Authorization and Appeals Guide

to Support Patient Access to SCEMBLIX

This guide was designed to help you and your practice optimize communications with health plans and facilitate access to SCEMBLIX for your patients, quickly and efficiently.

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.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX®
(asciminib) 20 mg, 40 mg tablets

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SCEMBLIX INDICATION 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

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Key Clinical Data

Clinical Considerations for SCEMBLIX

The following section includes information that can help you advocate for coverage for your patients who are clinically appropriate candidates for SCEMBLIX. You'll find "key considerations" throughout the section, which can help you as you fill out prior authorization (PA) forms for those patients.

SCEMBLIX is indicated for the treatment of adult patients with:

Ph+ CML in CP, previously treated with ≥2 TKIs

Recommended dosage[1]

80 mg qd

OR

40 mg bid

AM + PM

Ph+ CML in CP with the T315I mutation

Recommended dosage[1]

200 mg bid

AM + PM

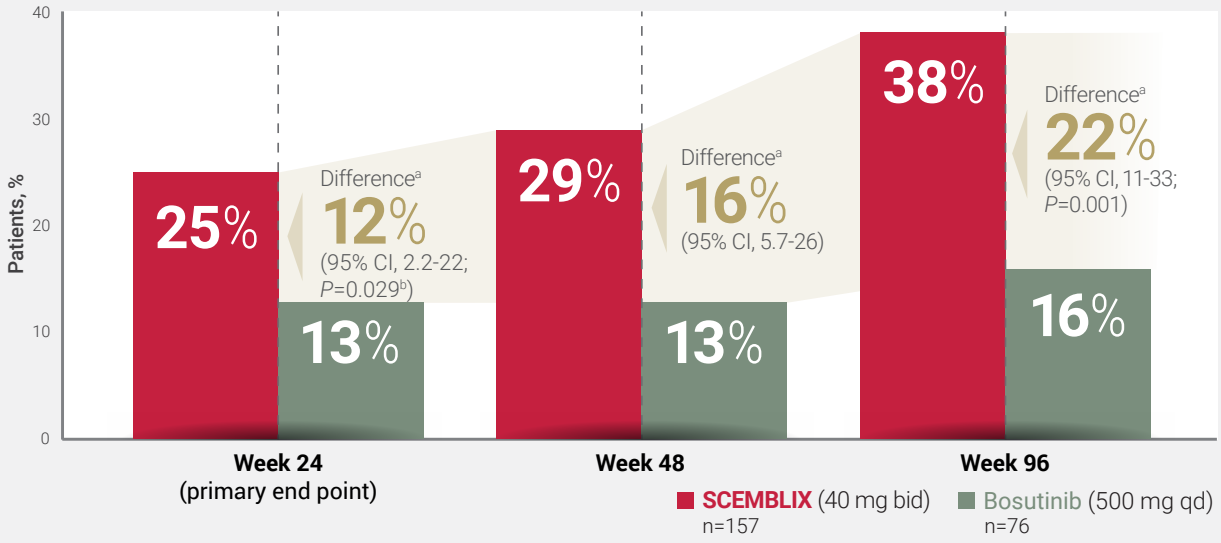
bid, twice a day; CML, chronic myeloid leukemia; CP, chronic phase; Ph+, Philadelphia chromosome-positive; qd, once daily; TKI, tyrosine kinase inhibitor.

SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP, Previously Treated With ≥2 TKIs[1]

ASCEMBL is a multicenter, randomized, active-controlled, open-label study assessing the efficacy and safety of SCEMBLIX vs bosutinib.[1,2]

The MMR benefit with SCEMBLIX vs bosutinib increased over time.[1]

MMR rate [1,3]



- Median follow-up was 28 months.[1]

MMR was defined as *BCR::ABL1*^{IS} ≤0.1%.[1]
The median duration of treatment was 24 months (range: 0 to 46 months) for patients receiving SCEMBLIX and 7 months (range: 0 to 43 months) for patients receiving bosutinib.[1]

[a]Estimated using a common risk difference stratified by baseline MCyR status.
[b]Estimated using a Cochran-Mantel-Haenszel 2-sided test stratified by baseline MCyR status.

