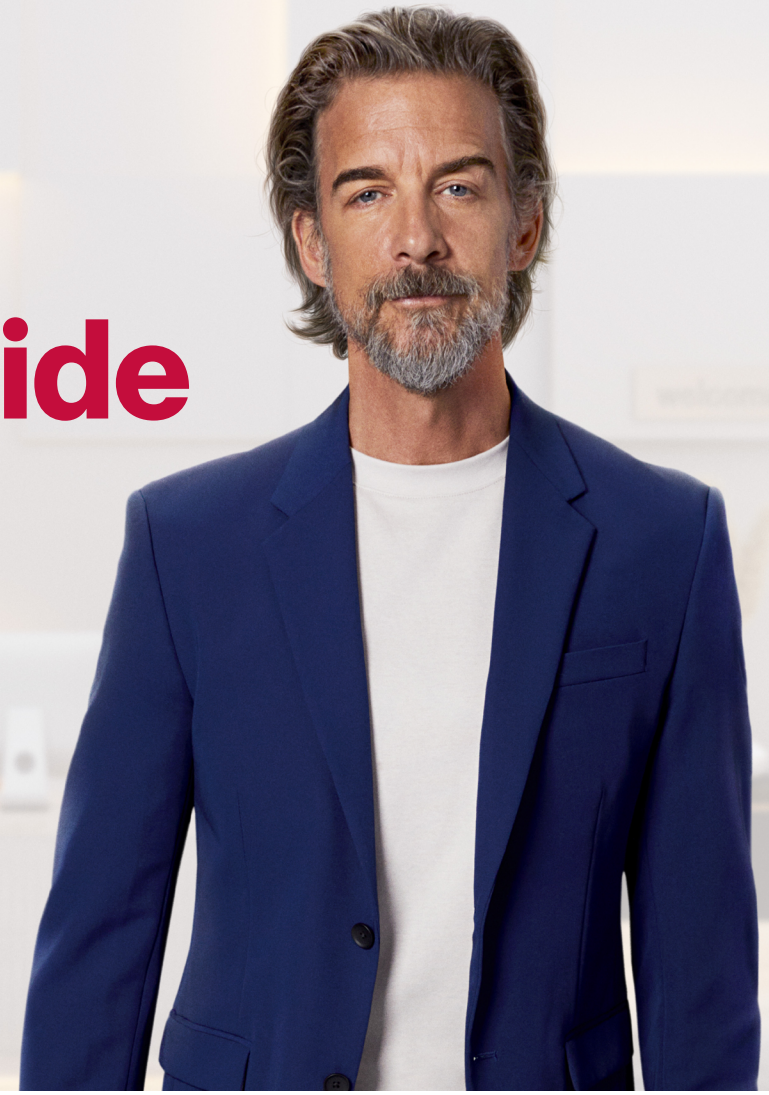
Novartis Patient Support™

Access and Support Guide

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



Not an actual patient.

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

Phone: 866-433-8000

Fax: 800-368-5564

Online: CoverMyMeds® Portal

SCEMBLIX HCP website: SCEMBLIX

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

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

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How to Use This Guide

We know that navigating prior authorizations (PA) and appeals for your patients can be a challenge. This guide provides you with helpful tools to assist you and your patients with common health plan criteria and support access for your patients prescribed 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.

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.

Table of Contents

Tip

Sample letters are provided in this guide. Simply click the links of each sample letter to open and fill in with necessary information.

Visit the **Novartis Patient Support website** to explore additional resources to help you get patients started on SCEMBLIX.

Please see Important Safety Information on pages 15-16 and click here for 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 coverage process and identify which steps apply to your patient.

Submit your patient's prescription

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

Conduct a benefits verification for your patient

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**.

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

Address the health plan's coverage policies

Prior authorization 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.

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

The patient's health plan has approved the PA, exception request, or appeal.

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

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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 a benefits verification of your patient's health plan to help determine the specific coverage criteria for SCEMBLIX**
- **Ensure that you understand and satisfy all plan-specific requirements**
  - The patient's health plan may have a unique PA form that can be located on their 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.com
LOG IN to your account
CLICK "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 patient signatures

Visit covermymeds.com and log in/ create an account to get started

>80%
SCEMBLIX PAs are approved

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

- **Consider including a Letter of Medical Necessity to explain the clinical rationale for SCEMBLIX**

- Click the link below to download the appropriate sample **Letter of Medical Necessity** for your office

Letter of Medical Necessity

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

Medical Necessity	Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.
Administrative Errors	An incorrect ICD-10-CM diagnosis code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.
Step Therapy	Depending on a health plan's formulary, patients are often required to receive a preferred medication before an alternative treatment can be prescribed.

