

FOR ADULTS WITH NEWLY DIAGNOSED OR PREVIOUSLY TREATED Ph+ CML-CP



CML IN REAL LIFE

TOUGH ON CML Good fit for Jen

Individual results may vary.

Jen has tried multiple TKIs.
Jen was compensated for
her time.

JEN | Real SCEMBLIX patient

NEWLY DIAGNOSED WITH Ph+ CML-CP? SCEMBLIX MAY BE YOUR NEXT STEP

Leukemia experts recommend asciminib (SCEMBLIX) as an option
for adults with newly diagnosed Ph+ CML in chronic phase*

Ph+ CML-CP, Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase; TKI, tyrosine kinase inhibitor.

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.1.2026. ©National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed July 16, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

APPROVED USES

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
- The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby



Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15.



**"IF YOU'RE NEWLY
DIAGNOSED, MY NUMBER
1 PIECE OF ADVICE IS
ALWAYS TO TALK TO YOUR
HEALTH CARE TEAM. ASK
QUESTIONS. BECAUSE THAT'S
WHAT THEY'RE THERE FOR."**

KAT
Real SCEMBLIX patient

Kat has tried multiple TKIs.
Kat was compensated for her time.

IMPORTANT SAFETY INFORMATION (continued)

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you: (continued)

Females who are able to become pregnant:

- Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
- You should use effective birth control (contraception) during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

 **SCEMBLIX®**
(asciminib) 20 mg, 40 mg tablets

TAKE AN ACTIVE ROLE IN YOUR TREATMENT DISCUSSIONS

You didn't choose this diagnosis, but you can help choose how to manage it. **Your first treatment is an important decision.** Your health care team wants to hear from you from the start. Ask about your options to help set clear goals and a treatment plan that is right for you.



What is Ph+ CML in chronic phase (CP)?

The chronic phase of CML is the earliest and most manageable phase of this cancer that affects the blood and bone marrow (a tissue that creates blood cells). If the condition is properly treated and managed, many patients can expect to live a normal lifespan.

Ph+ CML occurs in the body when 2 chromosomes fuse abnormally. This creates a new, atypical chromosome: the Philadelphia (Ph) chromosome.

The Ph chromosome creates the abnormal *BCR::ABL1* fusion gene, which generates an abnormal protein, BCR-ABL1. This protein causes uncontrolled growth of abnormal white blood cells, also known as leukemic cells.



What are tyrosine kinase inhibitors (TKIs)?

Tyrosine kinase inhibitors are oral medications approved to treat people with Ph+ CML-CP, including those newly diagnosed.

Not all TKIs are the same—you and your health care team may decide to switch to a different TKI if your treatment goals aren't reached or you experience unmanageable side effects.

Ask your health care team about SCEMBLIX.

IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

Taking SCEMBLIX with certain other medicines may affect each other causing side effects and may affect the way that SCEMBLIX works.





IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including:

- Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection



START ON A TREATMENT THAT MAY HELP YOU ACHIEVE YOUR TREATMENT GOALS

When setting treatment goals, you and your health care team should consider how well the medication is working and its possible side effects. Your health care team will monitor your blood regularly to see if your medication is helping you reach certain milestones. A key measure is the **BCR::ABL1** level in your blood: the lower, the better.

Measuring response

- **Major molecular response (MMR)** is achieved when the *BCR::ABL1* gene level in your blood has decreased by at least 1,000 times compared to the level measured at diagnosis
- **Deep molecular response (DMR)** is the next milestone after MMR. This is where the response is 10 times larger than MMR. DMR is reached when the abnormal gene level in the blood has decreased by at least 10,000 times (4-log reduction, also called MR4) compared to the level measured at diagnosis



Leukemia experts recognize MMR at Year 1 as an important milestone for patients with CML*

Treatment response milestones

Based on the body of evidence across TKI therapies in CML, reaching MMR in the first year has been associated with:

- Very low probability of loss of response to treatment
- High likelihood of reaching DMR afterward



**VISIT SCEMBLIX.COM TO
LEARN MORE ABOUT Ph+ CML-CP**

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.1.2026. ©National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed July 16, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

- **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of inflammation of the pancreas (pancreatitis). Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have severe stomach-area (abdominal) pain or discomfort, nausea, or vomiting