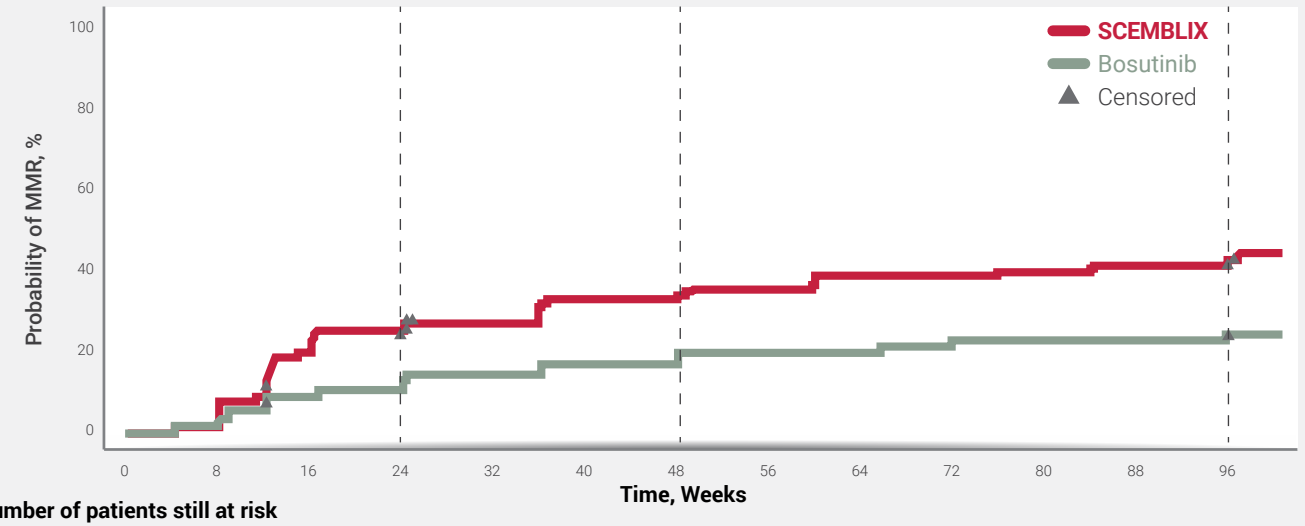
SCEMBLIX more than doubled the MMR rate (38% vs 16%) at Week 96 vs bosutinib[1]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP, Previously Treated With ≥2 TKIs[1] (cont)

At 96 Weeks, SCEMBLIX Demonstrated Durable Response Rates

Cumulative incidence of MMR[3]



Number of patients still at risk

SCEMBLIX	157	145	108	89	64	51	49	42	35	30	28	24	24
Bosutinib	76	66	52	41	22	15	11	10	9	8	6	6	6

Cumulative number of competing events

SCEMBLIX	0	8	17	27	44	49	51	54	56	61	62	64	64
Bosutinib	0	8	16	25	42	47	50	50	51	51	52	52	52

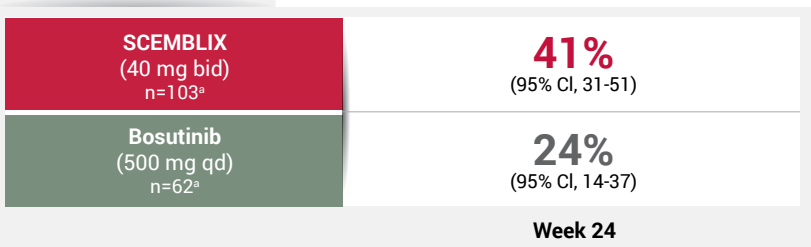
Percentages of patients who had previously received 2, 3, 4, or 5 or more prior lines of TKIs were 48%, 31%, 15%, and 6%, respectively.[1]

Almost all patients on SCEMBLIX who achieved MMR maintained it for more than 16 months (97% probability).[3]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

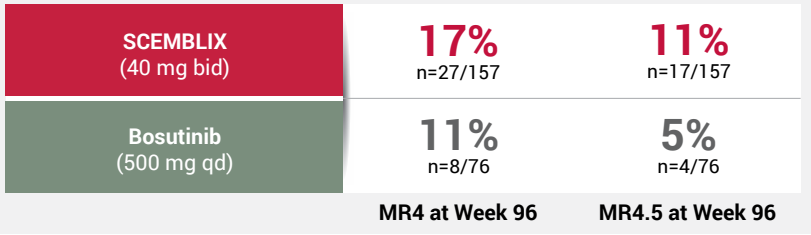
SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP, Previously Treated With ≥2 TKIs[1] (cont)

CCyR rate[1]



The CCyR rate at Week 96 was 40% (95% CI, 30-50) in patients receiving SCEMBLIX and 16% (95% CI, 8-28) for bosutinib. Note that any patients who achieved CCyR and later achieved MMR would not have been assessed for CCyR at Week 96. Of patients achieving CCyR during the study, 1 patient in the SCEMBLIX arm and 2 patients in the bosutinib arm lost response.[1,3]

MR4 and MR4.5 rates[3]



MR, molecular response.
MR4 is defined as *BCR::ABL*^{IS} ≤0.01%.[2]
MR4.5 is defined as *BCR::ABL*^{IS} ≤0.0032%.[2]
[a]CCyR analysis based on patients who were not in CCyR at baseline.

More patients achieved MR4 and MR4.5 at Week 96 with SCEMBLIX vs bosutinib[3]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP, Previously Treated With ≥2 TKIs[1] (cont)

A higher proportion of patients were still on SCEMBLIX at Week 96[3]

Proportion of patients still on treatment at the Week 96 analysis[3]

SCEMBLIX	Bosutinib
54%	20%
n=84/157	n=15/76

Discontinuation rate due to adverse reactions was more than 3 times lower with SCEMBLIX vs bosutinib[1,3]

Discontinuation rates due to adverse reactions at the Week 96 analysis[1,3]