See the following page for a helpful PA submission checklist.

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

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Preparing a PA Submission

Submission checklist

Check that you have completed the following when submitting a PA for your patient:

- **Complete the plan- and/or state-specific PA form**
  - Remember to conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for SCEMBLIX
- **Attach relevant clinical documentation supporting treatment with SCEMBLIX, such as:**

Patient Information

- Full name, date of birth, sex, and insurance policy information

Summary of Diagnosis

- Documented Ph+ CML-CP diagnosis (ICD-10-CM) and date of diagnosis
- Documented CML mutation status for second-line or later patients

Rationale for Treatment

- A clear summary statement citing the rationale for treatment with SCEMBLIX and reason(s) why other treatments may not be appropriate
- Include the applicable indication and ICD-10-CM code for your patient on your PA submission (consider attaching the SCEMBLIX Prescribing Information (PI) to support appropriate use for the indication)
- Rationale and clinical support for your recommendation, such as:
  - FDA-approved indications and clinical data included in the SCEMBLIX (asciminib) tablets 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)
  - Efficacy and safety trial data from ASC4FIRST, ASCEMBL, and/or X2101 clinical trials
  - Patient medical records (including Sokal risk score)
  - Intolerance of and/or resistance to other TKIs for second-line or later patients
  - 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

Previous Treatment History (if applicable)

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

Click here for a list of ICD-10-CM codes.

- Contact your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and coverage criteria
- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in the Novartis Patient Support program

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by 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.

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

Submitting an Exception

If the patient's health plan has placed certain restrictions on SCEMBLIX, such as formulary exclusion, you will need to submit an exception request.

Tips

- Conduct a benefits verification of your patient's health plan to help you determine the specific coverage criteria for SCEMBLIX
- Check to see if the patient's health plan has its own **Exception Request Form**—it can be located on their website or obtained by contacting their customer service
- You may also submit a **Formulary Exception Request** if your patient's health plan previously approved SCEMBLIX, but has since changed its formulary to exclude SCEMBLIX without grandfathering in current patients
- Consider asking your patient or their legal guardian to write their own exception request letter that is signed by the physician

See the following page for a helpful exception request checklist.

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

Exception Request Checklist

Request checklist

- **Complete the health plan's exception, if required**
  - Remember to 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, including:**
  - Patient's name, date of birth, and 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-CM code(s)
  - Rationale for choosing SCEMBLIX
  - Summary of the patient's current condition and, for second-line or later treatment, patient treatment history
    - **Click here** for a list of ICD-10-CM codes
  - If appropriate, a statement of the patient's financial hardship
- **Attach relevant clinical documentation:**
  - Medical records and clinical notes that support treatment with SCEMBLIX
  - Appropriate clinical information from the Prescribing Information for SCEMBLIX
  - Disease-specific criteria, including information such as the following:
    - Diagnosis and the date of diagnosis
    - Test results
    - Lab results
    - If appropriate, disease-specific scores
    - Assessment of disease severity
    - List of previous therapies used, duration of therapy, and reason for discontinuation
  - 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 the link below to download the appropriate sample **Letter of Medical Necessity** for your office

Letter of Medical Necessity

- Contact your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and coverage criteria
- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in the Novartis Patient Support program

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Submitting an Appeal

If the patient's PA or exception request for SCEMBLIX has been denied, the next step in the reimbursement process is to pursue 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 you determine the specific coverage criteria for SCEMBLIX**
- It is important to promptly submit the appeal upon receipt of the denial
- Review the appeals process for your patient's health plan
- When writing the appeal letter, be sure to clearly address the plan's specific reason(s) for denial
- Always refer to the health plan's website to locate their 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**

See page 11 for a helpful appeal submission checklist.

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Appeal Submission Checklist

Submission checklist

- **Fill out an Appeal Form in response to the denial, if required by the health plan**
  - Remember to 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, including:**
  - Patient's name, date of birth, and health plan information (policy number)
  - Denial date and denial reference number
  - Summary of patient's diagnosis and corresponding ICD-10-CM code(s)
    - **Click here** for a list of ICD-10-CM codes
  - Summary of patient's treatment history, if applicable, such as for second-line or later treatments
  - 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:**
  - Medical records and clinical notes that support treatment with SCEMBLIX
  - Appropriate clinical information from the Prescribing Information for SCEMBLIX
  - Include SCEMBLIX Prescribing Information as reference
  - Disease-specific criteria, including information such as the following:
    - Diagnosis and the date of diagnosis
    - Test results
    - Lab results
    - If appropriate, disease-specific scores
    - Assessment of disease severity
    - List of previous therapies used, duration of therapy, and reason for discontinuation
- **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 the link below to download a customizable sample **Letter of Appeal** for your office in Word doc format

Appeal Letter

- Contact your dedicated Associate Director, Access & Reimbursement (ADAR)—they can help you identify and understand plan requirements and coverage criteria
- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in the Novartis Patient Support program

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Peer-to-Peer Checklist

If your patient's insurance provider has issued a denial of coverage for SCEMBLIX, you may have the option to appeal in writing or by phone via a peer-to-peer review. Because these peer-to-peer calls are done on a patient-by-patient basis, the following is designed to help you prepare for these calls.

