Novartis Patient Support™

Potential *ICD-10-CM* Diagnosis Codes for SCEMBLIX® (asciminib) tablets

We know that navigating insurance and reimbursement can be a challenge. Novartis Patient Support is by your side to help throughout the process.

This guide provides an overview of International Classification of Diseases, 10th Revision, Clinical Modification *(ICD-10-CM)* diagnosis codes for SCEMBLIX.

When considering *ICD-10-CM* codes for SCEMBLIX:

- Review the health plan's guidance to ensure appropriate codes are selected based on a patient's medical record

Examples of potential codes that may be relevant for SCEMBLIX include:

Primary Diagnosis Codes

Indication(s)	*ICD-10-CM* Code	Description
► Newly diagnosed Ph+ CML-CP in adult patients	C92.10	Chronic myeloid leukemia, BCR-ABL-positive, not having achieved remission
► Ph+ CML-CP in adult patients previously treated	C92.11	Chronic myeloid leukemia, BCR-ABL-positive, in remission
► Ph+ CML-CP in adult patients with the T315I mutation	C92.12	Chronic myeloid leukemia, BCR-ABL-positive, in relapse

The codes listed above are provided for educational purposes only and are not a guarantee of coverage or reimbursement. Coverage and reimbursement may vary significantly by health plan, patient, and setting of care. It is the sole responsibility of the HCP to select the proper codes and ensure the accuracy of the statements used in seeking coverage and reimbursement for an individual patient.

Questions?

Reach out to your SCEMBLIX Associate Director, Access & Reimbursement (ADAR) or call Novartis Patient Support at 866-433-8000, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays, or go to www.scemblix-hcp.com.

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

Please see full Prescribing Information.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

Cardiovascular Toxicity (continued)

- 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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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

SCEMBLIX®
(asciminib) 20 mg, 40 mg tablets