SCEMBLIX	Bosutinib
8%	26%
n=12/156	n=20/76

- 6% of patients on SCEMBLIX (n=10/156) required dose reduction due to adverse reactions vs 28% on bosutinib (n=21/76)[1,4]
- 41% of patients on SCEMBLIX (n=64/156) required dose interruption due to adverse reactions vs 58% on bosutinib (n=44/76)[1,4]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP, Previously Treated With ≥2 TKIs[1] (cont)

All-grade adverse reactions (occurring in ≥10% of patients in any treatment arm) at the Week 96 analysis[1]

	SCEMBLIX (n=156)		Bosutinib (n=76)	
Adverse reaction	**All grades %**	**Grade 3 or 4 %**	**All grades %**	**Grade 3 or 4 %**
URTI[a]	26	0.6	12	1.3
Musculoskeletal pain[b]	24	2.6	17	1.3
Headache[c]	21	1.9	16	0
Fatigue[d]	20	0.6	11	1.3
Rash[e]	18	0.6	30	8
Hypertension[f]	14	7	5	3.9
Abdominal pain[g]	14	0	24	2.6
Diarrhea[h]	13	0	72	11
Arthralgia	13	0.6	3.9	0
Nausea	12	0.6	46	0

Serious adverse reactions occurred in 18% of patients who received SCEMBLIX. Serious adverse reactions in ≥1% included cardiac failure congestive (1.9%), pyrexia (1.9%), urinary tract infection (1.9%), headache (1.3%), and thrombocytopenia (1.3%). Two patients (1.3%) had a fatal adverse reaction, one each for mesenteric artery thrombosis and ischemic stroke.[1]

URTI, upper respiratory tract infection.
[a]Upper respiratory tract infection includes: nasopharyngitis, upper respiratory tract infection, rhinitis, pharyngitis, respiratory tract infection, and pharyngotonsillitis.
[b]Musculoskeletal pain includes: pain in extremity, back pain, myalgia, non-cardiac chest pain, neck pain, bone pain, spinal pain, arthritis, musculoskeletal pain, and musculoskeletal chest pain.
[c]Headache includes: headache and post-traumatic headache.
[d]Fatigue includes: fatigue and asthenia.
[e]Rash includes: rash, rash maculopapular, dermatitis acneiform, rash pustular, eczema, dermatitis, skin exfoliation, dermatitis exfoliative generalized, rash morbilliform, drug eruption, erythema multiforme, and rash erythematous.
[f]Hypertension includes: hypertension and hypertensive crisis.
[g]Abdominal pain includes: abdominal pain, abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, and epigastric discomfort.
[h]Diarrhea includes: diarrhea and colitis.

Consider mentioning select adverse reactions that are important clinical factors for individual patient appeals

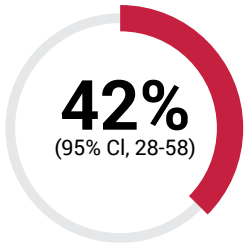
Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX for the Treatment of Adult Patients With Ph+ CML-CP With the T315I Mutation[1]

The clinical efficacy and safety of SCEMBLIX for the treatment of patients with Ph+ CML-CP with the T315I mutation were evaluated in a multicenter, open-label study.[1]

Efficacy in patients with the T315I mutation[1]

In a study of patients with the T315I mutation who received SCEMBLIX 200 mg bid:



of patients with the **T315I mutation achieved MMR** by 24 weeks (n=45)

MMR was achieved by 96 weeks in 49% (95% CI, 34-64) of the patients (n=45) treated with SCEMBLIX.[1]

The median duration of treatment was 108 weeks (range: 2 to 215 weeks).[1]

- MMR by Week 24 was achieved by 58% (n=11/19) in ponatinib-naive patients vs 31% (n=8/26) for patients pretreated with ponatinib[5]
- Percentages of patients who had previously received 1, 2, 3, 4, and 5 or more TKIs were 18%, 31%, 36%, 13%, and 2.2%, respectively[1]

Results from a study for the treatment of 185 patients with Ph+ CML-CP without (n=115) or with (n=70) the T315I mutation.
Patients received SCEMBLIX at doses ranging from 10 mg to 200 mg bid or 80 mg to 200 mg bid and continued treatment until unacceptable toxicity or treatment failure occurred.
These data represent patients with the T315I mutation who received SCEMBLIX 200 mg bid.[1]

Among the *BCR::ABL1* kinase domain mutations, the T315I confers complete resistance to imatinib, dasatinib, nilotinib, and bosutinib

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX Safety Profile in Patients With Ph+ CML-CP With the T315I Mutation

All-grade adverse reactions (in ≥10% of patients)[1]	SCEMBLIX[j] 200 mg bid (N=48)	
Adverse reaction	**All grades %**	**Grade 3 or 4 %**
Musculoskeletal pain[a]	42	4.2
Fatigue[b]	31	2.1
Nausea	27	0
Rash[c]	27	0
Diarrhea	21	2.1
Vomiting	19	6
Headache[d]	19	2.1
Abdominal pain[e]	17	8

All-grade adverse reactions (in ≥10% of patients)[1] (cont)	SCEMBLIX[j] 200 mg bid (N=48)	
Adverse reaction	**All grades %**	**Grade 3 or 4 %**
Arthralgia	17	0
Hemorrhage[f]	15	2.1
Cough[g]	15	0
Hypertension[h]	13	8
Pruritis	13	0
URTI[i]	13	0
Edema	10	4.2

