluded
- ☐ Sokal risk score
- ☐ Persistent or troublesome disease aspects/symptoms (if applicable)
- ☐ Description of impact on patient's quality of life
- ☐ For previously treated patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I/C]

Treatment History
[***Include a summary of your patient's treatment history (if applicable):***

- ☐ List of previously administered treatments (eg, TKI therapies)
  - Note: Document response to the treatments, reason for discontinuation, and treatment duration]

Rationale for Treatment
[***Provide your rationale for choosing SCEMBLIX:***

- ☐ Include the indication for which the patient is receiving SCEMBLIX (consider attaching the SCEMBLIX Prescribing Information to support appropriate use for the indication)
- ☐ Include clinical support for prescribing SCEMBLIX (This may be clinical trial data found in the SCEMBLIX Prescribing Information)
- ☐ Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for PH+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)*
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient
- ☐ If your patient is already taking SCEMBLIX, describe their response to SCEMBLIX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with SCEMBLIX
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe SCEMBLIX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of SCEMBLIX for this patient. The health plan coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP name and signature]
[Specialty, name of practice, phone number]

Encl: [Medical records, SCEMBLIX® (asciminib) tablets Prescribing Information, NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia]

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed October 1, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

IMPORTANT SAFETY INFORMATION (cont)

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

Please see full Prescribing Information.

Novartis Patient Support™

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

NOTE: This Sample Letter of Appeal is a template to help you write your own letter to insurance providers. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

SCEMBLIX® (asciminib) tablets Sample Letter of Appeal for Ph+ CML-CP

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed SCEMBLIX for this patient to treat [diagnosis and ICD-10 code] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for SCEMBLIX, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that SCEMBLIX is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with SCEMBLIX:

Summary of Patient's Medical History and Diagnosis

[***Include a summary of the patient's diagnosis and current condition:*** *Be sure to attach relevant medical records that support this information. The following topics are examples of information you may want to include:*

- ☐ Patient's Ph+ CML-CP diagnosis and date of diagnosis
- ☐ Documentation that other diagnoses have been excluded
- ☐ Sokal risk score
- ☐ Persistent, troublesome disease/condition aspects or symptoms (if applicable)
- ☐ Description of impact on patient's quality of life
- ☐ Any additional information the provider deems relevant
- ☐ For previously treated patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I/C]

Treatment History

[***Include a summary of your patient's treatment history (if applicable):***

- ☐ List of previously administered treatments (eg, TKI therapies)
  - Note: Document response to the treatments, reason for discontinuation, and treatment duration]

Previous therapy	Duration of therapy	Reason for discontinuation
[BRAND dose, frequency]	[Days/weeks/months/years]	[Reason for discontinuation]
[BRAND dose, frequency]	[Days/weeks/months/years]	[Reason for discontinuation]

Rationale for Treatment

[***Provide your rationale for choosing SCEMBLIX:***

- ☐ Include the indication for which the patient is receiving SCEMBLIX (consider attaching the SCEMBLIX Prescribing Information to support appropriate use for the indication)
- ☐ Include clinical support for prescribing SCEMBLIX (*This may be clinical trial data found in the* SCEMBLIX *Prescribing Information)*
- ☐ Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for Ph+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)*
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ If your patient is already taking SCEMBLIX, describe their response to SCEMBLIX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with SCEMBLIX]

Given [Patient's name's] current condition and treatment history, I believe SCEMBLIX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of SCEMBLIX for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: [Denial Letter, Medical records, SCEMBLIX® (asciminib) tablets Prescribing Information, NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia]

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INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

IMPORTANT SAFETY INFORMATION (cont)

Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

Please see full Prescribing Information.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

Novartis Patient Support™

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

NOTE: This Sample Prior Authorization Request Letter is a template to help you write your own letter to insurance providers. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

SCEMBLIX® (asciminib) tablets Sample Prior Authorization Request Letter for Ph+ CML-CP

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of SCEMBLIX [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10 code(s)]. As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing SCEMBLIX. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with SCEMBLIX:

I have attached relevant medical records, including the patient's diagnosis, test results, and treatment history.
[***Include a summary of the patient's treatment history (if applicable):***

