09-J4000-22

Original Effective Date: 03/15/22

Reviewed: 01/08/25

Revised: 02/15/25

Subject: Asciminib (Scemblix®) Tablets

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Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Asciminib (Scemblix) is a first-in-class oral ABL/BCR-ABL1 tyrosine kinase inhibitor (TKI) specifically targeting the ABL myristoyl pocket (STAMP). It was approved by the US Food and Drug Administration (FDA) in October 2021 for the treatment of adult patients with: (1) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), or (2) Ph+ CML in CP with the T315I mutation. Asciminib has demonstrated activity against many of the BCR-ABL kinase domain mutations causing resistant to imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), and bosutinib (Bosulif), including the T315I mutation. Asciminib is not effective against A337T or P465S mutations. Prior to FDA approval, asciminib was granted orphan designation status for the treatment of CML in February 2017. One unique aspect of asciminib treatment is that the dosage must be increased 5-fold (from 40 mg twice daily to 200 mg twice daily) in patients that have the T315I mutation. In June 2024, the manufacturer released a new 100 mg tablet strength, which now allows the 200 mg BID dosage to be achieved with two 100 mg tablets twice daily vs. five 40 mg tablets twice daily. In October 2024, the labeling was expanded to include the treatment of newly diagnosed Ph+ CML in CP. This indication is approved under accelerated approval based on major molecular response rate, and continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s). Per the National Comprehensive Cancer Network (NCCN) guidelines for Chronic Myeloid Leukemia, asciminib (allosteric TKI) is a category 1 recommended, preferred first-line regimen for both low-risk and intermediate- or high-risk chronic-phase Ph+ CML. For low-risk CML, first-generation TKI (imatinib) and second-generation TKIs (bosutinib, dasatinib, nilotinib) are also listed as category 1 recommended, preferred first-line regimens. For intermediate- or high-risk CML, second-generation TKIs are listed as category 1 recommended, preferred first-line regimens, while imatinib is listed as a category 2A recommendation under “Other recommended regimen”. For accelerated phase CML (AP-CML), asciminib is listed as a category 2A recommendation under “Useful in

certain circumstances". The NCCN guidelines for Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions include asciminib as a category 2A recommendation for the treatment of myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement.

The safety and efficacy in the treatment of patients with newly diagnosed Ph+ CML-CP was evaluated in the multi-center, randomized, active-controlled, and open-label study ASC4FIRST (NCT04971226). A total of 405 patients were randomized in a 1:1 ratio to receive either asciminib or investigator selected tyrosine kinase inhibitors (IS-TKIs). Prior to randomization, the investigator selected the TKI (imatinib, nilotinib, dasatinib, or bosutinib) to be used in the event of randomization to the comparator arm, based on patient characteristics and comorbidities. Patients were stratified according to EUTOS long-term survival (ELTS) risk group (low, intermediate, high), and pre-randomization selection of TKI (imatinib or other TKIs stratum composed of nilotinib, dasatinib, and bosutinib). Patients received either asciminib or IS-TKIs, and continued treatment until unacceptable toxicity or treatment failure occurred. Patients were 37% female and 63% male with median age 51 years (range, 18 to 86 years). Of the 405 patients, 24% were 65 years or older, while 6% were 75 years or older. Patients were White (54%), Asian (44%), Black or African American (1%), and 1% unknown. Of the 405 patients, 200 received asciminib, while 201 received IS-TKIs. Of the 201 patients receiving IS-TKIs, 99 received imatinib, 49 received nilotinib, 42 received dasatinib, and 11 received bosutinib. Four patients did not receive any treatment.

The median duration of treatment was 70 weeks (range, 1 to 108 weeks) for patients receiving asciminib, and 64 weeks (range, 1 to 103 weeks) for patients receiving IS-TKIs. By 48 weeks, 90% of patients on asciminib, and 81% of patients on IS-TKIs were still receiving treatment. The main efficacy outcome was major molecular response rate (MMR) at 48 weeks. Efficacy was established based on asciminib compared to IS-TKIs and asciminib compared to IS-TKIs within the imatinib stratum. The main efficacy outcomes from ASC4FIRST are summarized in the Table.