Serious adverse reactions occurred in 23% of patients who received SCEMBLIX. Serious adverse reactions in >1% included abdominal pain (4.2%), vomiting (4.2%), pneumonia (4.2%), musculoskeletal pain (2.1%), headache (2.1%), hemorrhage (2.1%), constipation (2.1%), arrhythmia (2.1%), and pleural effusion (2.1%).[1]

[a]Musculoskeletal pain includes: pain in extremity, back pain, myalgia, musculoskeletal pain, noncardiac chest pain, bone pain, arthritis, and musculoskeletal chest pain.
[b]Fatigue includes: fatigue and asthenia.
[c]Rash includes: rash, rash maculopapular, dermatitis acneiform, eczema, rash papular, skin exfoliation, and dyshidrotic eczema.
[d]Headache includes: headache and migraine.
[e]Abdominal pain includes: abdominal pain and hepatic pain.
[f]Hemorrhage includes: epistaxis, ear hemorrhage, mouth hemorrhage, postprocedural hemorrhage, skin hemorrhage, and vaginal hemorrhage.
[g]Cough includes: cough and productive cough.
[h]Hypertension includes: hypertension and hypertensive crisis.
[i]URTI includes: upper respiratory tract infection, nasopharyngitis, rhinitis, and pharyngitis.
[j]The denominator used to calculate the rate was 48 based on the number of patients with a baseline value and at least one post-treatment value.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX Safety Profile in Patients With Ph+ CML-CP With the T315I Mutation (cont)

Select laboratory abnormalities (≥10%) that worsened from baseline[1]	SCEMBLIX[a] 200 mg bid	
Laboratory abnormality	**All grades %**	**Grade 3 or 4 %**
ALT increased	**48**	**6**
Potassium increased	**48**	**2.1**
Lipase increased	**46**	**21**
Triglycerides increased	**46**	**2.1**
Neutrophil count decreased	**44**	**15**
Hemoglobin decreased	**44**	**4.2**
Lymphocyte count decreased	**42**	**4.2**
Phosphate decreased	**40**	**6**
Uric acid increased	**40**	**4.2**

Select laboratory abnormalities (≥10%) that worsened from baseline[1] (cont)	SCEMBLIX[a] 200 mg bid	
Laboratory abnormality	**All grades %**	**Grade 3 or 4 %**
AST increased	**35**	**2.1**
Calcium corrected decreased	**33**	**0**
Creatinine increased	**31**	**0**
Amylase increased	**29**	**10**
Platelet count decreased	**25**	**15**
Bilirubin increased	**23**	**0**
Cholesterol increased	**15**	**0**
ALP increased	**13**	**0**

Serious adverse reactions occurred in 23% of patients who received SCEMBLIX. Serious adverse reactions in >1% included abdominal pain (4.2%), vomiting (4.2%), pneumonia (4.2%), musculoskeletal pain (2.1%), headache (2.1%), hemorrhage (2.1%), constipation (2.1%), arrhythmia (2.1%), and pleural effusion (2.1%).[1]

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase.
[a]The denominator used to calculate the rate was 48 based on the number of patients with a baseline value and at least one post-treatment value.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Key Considerations for Health Plans