In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

SCEMBLIX HAD BETTER RESPONSE RATES THAN COMMONLY USED TKIs*

More people reached MMR at 48 and 96 weeks

For adults with newly diagnosed Ph+ CML-CP, SCEMBLIX is the only medication that was compared against all commonly used TKIs: GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). To learn more about this study, visit www.scemblix.com

Percentage of people who achieved MMR (see page 5 for more about MMR)

SCEMBLIX vs Commonly Used TKIs*

~2 out of 3 patients on
SCEMBLIX reached MMR

~3 out of 4 patients on
SCEMBLIX reached MMR

68%
(136 of 201 patients)
SCEMBLIX

49%
(100 of 204 patients)
commonly
used TKIs*

74%
(149 of 201 patients)
SCEMBLIX

52%
(106 of 204 patients)
commonly
used TKIs*

at 48 weeks

at 96 weeks

SCEMBLIX vs GLEEVEC

~2 out of 3 patients on
SCEMBLIX reached MMR

~3 out of 4 patients on
SCEMBLIX reached MMR

69%
(70 of 101 patients)
SCEMBLIX

40%
(41 of 102 patients)
GLEEVEC

76%
(77 of 101 patients)
SCEMBLIX

47%
(48 of 102 patients)
GLEEVEC

at 48 weeks

at 96 weeks

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

IMPORTANT SAFETY INFORMATION (continued)

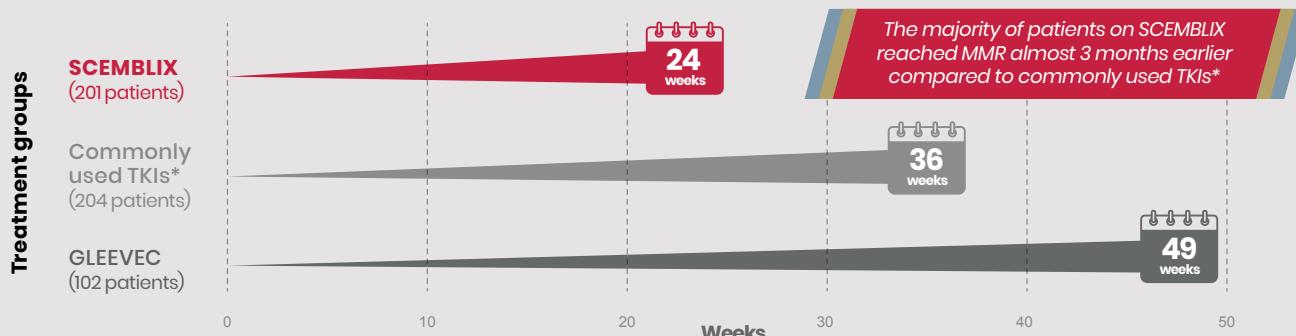
SCEMBLIX may cause serious side effects, including: (continued)

- **High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop high blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath

 **SCEMBLIX®**
(asciminib) 20 mg, 40 mg tablets

SCEMBLIX WORKED FAST

**The time by which half of the patients in each group
achieved major molecular response (MMR)**



*Data on file. NPS analysis of IQVIA SCEMBLIX OOP landscape readout on May 2025. Novartis Pharmaceuticals Corp; 2025

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

- Allergic reaction:** Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:
 - trouble breathing or swallowing
 - swelling of the face, lips, or tongue
 - skin rash or flushing of your skin
 - feeling dizzy or faint
 - fever
 - fast heartbeat



In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

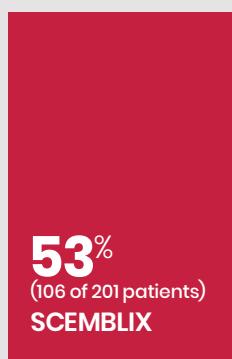
ANOTHER MILESTONE WAS STUDIED WITH SCEMBLIX AND COMMONLY USED TKIs*

MR4 rates by 48 weeks:

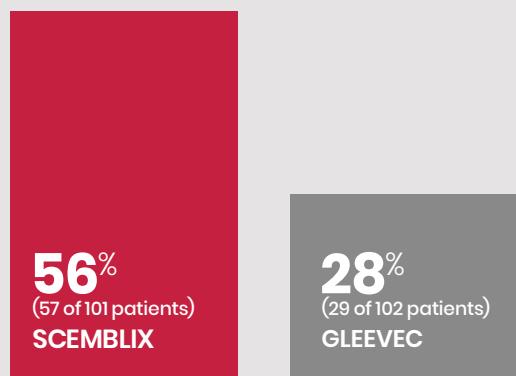
- 41% (82 of 201 patients) on SCEMBLIX and 22% (45 of 204 patients) on commonly used TKIs*
- 46% (46 of 101 patients) on SCEMBLIX and 16% (16 of 102 patients) on GLEEVEC

MR4 rates by 96 weeks

SCEMBLIX vs Commonly Used TKIs*



SCEMBLIX vs GLEEVEC



*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib).
Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

Ask your health care team to consider
SCEMBLIX for your first treatment.

IMPORTANT SAFETY INFORMATION (continued)

SCEMBLIX may cause serious side effects, including: (continued)

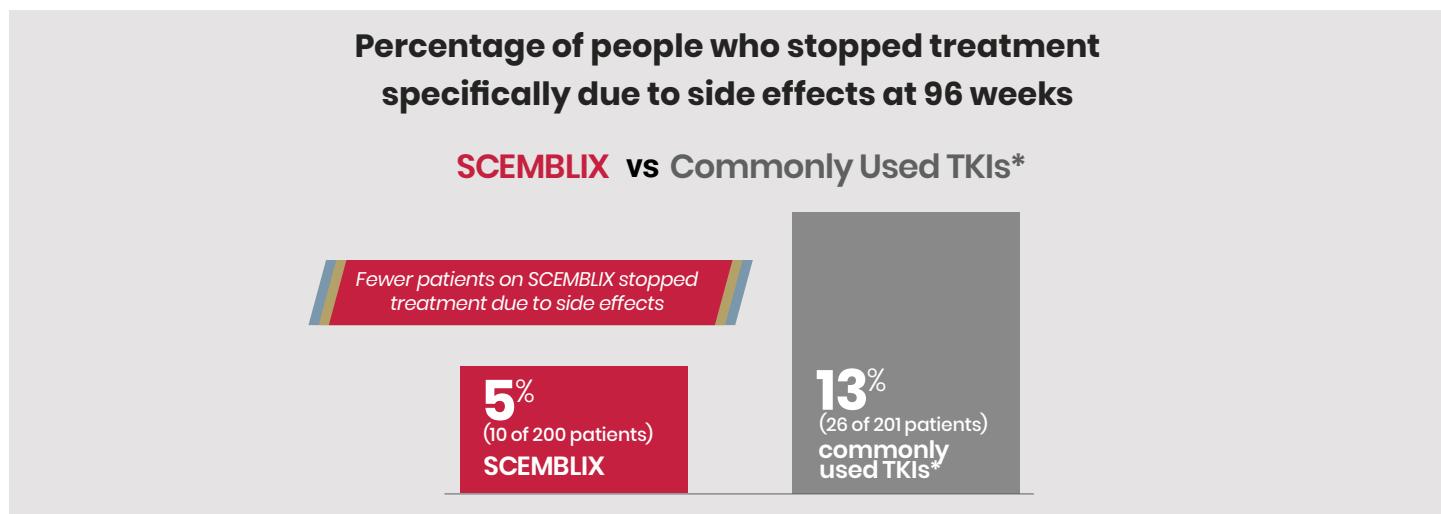
• **Heart and blood vessel (cardiovascular) problems:** SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots or blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. In the majority of cases, these heart and blood vessel problems happened in people with risk factors or a history of these problems, and previously treated with other tyrosine kinase inhibitor (TKI) medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:

- shortness of breath
- chest pain or pressure
- a feeling like your heart is beating too fast or you feel abnormal heartbeats
- swelling in your ankles or feet
- dizziness
- weight gain
- numbness or weakness on one side of your body
- decreased vision or loss of vision
- trouble talking
- pain in your arms, legs, back, neck, or jaw
- headache
- severe stomach-area (abdominal) pain



MORE PEOPLE WERE ABLE TO STAY ON SCEMBLIX THAN COMMONLY USED TKIs* BY 96 WEEKS

With a minimum of 96 weeks of follow-up, 82% of people on SCEMBLIX were still on treatment compared to 60% of people on commonly used TKIs.*



*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

COMMON SIDE EFFECTS

In this clinical study, the most common side effects reported ($\geq 20\%$) with SCEMBLIX were pain in the muscles, bones, or joints, and rash.

