

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

SCEMBLIX Sample Letter of Medical Necessity

[Date]

[Medical Director’s name]

[Payer name]

[Address]

Re: [Patient’s name]

[Policy number, ID, group number]

[Date of Birth]

Dear [Medical Director’s Name/Other],

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [payer name]. I am writing to explain why, in my clinical judgment, SCEMBLIX® (asciminib) tablets 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:

* Patient’s diagnosis and date of diagnosis
* Documentation that other diagnoses have been excluded
* [Disease-state-specific] test results
* Measurement tool/scale results (if applicable)
* Persistent or troublesome disease aspects/symptoms (if applicable)
* Disease-specific documentation
* 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 (Complete this section if applicable)]**

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

* Provide a comprehensive list of previous therapies used, duration of therapy, and reason for discontinuation (for example, intolerance or resistance to treatment)
* Specify which treatments the patient has tried
* Confirm if the patient has not received adequate results from any previous treatment]

|  |  |  |
| --- | --- | --- |
| 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 may serve as contraindications to certain other treatments
* Explain why the payer'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] current condition [and clinical rationale, NCCN guidelines, and/or treatment history], I believe SCEMBLIX is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included the relevant medical notes supporting my recommendation.

Please feel free to contact me, [HCP name, NPI number], by calling [office phone number] to answer any questions or participate in a peer-to-peer review discussing the necessity of SCEMBLIX for this patient. The 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]

**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 for SCEMBLIX**

**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

**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, 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, OATP1B, 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 or atorvastatin and SCEMBLIX at all recommended doses. Closely monitor for adverse reactions during concomitant use of other OATP1B or BCRP substrates and SCEMBLIX at all recommended doses

**Please see full Prescribing Information.**



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