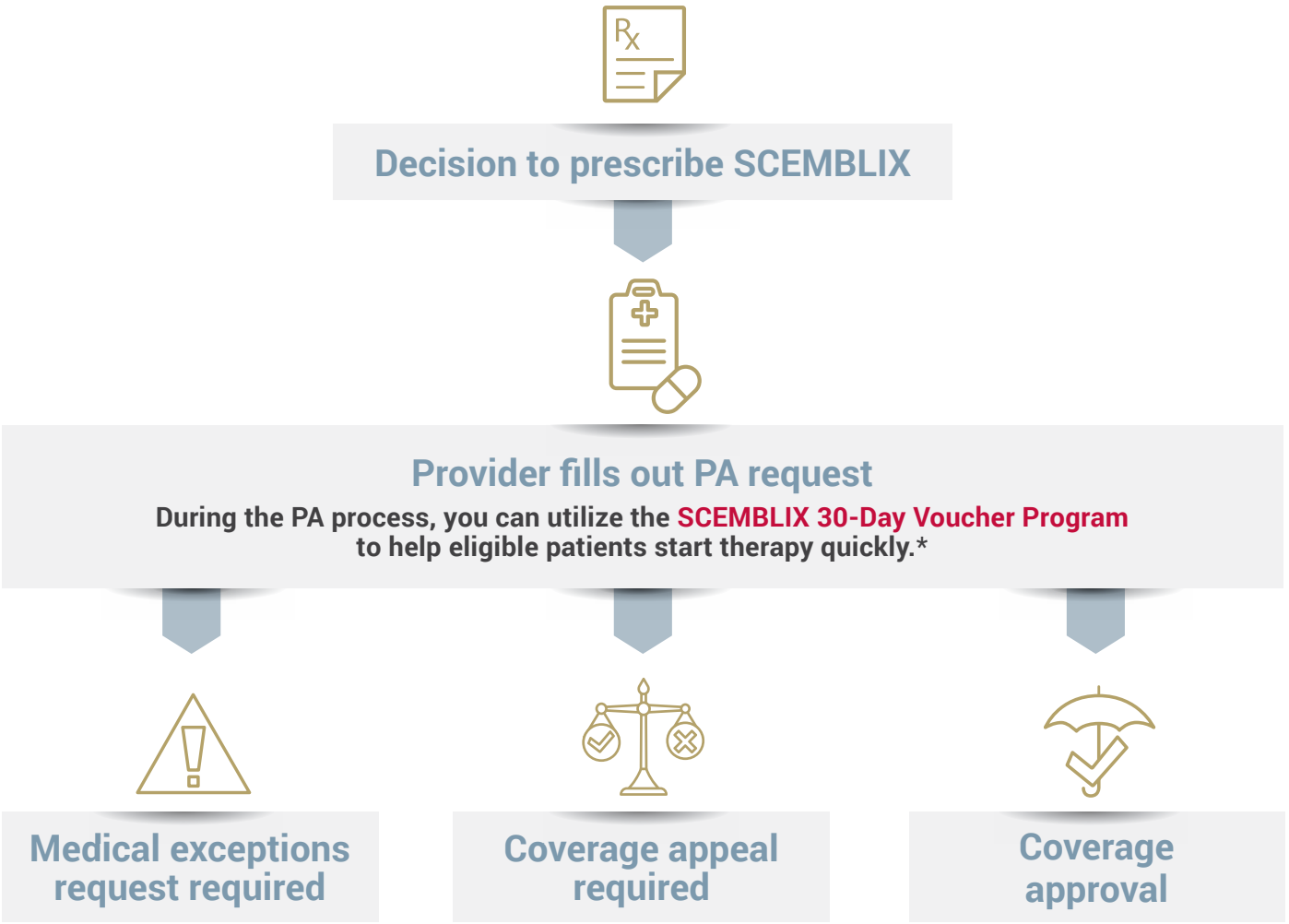
SCEMBLIX:

- More than doubled the MMR rate at Week 96 vs bosutinib in patients with 3L Ph+ CML-CP (38% vs 16%; difference: 22% [95% CI, 11-33; *P*=0.001])[1]
- More patients achieved CCyR at Week 24 with SCEMBLIX vs bosutinib (41% vs 24%; 95% CI, 3.6-31)[3]
- More patients achieved MR4 and MR4.5 at Week 96 with SCEMBLIX vs bosutinib (17% vs 11% and 11% vs 5%, respectively)[3]
- Demonstrated efficacy in patients with the T315I mutation who may have limited options

3L, third line.

Patient Access Support and Resources

The SCEMBLIX Patient Access Journey: Facilitating Patient Access



Click the icons
for more information and support resources for each step in the prescribing journey

*You may utilize Novartis Patient Assistance Now Oncology (PANO), which is a support center consisting of insurance specialists and case managers who provide access to information regarding an array of services.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Prescribing Details Support: Preparing to Prescribe SCEMBLIX

Once you've made the decision to prescribe SCEMBLIX, you have the option to complete a Service Request Form (SRF) through the Novartis Patient Assistance Now Oncology (PANO) program to receive additional support for your patient. Enrollment in the Novartis PANO program is not required but will ensure easier access to patient support services and may facilitate more timely initiation of SCEMBLIX.

While completing the SRF, be sure to include the appropriate ICD-10 and NDC codes. You'll need these codes to complete the PA request, as well as to prevent any issues with prescription fulfillment and/or reimbursement.

ICD-10 code*

Indication(s)	ICD-10 code	Description
Ph+ CML-CP in adult patients **previously treated with ≥2 TKIs**	C92.10	Chronic myeloid leukemia, *BCR::ABL1*-positive not having achieved remission
	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

*Appropriate patients for SCEMBLIX as per the prescribing information may be coded according to the billing codes on this page.

Click here for more information on the PANO program and to access the SRF.

PANO insurance specialists and case managers can support your patients with insurance benefits verification, including information on PAs and denial appeals.

TO LEARN MORE about what Novartis Oncology Patient Support can offer your patients, call 1-800-282-7630 or visit HCP.Novartis.com/Access.

ICD-10, International Classification of Diseases, Tenth Revision; NDC, National Drug Code.
REMEMBER: 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.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Prescribing Details Support: Specialty Pharmacy Network

SCEMBLIX is available for purchase at all licensed pharmacies. All orders must be placed with one of the specialty distributors listed below:

Distributors

ASD Healthcare Inc.	Cardinal Health	McKesson Specialty	McKesson Plasma and Biologics
800-746-6273	855-855-0708	855-477-9800	877-625-2566

How supplied/storage and handling

Strength of each tablet	Tablets per bottle	NDC
20-mg film-coated tablets	60 film-coated tablets	0078-1091-20
40-mg film-coated tablets	60 film-coated tablets	0078-1098-20

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) (see USP Controlled Room Temperature). Store in the original package to protect from moisture.[1]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX Patient Support: The Right Support at the Right Time

Novartis is committed to providing support to meet the needs of patients and caregivers. Novartis Oncology Patient Support is the single source for the tools your patients may need when appropriate. Below is an overview of the patient service and access support offerings for patients who have been prescribed SCEMBLIX:

Patient Navigator Program

The Novartis Patient Navigator Program is staffed by a dedicated team of specialists who support eligible patients during their treatment journey.* Patients who enroll in the program receive a series of phone calls from a specially trained navigator who will support and guide them through various aspects of initiating their prescribed therapy.