These are not all of the possible side effects of SCEMBLIX. Call your health care team for medical advice about side effects.

Everyone responds differently to treatment.
It's important to discuss the potential side effects of each treatment you and your health care team are considering.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of SCEMBLIX include:

- muscle, bone, or joint pain
- rash
- tiredness
- nose, throat, or sinus (upper respiratory tract) infections
- headache
- stomach-area (abdominal) pain
- diarrhea
- decreased white blood cell counts, platelet counts, and red blood cell counts
- decreased blood calcium corrected levels
- increased blood pancreas enzyme (lipase and amylase) levels
- increased blood fat (cholesterol and triglycerides) levels
- increased blood uric acid levels
- increased blood liver enzyme levels
- increased blood alkaline phosphatase levels
- increased blood creatine kinase levels



ORAL TABLETS, DAILY DOSING

Once you start SCEMBLIX, it's important to take your medication exactly as prescribed by your health care team. Also, be sure to keep up with blood tests so your health care team can see how you're responding to treatment.

KAT
Real SCEMBLIX patient

Kat was compensated for her time

Important things about your daily SCEMBLIX routine



It's important to **take SCEMBLIX at the same time every day**. **Don't stop taking SCEMBLIX or change your dose or schedule** unless directed by your health care team.



SCEMBLIX comes in 20 mg, 40 mg, and 100 mg oral tablets. Your health care team will discuss with you how many times a day to take SCEMBLIX.



Do NOT take SCEMBLIX with food. Avoid eating for at least 2 hours before and 1 hour after you take SCEMBLIX.



Swallow SCEMBLIX tablets whole. Don't break, crush, or chew SCEMBLIX tablets.



If you miss a dose:

If you take SCEMBLIX **once a day** and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time.



If you take SCEMBLIX **twice a day** and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time.

IMPORTANT SAFETY INFORMATION (continued)

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

 **SCEMBLIX®**
(asciminib) 20 mg, 40 mg tablets

QUESTIONS TO SEE IF SCEMBLIX MAY BE RIGHT FOR YOU

Whether you're newly diagnosed with Ph+ CML in chronic phase or already taking another CML medication, it's important to take an active role in your treatment. Use this guide to discuss with your health care team if SCEMBLIX may be right for you.



Questions to ask your health care team:

1. How is SCEMBLIX different from other medications that treat Ph+ CML-CP?
2. When might I expect to see results with SCEMBLIX?
3. What are the most serious and common side effects of SCEMBLIX?
4. How will I know if SCEMBLIX is working?
5. What are some treatment milestones I should know about?
6. What are the results of my latest blood work?



Are you experiencing side effects from your current treatment for Ph+ CML-CP? Tell your health care team.

Below are some side effects that may occur during treatment for Ph+ CML-CP. Check any that apply.

<input type="checkbox"/> Diarrhea	<input type="checkbox"/> Bone, muscle, and joint pain
<input type="checkbox"/> Nausea/vomiting	<input type="checkbox"/> Something else: _____
<input type="checkbox"/> Rash/itching	_____

Ph+ CML medications can cause other side effects, so discuss any side effects you're experiencing with your health care team.



Scan the code for a more in-depth guide for talking with your health care team about SCEMBLIX.

IMPORTANT SAFETY INFORMATION (continued)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please [click here](#) for full Prescribing Information, including Patient Information.

 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15. 11

NOVARTIS PATIENT SUPPORT™

PERSONALIZED SUPPORT TO HELP YOU START, STAY, AND SAVE ON SCEMBLIX

Once you've been prescribed SCEMBLIX, you or your loved one can sign up for Novartis Patient Support. You'll have a go-to team member who will reach out from the start and get to know you. And once your health care provider has filed the paperwork with your insurance, Novartis Patient Support can help with the rest.

FINANCIAL SUPPORT

77% of SCEMBLIX claims resulted in \$0 out-of-pocket for patients.*

*Reflects use of \$0 Co-Pay Plus Program.

How can I save on SCEMBLIX?