Table: Efficacy Results in Patients with Newly Diagnosed Ph+ CML-CP (ASC4FIRST)

Scemblix 80 mg once daily		IS-TKIs 100 to 400 mg once or twice daily		Difference (95% CI)	p-value
		All patients (n=204)	Imatinib stratum (n=102)		
MMR rate, % (95% CI) at 48 weeks					
All patients (n=201)	68 (61, 74)	49 (42, 56)		19 (10, 28)	< 0.001
Imatinib stratum (n=101)	69 (59, 78)		40 (31, 50)	30 (17, 42)	< 0.001

S-TKIs include imatinib (400 mg once daily) and other TKIs of nilotinib (300 mg twice daily), dasatinib (100 mg once daily) or bosutinib (400 mg once daily).

MMR rates at 48 weeks in patients receiving asciminib and IS-TKIs within the other TKIs stratum (i.e., second generation TKI) were 66% (95% CI: 56%, 75%) and 57.8% (95% CI: 48%, 68%), respectively (difference, 8.2 percentage points; 95% CI, -5.1 to 21.5; and non-statistically significant). Direct comparison between asciminib and second-generation TKIs was not a primary objective. Median time to

MMR in patients receiving asciminib, IS-TKIs, and IS-TKIs within the imatinib stratum were: 24 weeks (95% CI: 24 to 25 weeks), 36 weeks (95% CI: 36 to 49 weeks), and 49 weeks (95% CI: 36 to 60 weeks), respectively. Adverse events of grade 3 or higher and events leading to discontinuation of the trial regimen were less frequent with asciminib (38% and 4.5%, respectively) than with imatinib (44.4% and 11.1%) and second-generation TKIs (54.9% and 9.8%).

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of asciminib (Scemblix) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. **ONE** of the following to support clinical use is met ("1", "2", or "3"):
   1. **BOTH** of the following are met regarding FDA labeling or NCCN Compendium ("a" and "b"):
      a. **EITHER** of the following (indication and usage) ["i" or "ii"]:
         i. Member is diagnosed with a condition that is consistent with an indication listed in the asciminib FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
         ii. Indication **AND** usage are recognized in the NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation (see Table 2)
      b. **EITHER** of the following (diagnostic testing) ["i" or "ii"]:
         i. The requested indication for asciminib requires genetic/specific diagnostic testing per FDA labeling* or NCCN Compendium, **AND BOTH** of the following:
            - The genetic/specific diagnostic testing has been completed
            - The results of the testing indicate therapy is appropriate – documentation must be submitted
         ii. The requested indication for asciminib does **NOT** require specific genetic/diagnostic testing per FDA labeling or NCCN Compendium

      **FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools*
   2. Asciminib is designated as an orphan drug by the FDA for the requested indication **AND** the indication is **NOT** included in the FDA labeling or the NCCN compendium as a 1 or 2A recommendation (i.e., "Designated") [orphan drug designations can be found at http://www.accessdata.fda.gov/scripts/opdlisting/oopd/]

3. The indication and usage are supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article

   NOTE:

   - Case reports, posters, and abstracts (including published meeting abstracts) are **NOT** accepted as evidence to support for use.
   - Clinical studies must be supportive of use for a similar patient population (e.g., indication, diagnosis, disease severity, genetic or tumor mutations) and for the intended treatment plan, including any concomitant therapy.

B. For the diagnosis of chronic-phase, Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) **ONLY** - **EITHER** of the following ("1" or "2"):

   1. If the member does **NOT** have a T315I mutation **OR** if the mutation status is unknown, **BOTH** of the following must be met ("a", "b", and "c"):

      a. **ANY** of the following** ("i", "ii", or "iii"):

         i. Member has previously received dasatinib (Sprycel) for at least 3 months and was unable to achieve treatment goals - prior treatment must be supported by either prior claims for dasatinib or medical record documentation

         ii. Member has an FDA-labeled contraindication to or had persistent intolerable adverse effects despite appropriate dose modification to dasatinib that are **NOT** expected to occur with asciminib - the specific adverse effect(s) or contraindication, and rationale for choosing asciminib must be provided

         iii. Member is poor candidate for dasatinib treatment due to an existing comorbidity and interaction with the adverse effect profile of dasatinib (e.g., pulmonary hypertension, high-risk of bleeding, preexisting fluid retention) - the member's specific comorbidities and rationale for choosing asciminib must be provided

      b. The dosage does not exceed 80 mg once daily or 40 mg twice daily

      c. The member does **NOT** have a known A337T, F359V/I/C, M244V, or P465S mutation