30-Day Voucher Program

If your patients have been prescribed SCEMBLIX, they may be eligible to receive up to a 30-day free supply, which will allow them to start their prescribed treatment quickly. Program rules may vary.

$0 Universal Co-pay Card

Your patients may be eligible for immediate co-pay savings on their next prescription of SCEMBLIX. Eligible patients with private insurance may pay $0 per month. Novartis will pay the remaining co-pay, up to $15,000 per calendar year, per product.†

PANO

Patient Assistance Now Oncology (PANO) is a support center consisting of insurance specialists and case managers who provide access to information regarding an array of services. Consider PANO your first stop for information about Novartis Oncology Patient Support services. Dedicated support specialists help direct callers to the services that best fit their needs.

For more information about the patient support services available for SCEMBLIX, please see the Patient Services and Access Support Guide.

*The Novartis Patient Navigator Program is available for select Novartis Oncology products. Patient Navigator services do not involve the practice of nursing or provide clinical advice and counseling.
†Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit Copay.NovartisOncology.com or call 1-877-577-7756.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

PA Support: Common PA Requirements

Most health plans require a PA for SCEMBLIX. Proper completion of PA forms may prevent coverage delays and may facilitate a timely and efficient approval process. Refer to your patient's prescription insurance provider or health plan for specific PA forms or requirements for access to SCEMBLIX.

Common PA requirements

Patient Information

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

Summary of Diagnosis

- Documented Ph+ CML-CP diagnosis (ICD-10-CM) and date of diagnosis
- Documented CML mutation status

Previous Treatment History

- Documented treatment failure on ≥2 other TKIs
- List of previously administered treatments (eg, TKI therapies)
  Note: Document response to the treatments, reason for discontinuation, and treatment duration

Rationale for Treatment

- **A clear summary statement citing the rationale for treatment** with SCEMBLIX and reason(s) why other treatments may not be appropriate
- **Rationale and clinical support for your recommendation,** such as:
  - Intolerability of and/or resistance to other TKIs
  - Applicable therapy guidelines
  - Efficacy and safety trial data from ASCEMBL and/or X2101 clinical trials
  - Patient medical records (including Sokal risk score)
  - Contraindications to other TKIs

Refer back to the Key Clinical Data section for clinical data that might be important to include in PAs

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

Be sure to provide your contact information, including a phone number, when sending the PA documentation.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

PA Support: Sample PA Letter

[Date]

[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State Zip]

Re: [Patient's Name]
Patient DOB: [MM/DD/YYYY] [Type of Insurance]
Group/Policy Numbers: [XXXXXX] Subscriber ID Number: [XXX-XX-XXXX]

To Whom It May Concern:

This letter is being submitted for the prior authorization of SCEMBLIX® (asciminib) tablets, on behalf of the above referenced patient for the treatment of Ph+ CML-CP [ICD-10 code]. The authorization requested is for the current date of [date] through the date of [future date].

Sincerely,

[Your name]
[Your street address, email address, office phone number, fax number, cell phone number]

PA Support: Steps to Take if PA Form Is Incomplete

In cases where the initial request for coverage of SCEMBLIX has been denied by the insurance company, the first step is to review the reason for denial and make certain the initial request was submitted with complete information and clinical rationale for use of SCEMBLIX.

In addition, you should request a copy of the denial letter to better understand the reasons for the denial.

Common Information Missing on PA

- Patient medical history (age, sex, policy number)
- Diagnostic code (ICD-10)
- History of previous TKI therapies and documentation of treatment failure due to lack of response or intolerability
- Additional clinical information requested on the PA form

This information can be corrected and resubmitted to the insurance company for reconsideration of coverage.

If a health plan has not developed a policy for SCEMBLIX yet, you should be able to use the oral oncology PA form found on a plan's website

Medical Exceptions Support:
Steps to Take if SCEMBLIX Is Not on a Health Plan's Formulary

There may be cases when a health plan imposes an NDC block on new products. A letter of medical necessity can be used when SCEMBLIX is not listed on the plan's formulary or if the plan has implemented an NDC block. In some cases, the plan may be in the process of reviewing SCEMBLIX for addition to the formulary and access may not be available immediately.

If SCEMBLIX is not covered on the formulary and you believe treatment is medically necessary for your patient, you may:

INITIATE

A **medical exceptions appeal** by submitting a Letter of Medical Necessity to the plan along with a copy of the patient's relevant medical records.

You may refer to the PA Checklist for a summary of pertinent clinical information that may be included in your medical necessity letter to support treatment with SCEMBLIX.