Cost shouldn't be a barrier between you and the treatment you need. Your support will be based on your unique financial situation. This includes things like your prescription and insurance coverage. Novartis Patient Support offers options to help you afford your treatment.



What is Co-Pay Plus?

The Co-Pay Plus offer can help cover out-of-pocket costs related to your SCEMBLIX prescription, including refills. If you have private insurance, you may be eligible.

\$0 Co-Pay Plus* offer

Pay as little as \$0 with your Co-Pay Plus offer.

- ▶ Eligible patients with private insurance may pay as little as \$0
- ▶ Have an annual benefit limit of \$15,000 per calendar year
- ▶ Your annual benefit limit automatically resets every year, provided you continue to be eligible. There's no need to sign up again



30-day Free Trial Offer for SCEMBLIX†

Your Free Trial Offer for SCEMBLIX is good for a 30-day supply of your medication at no cost to you. This offer is available to all with a valid prescription.‡ The majority (95%) of SCEMBLIX claims resulted in \$0 out-of-pocket for patients with private insurance.* For one time use only.

*With the use of the \$0 Co-Pay Plus offer for patients with private insurance.

NOVARTIS PATIENT ASSISTANCE FOUNDATION SUPPORT

Novartis Patient Assistance Foundation, Inc. (NPAF), an independent 501(c)(3) non-profit organization, provides Novartis medications free of cost to eligible patients who have limited or no prescription insurance coverage and cannot afford the cost of their medication.

To be eligible, you must:

- ▶ Reside in the United States or a US territory
- ▶ Be treated by a licensed US health care provider on an outpatient basis
- ▶ Meet income and insurance guidelines

Visit www.PAP.Novartis.com or call NPAF at 1-800-277-2254 to learn more about eligibility and how to apply.



INSURANCE SUPPORT

SCEMBLIX is covered with no steps for 72% of patients with insurance*

*CVS, Express Scripts and Optum.

How can my Novartis Patient Support team help me navigate insurance coverage?

Getting you the medication you need is our number one priority. Novartis Patient Support is here to help. You'll work with an experienced team member who can:

- ▶ Help you navigate the insurance process
- ▶ Provide information to your health care provider to assist them with your insurance needs
- ▶ Assist you if there are changes to your insurance coverage

***Limitations apply.** Valid only for those with private insurance. The Program includes the Co-Pay Plus offer, Plus Card (if applicable), and Rebate, with a combined annual limit up to \$15,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time 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.

^{*}Confirm your specialty pharmacy accepts this offer before filling your prescription.

ONGOING SUPPORT

Once you've started treatment, your Novartis Patient Support team will be there for you.

Live, one-on-one support is just a phone call away for:

- ▶ Guidance on your health plan coverage process
- ▶ Options for saving on your prescription
- ▶ Setting up your routine and getting more help with SCEMBLIX
- ▶ Educational resources about SCEMBLIX and living with Ph+ CML in CP and Ph+ CML in CP with the T315I mutation
- ▶ Your choice of texts, calls, and emails to keep you connected to ongoing support

Novartis Patient Support doesn't replace medical guidance from your health care provider. Our goal is to help you feel informed about your treatment from day one.

How do I sign up for Novartis Patient Support?

Once your health care provider prescribes SCEMBLIX, there are 3 ways you can sign up for Co-Pay Plus and Novartis Patient Support:



Online

Enter your information securely online at
support.scemblix.com



Call 866-433-8000

Monday–Friday, 8 AM to 8 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up.



Ask your provider

Your health care provider and/or their office staff can help you sign up.

SUMMARY OF IMPORTANT INFORMATION FOR SCEMBLIX

What is SCEMBLIX?

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
- The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby

Females who are able to become pregnant:

- Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
- You should use effective birth control (contraception) during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

Tell your doctor about all the medicines you take, including

prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

Taking SCEMBLIX with certain other medicines may affect each other causing side effects and may affect the way that SCEMBLIX works.

How should I take SCEMBLIX?

- Take SCEMBLIX exactly as your doctor tells you to take it
- **Do not** change your dose or schedule or stop taking SCEMBLIX unless your doctor tells you to
- Take SCEMBLIX without food. **You should avoid eating** for at least 2 hours before and 1 hour after taking SCEMBLIX
- Swallow SCEMBLIX tablets whole. **Do not break, crush, or chew SCEMBLIX tablets**
- If you take SCEMBLIX **1 time a day** and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time
- If you take SCEMBLIX **2 times a day** and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time

What are the possible side effects of SCEMBLIX?