   2. If the member has a T315I mutation (documentation of the mutation must be submitted), **ALL** of the following must be met ("a", "b", and "c"):

      a. The dosage does not exceed 200 mg twice daily

      b. The member does **NOT** have a known A337T, F359V/I/C, M244V, or P465S mutation

      c. **ANY** of the following** ("i", "ii", or "iii"):

         i. Member has previously received ponatinib (Iclusig) for at least 3 months and was unable to achieve treatment goals – prior treatment must be supported by either prior claims for ponatinib or medical record documentation

         ii. Member has an FDA-labeled contraindication to or had persistent intolerable adverse effects despite appropriate dose modification to ponatinib (Iclusig) that are **NOT** expected to occur with asciminib - the specific adverse effect(s) or contraindication, and rationale for choosing asciminib must be provided

         iii. Member is poor candidate for ponatinib treatment due to an existing comorbidity and interaction with the adverse effect profile of ponatinib (e.g., prior heart attack) – the member's specific comorbidities and rationale for choosing asciminib must be provided

***Step therapy requirement does **NOT** apply if a prior health plan paid for the medication - documentation of a paid claim within the past 90 days must be submitted*

C. The dosage of asciminib does not exceed the maximum FDA-approved dose and frequency for the requested indication with the following exceptions ("1" or "2"):
   - Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or other compendia in Table 3)
   - Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article

     NOTE: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

D. The dose will be achieved using the fewest number of tablets per day

Approval duration: 6 months

Continuation of asciminib (Scemblix) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

A. Asciminib has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member has previously met **ALL** indication-specific criteria for coverage

B. The dosage of asciminib does not exceed the maximum FDA-approved dose and frequency with the following exceptions:
   1. Dose and frequency for the indication are supported by standard reference compendia (see NCCN Compendium or Table 3)
   2. Dose and frequency for the indication are supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article

      NOTE: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

C. The dose of asciminib will be achieved using the fewest number of tablets per day

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved: Asciminib is indicated for the treatment of adult patients with: (1) 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), (2) Previously treated Ph+ CML in CP, and (3) Ph+ CML in CP with the T315I mutation. The recommended dose and schedule of asciminib for patients with newly diagnosed or previously treated Ph+ CML-CP is 80

mg taken orally once daily at approximately the same time each day or 40 mg twice daily at approximately 12-hour intervals. The recommended dose and schedule of asciminib for patients with Ph+ CML-CP with the T315I mutation is 200 mg taken orally twice daily at approximately 12-hour intervals. Asciminib is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking. Continue treatment as long as clinical benefit is observed or until unacceptable toxicity occurs.