REQUEST

A **peer-to-peer review** with the plan's medical director. In a peer-to-peer review, the prescriber may request to speak with the plan's medical director and engage in a clinical discussion regarding the medical necessity for SCEMBLIX and an appropriate treatment plan for the patient.

You may refer to the Peer-to-Peer Checklist to help you prepare for this discussion.

SUBMIT

A **formulary exception request** for patients with Medicare coverage.

APPLY

For **patient assistance** through various patient advocacy programs if all other coverage attempts have been exhausted.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Medical Exceptions Support:
Steps to Take if SCEMBLIX Is Not on a Health Plan's Formulary (cont)

Many payers will allow up to 3 levels of appeals for PA denials. For second- and third-level appeals, it may be helpful to include:

- The original letter of denial
- Specific medical notes in response to the denial (a third level of appeal may include review by an independent non–insurance-affiliated external review board or hearing)
- Peer-reviewed journal articles or clinical practice guidelines referencing nationally recognized guidelines

Contact the plan for specific guidance or refer to the plan's website to access a formulary exception request form.

For patients with Medicare coverage, a Formulary Exception may be requested to obtain SCEMBLIX if it is not covered by the plan's formulary or to request having a utilization management requirement waived (eg, step therapy, PA, quantity limit).

The formulary exception request form should accompany a Letter of Medical Necessity and a copy of the patient's relevant medical records.

Letter of Medical Necessity

This sample letter is provided for your guidance only. It provides an example of the types of information that may be provided when responding to a request from a patient's insurance company to provide a letter of appeal for SCEMBLIX. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for SCEMBLIX and is not intended to be a substitute for or to influence the independent medical judgment of the physician.

[Date]

[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State Zip]

Re: [Patient's Name]
Patient DOB: [MM/DD/YYYY] [Type of Insurance]
Group/Policy Numbers: [XXXXXX] Subscriber ID Number: [XXX-XX-XXXX]

To Whom It May Concern:

I am writing on behalf of [patient name] to document the medical necessity for administering SCEMBLIX® (asciminib) tablets for the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).

Diagnosis:

☐ [Ph+ CML-CP including additional genetic mutations, if applicable]

Tried/failed therapies:

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure]

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure]

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure]

(cont on next page)

Letter of Medical Necessity (cont)

Rationale for SCEMBLIX:

- ☐ Current laboratory values/test result assessments
- ☐ Contraindications to other TKIs
- ☐ Unable to tolerate common adverse reactions of other TKIs

[Add additional notes, if needed]

In 2021, the US Food and Drug Administration (FDA) approved the use of SCEMBLIX for the treatment of adult patients with Ph+ CML in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs) and adult patients with Ph+ CML-CP with the T315I mutation.

I have included [materials/evidence] supporting the use of SCEMBLIX to treat CML for [patient's name]. [Include a brief explanation of how the materials/evidence support your reasoning].

[Add additional notes, if needed]

Given my knowledge of [patient's name] medical condition and [his/her] treatment history, I believe SCEMBLIX is medically necessary and most appropriate for my patient at this time. I ask that you consider the above information in your coverage decision. Should you have any questions, please do not hesitate to contact me at [office/cell phone number] or [email address].

Sincerely,

[Your name]
[Your street address, email address, office phone number, fax number, cell phone number]

Enclosures:
[Excerpts of medical records]
[Journal or peer literature supporting the service in question]
[SCEMBLIX full Prescribing Information]

Coverage Appeals Support: Steps to Take if Policy Criteria Have Not Been Met

Some plans may require patients to try and fail additional therapies prior to approval of coverage of SCEMBLIX. In other situations, the PA criteria for SCEMBLIX may not have been met. If you believe treatment is medically necessary for your patient, you may:

SUBMIT

A Coverage Appeals Letter and provide the documentation necessary to support treatment with SCEMBLIX, including a copy of the patient's relevant medical records and a Letter of Medical Necessity. There can be multiple levels of appeal.

Please refer to the plan's specific appeal guidelines.

INITIATE

A **medical exceptions appeal** by submitting a Letter of Medical Necessity to the plan along with a copy of the patient's relevant medical records.

You may refer back to the PA Checklist for a summary of pertinent clinical information that may be included in your medical necessity letter to support treatment with SCEMBLIX.

REQUEST

A **peer-to-peer review** with the plan's medical director. In a peer-to-peer review, the prescriber may request to speak with the plan's medical director and engage in a discussion regarding the medical necessity for SCEMBLIX and an appropriate treatment plan for the patient.

You may refer to the Peer-to-Peer Checklist to help you prepare for this discussion.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Coverage Appeals Letter

This sample letter is provided for your guidance only. It provides an example of the types of information that may be provided when responding to a request from a patient's insurance company to provide a letter of appeal for SCEMBLIX. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for SCEMBLIX and is not intended to be a substitute for or to influence the independent medical judgment of the physician.

