Adult Patients with Ph+ CML-CP

Diagnosis Details:

Indications

☐ Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)

☐ Ph+ CML in CP with T315I mutation

Sample ICD-10 Code*

☐ C92.10 ☐ C92.11 ☐ C92.12

Testing and Treatment History:

Tests

☐ *BCR::ABL1* Test **Result/Date** _____ ☐ ECG **Result/Date** _____ ☐ Mutation Panel Test **Result/Date** _____
(eg, T315I, V299L, G250E, F317L, Y253H, E2FFK/V)

☐ >10% ☐ >1%-10% ☐ >0.1%-1% ☐ ≤0.1%

☐ Risk Score: ☐ Low ☐ Intermediate ☐ High

Reminder: List all previous TKIs, current treatment, and any dose adjustments

Current and Previous Treatment(s)

☐ **Bosutinib**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

☐ **Dasatinib**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

☐ **Imatinib**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

☐ **Nilotinib**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

☐ **Ponatinib**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

☐ **SCEMBLIX**
Date/Duration: _____
Initial Dosage Received: _____
Other Dosage Received: _____
☐ Current ☐ Previous

History of TKI Intolerance, Resistance, Comorbidities or Contraindication:

Treatment 1: _____

☐ Primary Resistance ☐ Secondary Resistance

☐ Intolerance - Adverse Events: _____
(rash, diarrhea, abdominal pain, nausea, neutropenia, hepatic toxicity, etc)

☐ Lab Abnormalities: _____
(creatine increased, lymphocyte count decreased, ALT increase, etc)

☐ History of Chronic Lung Disease
(pulmonary arterial hypertension, interstitial pneumonitis)

☐ Cardiovascular Risk: _____
(History of myocardial infarction, stroke, etc)

☐ Other: _____

☐ Contraindication: _____

Treatment 2: _____

☐ Primary Resistance ☐ Secondary Resistance

☐ Intolerance - Adverse Events: _____
(rash, diarrhea, abdominal pain, nausea, neutropenia, hepatic toxicity, etc)

☐ Lab Abnormalities: _____
(creatine increased, lymphocyte count decreased, ALT increase, etc)

☐ History of Chronic Lung Disease
(pulmonary arterial hypertension, interstitial pneumonitis)

☐ Cardiovascular Risk: _____
(History of myocardial infarction, stroke, etc)

☐ Other: _____

☐ Contraindication: _____

Reminder: Document reason(s) for discontinuation and contraindication(s) for other approved products

Contact your Novartis Account Representative for the Authorization and Appeals guide for additional support.

Consult payer coverage policy for prior authorization criteria and documentation requirements.

Novartis Pharmaceuticals Corporation does not guarantee success in obtaining reimbursement or finance assistance. Third-party payment for medical products and services is affected by numerous factors, not all of which can be anticipated or resolved.

*The sample diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement, and include potential codes that would include FDA-approved indications for SCEMBLIX. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Please see Important Safety Information on pages 2-3 and click here for full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

SCEMBLIX INDICATIONS and IMPORTANT SAFETY INFORMATION

INDICATIONS

SCEMBLIX is indicated for the treatment of adult patients with:

- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- 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 asymptomatic 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

Please see additional Important Safety Information on page 3 and click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION for SCEMBLIX (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 3 fatalities were reported
- Arrhythmia, including QTc prolongation, have occurred in patients receiving SCEMBLIX. Some of these arrhythmias were grade 3
- 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 upper respiratory tract infections, musculoskeletal pain, headache, fatigue, nausea, rash, and diarrhea
- Most common laboratory abnormalities (≥20%) were platelet count decreased, triglycerides increased, neutrophil count decreased, hemoglobin decreased, creatine kinase increased, alanine aminotransferase increased, lipase increased, amylase increased, aspartate aminotransferase increased, uric acid increased, and lymphocyte count decreased

DRUG INTERACTIONS

- Asciminib is an inhibitor of CYP3A4, CYP2C9, and P-gp. 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

Click here for full Prescribing Information.

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