Dose Modifications

- **Hepatic Impairment:** Dosage adjustment is not necessary in patients with mild (total bilirubin level at or below the ULN and AST level greater than the ULN **OR** total bilirubin level of 1 to 1.5 times the ULN and any AST level) to severe (total bilirubin level more than 3 times the ULN and any AST level) hepatic impairment.
- **Renal Impairment:** Dosage adjustment is not necessary in patients with mild to severe renal impairment (estimated glomerular filtration rate of 15 to 89 mL/min/1.73 m^2).
- **Toxicity:**
  - Chronic phase Ph+ CML with the T315I mutation:
    - First reduction: 160 mg PO twice daily.
    - Subsequent reductions: Permanently discontinue therapy in patients unable to tolerate 160 mg PO twice daily.
  - Newly diagnosed or previously treated chronic phase Ph+ CML:
    - First reduction: once-daily dosing, 40 mg PO once daily; twice-daily dosing, 20 mg PO twice daily.
    - Subsequent reductions: Permanently discontinue therapy in patients unable to tolerate 40 mg PO once daily or 20 mg PO twice daily.
  - Hematologic Toxicity
    - Absolute neutrophil count (ANC) less than 1 x 10^9 cells/L OR platelet count less than 50 x 10^9 cells/L: Hold asciminib therapy until toxicity is resolved to ANC of 1 x 10^9 cells/L or more or platelet count of 50 x 10^9 cells/L or more. If the toxicity resolves within 2 weeks, resume therapy at the starting dosage. If the toxicity resolves after more than 2 weeks, resume therapy at a reduced dosage. For recurrent severe myelosuppression, resume at a reduced dosage after toxicity resolves.
  - Pancreatic Toxicity
    - Elevated amylase and/or lipase level to more than 2 times the ULN and asymptomatic: Hold asciminib therapy until toxicity is resolved to amylase or lipase level less than 1.5 times the ULN. If the toxicity resolves, resume therapy at a reduced dosage; permanently discontinue therapy if the toxicity recurs at a reduced dosage. If the toxicity does not resolve, permanently discontinue therapy and evaluate the patient for pancreatitis.
  - Elevated amylase and lipase levels and symptomatic (e.g., abdominal pain)
    - Hold asciminib therapy and evaluate the patient for pancreatitis.

- Other Non-Hematologic Toxicity (including hypertension, hypersensitivity, and cardiovascular toxicity)
  - Grade 3 or higher toxicity: Hold asciminib therapy until toxicity recovers to grade 1 or less. If the toxicity resolves, resume therapy at a reduced dosage. If the toxicity does not resolve, permanently discontinue therapy.

Drug Availability:

Package Configuration	Tablet Strength	NDC Number
Bottle of 60 tablets	20 mg	00078-1091-20
Bottle of 60 tablets	40 mg	00078-1098-20
Bottle of 60 tablets	100 mg	00078-1196-20

- 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]. Dispense and store in the original container in order to protect from moisture.

PRECAUTIONS:

CONTRAINDICATIONS

- None

WARNINGS

- **Myelosuppression**: Severe thrombocytopenia and neutropenia events may occur. Monitor complete blood counts regularly during therapy and manage by treatment interruption or dose reduction.
- **Pancreatic Toxicity**: Monitor serum lipase and amylase. Interrupt, then resume at reduced dose or discontinue asciminib based on severity. Evaluate for pancreatitis when lipase elevation is accompanied by abdominal symptoms.
- **Hypertension**: Monitor blood pressure and manage hypertension as clinically indicated. Interrupt, dose reduce, or stop asciminib if hypertension is not medically controlled.
- **Hypersensitivity**: May cause hypersensitivity reactions. Monitor patients for signs and symptoms and initiate appropriate treatment as clinically indicated.
- **Cardiovascular Toxicity**: Cardiovascular toxicity may occur. Monitor patients with history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated.
- **Embryo-Fetal Toxicity**: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

BILLING/CODING INFORMATION:

HCPCS Coding

J8999	Prescription drug, oral, chemotherapeutic, nos

ICD-10 Diagnosis Codes That Support Medical Necessity

C92.10 – C92.12	Chronic myeloid leukemia, bcr/abl-positive
C94.80 - C94.82	Other specified leukemias
C95.10 - C95.12	Chronic leukemia of unspecified cell type
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

DEFINITIONS:

Accelerated Phase CML: is a phase of chronic myelogenous leukemia in which the disease is progressing.

Blast Phase CML: is the final phase in the evolution of CML, and behaves like an acute leukemia, with rapid progression and short survival.

Chronic Phase CML: approximately 85% of members with CML are in the chronic phase at the time of diagnosis. During this phase, members are usually asymptomatic or have only mild symptoms of fatigue, left side pain, joint and/or hip pain, or abdominal fullness.

Chronic Myelogenous Leukemia (CML): also known as chronic granulocytic leukemia (CGL), is a cancer of the white blood cells. It is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid cells in the bone marrow and the accumulation of these cells in the blood.

Cytogenetic: is a branch of genetics that is concerned with the study of the structure and function of the cell, especially the chromosomes. It includes routine analysis of G-banded chromosomes, other cytogenetic banding techniques, as well as molecular cytogenetics such as fluorescent in situ hybridization (FISH) and comparative genomic hybridization (CGH).