- ☐ Include the indication for which the patient is receiving SCEMBLIX (consider attaching the SCEMBLIX Prescribing Information to support appropriate use for the indication)
- ☐ Provide a comprehensive list of previously administered treatments including documented treatment failure on other tyrosine kinase inhibitors, response to treatments, reason for discontinuation, and treatment duration
- ☐ Consider reference to NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which include asciminib as an NCCN Category 1 Preferred option for Ph+ CML-CP patients (NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia)*
- ☐ Include clinical support for prescribing SCEMBLIX (This may be clinical trial data found in the SCEMBLIX Prescribing Information)
- ☐ Detail any comorbidities that could serve as contraindications to certain other treatments]

Previous therapy	Duration of therapy	Reason for discontinuation
[BRAND dose, frequency]	[Days/weeks/months/years]	[Reason for discontinuation]
[BRAND dose, frequency]	[Days/weeks/months/years]	[Reason for discontinuation]

Given [Patient's name's] current condition and treatment history, I believe SCEMBLIX should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

The prior authorization decision may be faxed to [fax number] or mailed to [HCP business office address]. Thank you for your prompt attention to this matter.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: [Medical records, SCEMBLIX® (asciminib) tablets Prescribing Information, NCCN Guidelines® Version 3.2025 Chronic Myeloid Leukemia]

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INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
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- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Hypertension

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Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

IMPORTANT SAFETY INFORMATION (cont)

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

Please see full Prescribing Information.

Novartis Patient Support™

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

NOTE: This Sample Letter of Appeal for Specialty Exclusions is a template to help you write your own letter to insurance providers. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

SCEMBLIX® (asciminib) Sample Letter of Appeal for Specialty Exclusions

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. This letter is a formal appeal of your coverage decision for SCEMBLIX for the patient referenced above. Upon review of the denial of coverage, it appears that the reason(s) for the denial is due to the patient's insurance plan potentially participating in an alternate funding program (also known as Specialty Carve-Outs or third-party disruptors).

These programs often disrupt the normal coverage process to make it appear that the patient is "uninsured for specialty drug" and may require the insured patient to apply to charitable foundation drug programs as a requirement for or prerequisite to cover their prescribed therapy.

Generally, charitable foundation support is reserved for patients who are most in need, such as the uninsured, underinsured, or those with financial hardship that would otherwise prevent them from being able to access their medicine.

I request [health plan] denial decision be reversed, and coverage approved for SCEMBLIX based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that SCEMBLIX is the appropriate therapy for [Patient's name] and the following information supports my recommendation for treatment:

Summary of Patient's Medical History and Diagnosis

[Patient's name] is [a/an] [age]-year-old [male or female] who has been diagnosed with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) as of [date]. This patient has been in my care since [date].

[Include a summary of the patient's diagnosis and current condition: *Be sure to attach relevant medical records that support this information.*
The following topics are examples of information you may want to include:

- ☐ Patient's diagnosis of Ph+ CML-CP and date of diagnosis
  - ☐ Documented CML mutation status for second-line or later patients
- ☐ Documentation that other diagnoses have been excluded
- ☐ Sokal risk score
- ☐ For previously treated patients, documentation that the patient has been tested and does not have the following mutations: A337T, P465S, M244V, or F359V/I/C
- ☐ Persistent, troublesome disease/condition aspects or symptoms (if applicable)
- ☐ Description of impact on patient's quality of life]

Treatment History

[Include a summary of your patient's treatment history (if applicable):

- ☐ List of previously administered treatments (eg, documented treatment failures on tyrosine kinase inhibitors [TKIs])
- ☐ Document response to the treatments, reason for discontinuation, and treatment duration
- ☐ Confirm that the patient has not received adequate results from any previous treatment]

Rationale for Treatment

[Provide your rationale for choosing SCEMBLIX:

- ☐ Include clinical support for prescribing SCEMBLIX (*This may be clinical trial data found in the SCEMBLIX Prescribing Information)*
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ If your patient is already taking SCEMBLIX, describe their response to SCEMBLIX and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with SCEMBLIX]

National Comprehensive Cancer Network® (NCCN®) recommended

- ☐ [The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend asciminib (SCEMBLIX®) as an NCCN Category 1, Preferred first-line treatment option for newly diagnosed patients with Ph+ CML-CP*]