SCEMBLIX may cause serious side effects, including:

- **Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection
- **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of inflammation of the pancreas (pancreatitis). Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have severe stomach-area (abdominal) pain or discomfort, nausea, or vomiting
- **High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop high blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath



SUMMARY OF IMPORTANT INFORMATION FOR SCEMBLIX (cont)

• Allergic reaction: Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:

- trouble breathing or swallowing
- swelling of the face, lips, or tongue
- skin rash or flushing of your skin
- feeling dizzy or faint
- fever
- fast heartbeat

• Heart and blood vessel (cardiovascular) problems:

SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots or blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. In the majority of cases, these heart and blood vessel problems happened in people with risk factors or a history of these problems, and previously treated with other tyrosine kinase inhibitor (TKI) medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:

- shortness of breath
- chest pain or pressure
- a feeling like your heart is beating too fast or you feel abnormal heartbeats
- swelling in your ankles or feet
- dizziness
- weight gain
- numbness or weakness on one side of your body
- decreased vision or loss of vision
- trouble talking
- pain in your arms, legs, back, neck, or jaw
- headache
- severe stomach-area (abdominal) pain

The most common side effects of SCEMBLIX include:

- muscle, bone, or joint pain
- rash
- tiredness
- nose, throat, or sinus (upper respiratory tract) infections
- headache
- stomach-area (abdominal) pain
- diarrhea
- decreased white blood cell counts, platelet counts, and red blood cell counts

The most common side effects of SCEMBLIX include: (continued)

- decreased blood calcium corrected levels
- increased blood pancreas enzyme (lipase and amylase) levels
- increased blood fat (cholesterol and triglycerides) levels
- increased blood uric acid levels
- increased blood liver enzyme levels
- increased blood alkaline phosphatase levels
- increased blood creatine kinase levels

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

How should I store SCEMBLIX?

- Store SCEMBLIX at room temperature between 68°F to 77°F (20°C to 25°C)
- Store SCEMBLIX in the original container to protect it from moisture

Keep SCEMBLIX and all medicines out of the reach of children.

General information about the safe and effective use of SCEMBLIX

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SCEMBLIX for a condition for which it was not prescribed. Do not give SCEMBLIX to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for more information about SCEMBLIX that is written for health care professionals.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088

FOR ADULTS WITH NEWLY DIAGNOSED OR PREVIOUSLY TREATED Ph+ CML-CP



CML IN REAL LIFE

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JEN | Real SCEMBLIX patient

In a head-to-head clinical study of adults with newly diagnosed Ph+ CML-CP

**SCEMBLIX had better response rates than commonly used TKIs*****More people achieved MMR with SCEMBLIX than with commonly used TKIs* at 48 weeks****SCEMBLIX vs all commonly used TKIs*:**

- 68% (136 of 201 patients) vs 49% (100 of 204 patients) at 48 weeks

SCEMBLIX vs GLEEVEC*:

- 69% (70 of 101 patients) vs 40% (41 of 102 patients) at 48 weeks

In this clinical study, the most common side effects reported ($\geq 20\%$) with SCEMBLIX were pain in the muscles, bones, or joints, and rash.

*SCEMBLIX was studied vs GLEEVEC® (imatinib), TASIGNA® (nilotinib), Sprycel® (dasatinib), and Bosulif® (bosutinib). Sprycel is a registered trademark of Bristol-Myers Squibb Company. Bosulif is a registered trademark of Pfizer Inc.

Ask your health care team about SCEMBLIX.

APPROVED USES

SCEMBLIX is a prescription medicine used to treat adults with:

- Newly diagnosed or previously treated Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
- The approval of SCEMBLIX in patients newly diagnosed is based on a study that measured major molecular response (MMR) rate. There are ongoing studies to confirm the clinical benefit of SCEMBLIX for this use and how SCEMBLIX works over a longer period of time
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby

Please see Important Safety Information throughout and the Summary of Important Information on pages 14–15.



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 **SCEMBLIX®**
(asciminib) 20 mg, 40 mg tablets

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