Philadelphia chromosome or Philadelphia translocation: is a specific chromosomal abnormality that is associated with chronic myelogenous leukemia (CML).

RELATED GUIDELINES:

Allogeneic Bone Marrow and Stem Cell Transplantation, 02-38240-01
Bosutinib (Bosulif) Tablets, 09-J1000-84
Nilotinib (Tasigna) Capsules, 09-J1000-48
Oral Oncology Medications, 09-J3000-65

OTHER:

Table 1: CML Risk Scores

Score	Calculation	Risk Definition by Calculation
Sokal score	Exp 0.0116 x (age - 43.4) + (spleen size - 7.51) + 0.188 x [(platelet count/700)^2 - 0.562] + 0.0887 x (blast cells - 2.10)	• Low: <0.8 • Intermediate: 0.8 to 1.2 • High: >1.2
Hasford (EURO) score	[0.666 when age ≥50 + (0.042 x spleen size) + 1.0956 when platelet count ≥1,500 x 10^3/L + (0.0584 x blast cells) + 0.2039 when basophils ≥3% + (0.0413 x eosinophils)] x 1,000	• Low: ≤780 • Intermediate: >780 to 1,480 • High: >1,480
EUTOS long-term survival (ELTS) score	0.0025 x (age/10)^3 + 0.0615 x spleen size + 0.1052 x blasts cells + 0.4104 x (platelet count/1,000)$^{-0.5}$	• Low: ≤1.5680 • Intermediate: >1.5680 to ≤2.2185 • High: >2.2185

Age is in years. Spleen is in centimeters below the costal margin (maximum distance). Blast cells, eosinophils, and basophils are in percent of peripheral blood differential. All factors must be collected prior to any treatment.

Online calculator for Sokal and Hasford (EURO) scores can be found at: https://www.leukemia-net.org/content/leukemias/cml/euro__and_sokal_score/index_eng.html

Online calculator for the ELTS score can be found at: https://www.leukemia-net.org/content/leukemias/cml/elts_score/index_eng.html

Table 2

NCCN Categories of Evidence Consensus	
Category 1	Based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there NCCN consensus that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Table 3

Other Compendia	
Compendium	**Covered Uses**
AHFS-DI	Narrative text is supportive
Clinical Pharmacology	Narrative text is supportive
Lexicomp	Evidence rating A, B or G
Thomson Micromedex DrugDex	Meets requirements for **BOTH** of the following: • Strength of recommendation: Class I (Recommended) or IIa (Recommended, In Most Cases) • Efficacy: Class I (Effective) or IIa (Evidence Favors Efficacy)
AHFS-DI - American Hospital Formulary Service Drug Information	

Table 4

Lexicomp Recommendation Ratings	
A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (e.g., results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (e.g., retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (e.g., when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Table 5

Thomson Micromedex DrugDex Recommendation Ratings: Strength of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered
Class IIa	Recommended, in most cases	The given test or treatment is generally considered to be useful and is indicated in most cases.
Class IIb	Recommended in some cases	The given test or treatment may be useful, and is indicated in some, but not most, cases
Class III	Not recommended	The given test or treatment is not useful and should be avoided
Class Indeterminate	Evidence Inconclusive	

Table 6

Thomson Micromedex DrugDex Recommendation Ratings: Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence favors efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/08/25.

GUIDELINE UPDATE INFORMATION:

03/15/22	New Medical Coverage Guideline.
02/15/23	Review and revision to guidelines consisting of updating the description, position statement, and references. A337T and P465S added as mutations for which asciminib is not effective.
02/15/24	Review and revision to guideline consisting of updates to the description section (NCCN info), position statement, billing/coding section, and references. Added a new mutation, F359V/I/C, that is a contraindication for the use of Scemblix.
08/15/24	Revision to guideline consisting of updates to the description section, dosage/administration, and references. A new 100 mg tablet strength is now available.
02/15/25	Review and revision to guideline consisting of updates to the description section (NCCN info), position statement, billing/coding section, and references. For previously untreated chronic-phase Ph+ CML, dasatinib is the preferred TKI. Added a new mutation, M244V, that is a contraindication for the use of Scemblix.