Tips

- Request an expedited review with a like specialist (eg, oncologist, hematologist)
- Verify the date and time of the peer-to-peer review to ensure office staff availability
- In preparation for the call, it is important that you review your patient's denial of coverage letter and insurance plan so that you are aware of:
  - The specific reason(s) the claim was denied
  - The provision or stipulation in your patient's plan that supports the denial
  - The criteria for appealing and reversing the denial
- Because you are appealing on behalf of your patient, you should obtain:
  - Supporting documentation from your patient's medical records, including prior TKI use and reasons for discontinuation if the treatment is being prescribed for second-line or later use
  - Health plan information, including current coverage, covered benefits, exclusions, and limitations
  - All correspondence with the health plan, including denial of coverage letter and copies of relevant claims
- Preparing additional materials to support your recommendation for SCEMBLIX can be helpful and may include the following:
  - SCEMBLIX Prescribing Information
  - Current NCCN Guidelines for Chronic Myeloid Leukemia
  - Citations from relevant published studies
  - Any other available evidence
  - State-specific laws (eg, step-therapy legislation)

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

Peer-to-Peer Checklist (cont)

Tips (cont)

What to Prepare: A Pre-call Checklist

- **During the call, make sure you:**
  - Review your patient's medical history based on the plan's PA criteria and explain the rationale behind your recommendation for SCEMBLIX as it relates to your patient's current condition and, if relevant, any prior therapies
  - Discuss pertinent SCEMBLIX clinical information, including efficacy and safety demonstrated in clinical trials
  - Present medical justification for bypassing the plan's formulary in prescribing SCEMBLIX, including clinical research, appropriate treatment guidelines, and other supportive evidence
- **Present your case in accordance with the insurance plan's policy, appeals process, utilization management/PA criteria, and time frame**
- **Keep the call brief and only discuss relevant information**

This guidance is meant to facilitate your preparation for calls with the medical director of the insurance plan for your patients for whom you have prescribed SCEMBLIX. This document is not intended to provide comprehensive or exhaustive guidance, nor does it guarantee that if you follow these steps, your call or appeal will be successful.

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Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

Sample Letters

Click the links below to download customizable letters for your office in Word document format:

Physician Letters

Letter of Medical Necessity

Appeal Letter

Novartis Patient Support

Patients are our top priority

Not an actual Novartis Patient Support Team member.

Novartis Patient Support provides comprehensive resources to help patients start and stay on SCEMBLIX.

We'll help get your patients started and guide them along the way with:

- Dedicated assistance with insurance and reimbursement
- Personalized support for your patients on therapy
- Single point of contact for you and your patients

Our offerings include:

Insurance Support

We help to minimize the hassle of navigating insurance and reimbursement barriers.

Financial Support

We connect and deliver relevant saving options to your patients.

Patients prescribed SCEMBLIX may be eligible to receive the $0* Co-Pay Plus offer and up to a free 30-day supply,† which will allow them to start their prescribed treatment quickly. Program rules may vary.

Ongoing Support

We provide resources and ongoing, personalized support to help your patients along their treatment journey.

Questions?

Call Novartis Patient Support at **866-433-8000**, Monday through Friday from 8:00 AM to 8:00 PM ET, excluding holidays.
Visit the **SCEMBLIX website** for more information.

***Limitations apply.** Up to a $15,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Novartis reserves the right to rescind, revoke, or amend this program without notice.

†**No purchase required.** This free trial is not health insurance. Void where prohibited by law. Valid only in the US and Puerto Rico. Claims shall not be submitted to any public or private third-party payer or any federal or state health care program for reimbursement. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this offer without notice. Additional limitations apply. See full Terms & Conditions for details.

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SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Glossary

- **Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage
- **Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other health care services
- **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 United States
- **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 non-preferred 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
- **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 plans' 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

Please see Important Safety Information on pages 15-16 and click here for full Prescribing Information.

SCEMBLIX 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 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

Please click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

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 click here for full Prescribing Information.

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SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080