[Date]

ATTN: Appeals Department
[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State ZIP]

Re: [Patient's Name]
Patient DOB: [MM/DD/YYYY] [Type of Insurance]
Group/Policy Numbers: [XXXXXX] Subscriber ID Number: [XXX-XX-XXXX]

To Whom It May Concern: [If you have the name of the Appeals Coordinator, use "Dear (name)],

This is a formal appeal of the prior authorization denial of SCEMBLIX® (asciminib) tablets, for my patient, [name].
I have reviewed your letter with my patient and the reason for denial: [include denial details from letter]. I continue to recommend SCEMBLIX as my treatment of choice in this case based on my experience treating adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP), as well as my knowledge of this patient and this patient's continued disease activity. In support of our appeal, medical records have been included for your review. They indicate the following:

Diagnosis:

☐ [Ph+ CML-CP including additional genetic mutations, if applicable]

Tried/failed therapies:

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure (intolerability, resistance)]

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure (intolerability, resistance)]

☐ [Name of therapy
–Dosage form
–Duration of therapy
–Reason for failure (intolerability, resistance)]

Rationale for SCEMBLIX:

☐ Current laboratory values/test result assessments

☐ Contraindications to other TKIs

☐ Unable to tolerate common AEs of other TKIs

(cont on next page]

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Coverage Appeals Letter (cont)

[Add additional notes, if needed]

In 2021, the US Food and Drug Administration (FDA) approved the use of SCEMBLIX for the treatment of adult patients with Ph+ CML in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs) and adult patients with Ph+ CML-CP with the T315I mutation.

I have included [materials/evidence] supporting the use of SCEMBLIX to treat Ph+ CML-CP for [patient's name]. [Include a brief explanation of how the materials/evidence support your reasoning].

[Add additional notes, if needed]

It is my expert opinion as [patient's name] oncologist that SCEMBLIX is medically necessary for this patient at this time. I may be reached at [phone number] or [email] should you require additional information on this patient.

Otherwise, I look forward to your positive response to this appeal.
Sincerely,

[Your name]
[Your street address, email address, office phone number, fax number, cell phone number]

Enclosures:
[Excerpts of medical records] [Journal or peer literature supporting the service in question]
[SCEMBLIX full Prescribing Information]

Peer-to-Peer Checklist

Not actual providers

Best Practices for Peer-to-Peer Call Preparation

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 types of discussions are done on a patient-by-patient basis, this resource is designed to help you prepare for these calls.

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.

Peer-to-Peer Checklist (cont)

What to Prepare: a Pre-call Checklist

Because you are appealing on behalf of your patient, you should obtain:

- ☐ The most recent and accurate coverage information about your patient's specific health plan
- ☐ General information about your patient's covered benefits, including the plan's exclusions and limitations
- ☐ The plan's PA criteria
- ☐ The appeal procedures, requirements, forms, time frames, and deadlines
- ☐ Denial of coverage letter received from your patient's insurance plan
- ☐ Copies of all relevant claims and correspondence to or from the plan

To support your recommendation for SCEMBLIX, you should prepare:

- ☐ Supporting documentation from your patient's medical records, including prior therapy use and reasons for discontinuation
- ☐ Supporting evidence of medical necessity
- ☐ Additional materials that may be helpful, including:
  - ☐ Citations from relevant published studies
  - ☐ Current treatment guidelines
  - ☐ SCEMBLIX package insert
  - ☐ SCEMBLIX Authorizations and Appeals Guide
  - ☐ Any other available evidence
  - ☐ State-specific laws (eg, step-therapy legislation)

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Peer-to-Peer Checklist (cont)

How to Improve Your Chances of Success

The typical peer-to-peer call lasts only 5 to 10 minutes. Within this short window of time, it is important to present a sound clinical justification to the plan's medical director, appropriately address the denial of coverage, and potentially gain approval for the use of SCEMBLIX for your patient.

Your appeal will have a greater chance of success if your case is presented in accordance with the insurance plan's policy, appeals process, utilization management/PA criteria, and time frame.

Therefore, 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 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

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 prior therapy use
- ☐ 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

The closer your case aligns with the plan's explicit coverage guidelines and the more justified the medical necessity is for initiating treatment with SCEMBLIX, the greater the likelihood of gaining coverage for your patient.

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

Important Safety Information

Please see Important Safety Information on pages 32-34 and click here for full Prescribing Information.

SCEMBLIX INDICATION 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 34 and click here for full Prescribing Information.

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

Please see additional Important Safety Information starting on page 33 and click here for full Prescribing Information.

Contact your Novartis Sales Representative or Reimbursement Specialist directly
or call 1-800-282-7630 about support services your patient may be eligible for.

Novartis PANO representatives are available and committed to supporting your access to patient support resources
and to facilitating timely access to SCEMBLIX for your patients.
Call 1-800-282-7630 or visit www.hcp.novartis.com/access
for more details on the resources available to you and your staff.

References: 1. Scemblix [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp. **2.** Réa D, Mauro M, Boquimpani C, et al. *Blood*. 2021;138(21):2031-2041. **3.** Data on file. CABL001A2301 clinical study report. Novartis Pharmaceuticals Corp; 2022. **4.** Data on file. CABL001A Week 96 SCS. Novartis Pharmaceuticals Corp; 2022. **5.** Data on file. ABL001 Investigator's Brochure. Novartis Pharmaceuticals Corp; 2021.

Please see Important Safety Information on pages 32-34
and click here for full Prescribing Information.

NOVARTIS

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080