Given [Patient's name's] current condition and treatment history, I believe SCEMBLIX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of SCEMBLIX for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Denial letter, Medical records, SCEMBLIX Prescribing Information

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed October 20, 2025. To view the most recent and complete version of the guideline, go online to www.NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX® (asciminib) tablets is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
  - This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)
- Previously treated Ph+ CML in CP
- Ph+ CML in CP with the T315I mutation

IMPORTANT SAFETY INFORMATION

Myelosuppression

- Thrombocytopenia, neutropenia, and anemia, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Perform complete blood counts every 2 weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression
- Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Pancreatic Toxicity

- Pancreatitis (including grade 3 reactions) and elevation in serum lipase and amylase (including grade 3/4 elevations), have occurred in patients receiving SCEMBLIX
- Assess serum lipase and amylase levels monthly during treatment with SCEMBLIX, or as clinically indicated. Monitor patients for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis
- If lipase and amylase elevation are accompanied by abdominal symptoms, temporarily withhold SCEMBLIX and consider appropriate diagnostic tests to exclude pancreatitis
- Based on the severity of lipase and amylase elevation, reduce dose, temporarily withhold, or permanently discontinue SCEMBLIX as described in the prescribing information

Hypertension

- Hypertension, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX
- Monitor and manage hypertension using standard antihypertensive therapy during treatment with SCEMBLIX as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypertension

Hypersensitivity

- Hypersensitivity, including grade 3/4 reactions, have occurred in patients receiving SCEMBLIX. Reactions included rash, edema, and bronchospasm
- Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated
- For grade 3 or higher reactions, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of hypersensitivity

IMPORTANT SAFETY INFORMATION (cont)

Cardiovascular Toxicity

- Cardiovascular toxicity (including ischemic cardiac and central nervous system conditions; and arterial thrombotic and embolic conditions) and cardiac failure have occurred in patients receiving SCEMBLIX. Some toxicities were grade 3/4 and 5 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3/4
- Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated
- For grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue SCEMBLIX as described in the prescribing information depending on persistence of cardiovascular toxicity

Embryo-Fetal Toxicity

- SCEMBLIX can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus if SCEMBLIX is used during pregnancy or if the patient becomes pregnant while taking SCEMBLIX
- Verify the pregnancy status of females of reproductive potential prior to starting treatment with SCEMBLIX. Advise females to use effective contraception during treatment and for at least 1 week after the last SCEMBLIX dose

ADVERSE REACTIONS

- Most common adverse reactions (≥20%) were musculoskeletal pain, rash, fatigue, upper respiratory tract infection, headache, abdominal pain, arthralgia, and diarrhea
- Most common select laboratory abnormalities (≥20%) were lymphocyte count decreased, leukocyte count decreased, platelet count decreased, neutrophil count decreased, calcium corrected decreased, lipase increased, cholesterol increased, uric acid increased, alanine aminotransferase increased, alkaline phosphatase increased, hemoglobin decreased, triglycerides increased, creatine kinase increased, amylase increased, and aspartate aminotransferase increased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, P-gp, and BCRP. Asciminib is a CYP3A4 substrate
- Closely monitor for adverse reactions during concomitant use of strong CYP3A4 inhibitors and SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of itraconazole oral solution containing hydroxypropyl-β-cyclodextrin and SCEMBLIX at all recommended doses
- Closely monitor for adverse reactions during concomitant use of certain CYP3A4 substrates and SCEMBLIX at 80 mg total daily dose. Avoid use of SCEMBLIX at 200 mg twice daily
- Avoid concomitant use of CYP2C9 substrates and SCEMBLIX at all recommended doses. If coadministration with 80 mg total daily dose is unavoidable, reduce the CYP2C9 substrate dosage as recommended in its prescribing information. If coadministration with 200 mg twice daily is unavoidable, consider alternative therapy with a non-CYP2C9 substrate
- Closely monitor for adverse reactions during concomitant use of certain P-gp substrates and SCEMBLIX at all recommended doses
- Avoid concomitant use of rosuvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other BCRP substrates and SCEMBLIX at all recommended doses

Please see full Prescribing Information.

NOVARTIS

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