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Reimbursement Recommendation

Asciminib (Scemblix)

Indication: For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) who have previously received 1 tyrosine kinase inhibitor.

Sponsor: Novartis Pharmaceuticals Canada Inc.

Recommendation: Do not reimburse

Summary

What Is the Reimbursement Recommendation for Scemblix?

Canada's Drug Agency (CDA-AMC) recommends that Scemblix should not be reimbursed by public drug plans for the treatment of adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase previously treated with 1 tyrosine kinase inhibitor (TKI).

Why Did CDA-AMC Make This Recommendation?

- Evidence from a clinical trial (ASC2ESCALATE) of 101 patients who could not tolerate or did not respond to their first-line TKIs suggested that Scemblix was associated with a clinically meaningful proportion of patients achieving major molecular response (MMR) at 9 months. However, these results were highly uncertain because of the lack of a control group that did not compare Scemblix to other treatments and the short and incomplete study duration that relied on early data that had not reached the primary end point. Additionally, there was no indirect comparison with other available drugs, so it was not possible to determine the benefit or risks of Scemblix compared to other treatments.
- Patients and clinicians identified the need for additional effective treatments that improve symptom control, reduce side effects, and enhance quality of life. Patients also want multiple treatment options as resistance or intolerance to other TKIs are common. However, the committee was unable to conclude that Scemblix would meet the clinical needs of patients and provide an effective treatment with improved symptom control and quality of life, or superiority in efficacy relative to other treatments in Ph+ CML in second line.

Additional Information

What Is CML?

CML is a cancer of the bone marrow and blood cells that is commonly caused by an abnormal chromosome known as the Philadelphia chromosome. In 2019, the incidence rate of CML in Canada was 2.3 per 100,000 population.

Unmet Needs in CML

Some patients must discontinue their currently available TKI therapy because of side effects or because their disease no longer responds to the therapy. Treatment intolerance is a main reason for treatment discontinuation across all lines of therapy, often leading to further toxicity

Summary

with alternative TKIs. There is a need for more tolerable treatment options that support long-term adherence and effective disease control.

How Much Does Scemblix Cost?

Scemblix is available as 20 mg and 40 mg tablets. At the submitted price of $63.00 per 20 mg tablet and $85.00 per 40 mg tablet, the 28-day cost of Scemblix is expected to be approximately $4,760 per patient, based on the Health Canada–recommended dosage.

Recommendation

The pan-Canadian Oncology Drug Review Expert Review Committee (pERC) recommends that asciminib not be reimbursed for adult patients with Ph+ CML in chronic phase who have previously received only 1 TKI.

Rationale for the Recommendation

Evidence from 1 phase II, single-arm, open-label trial (ASC2ESCALATE), which included 101 patients with "warning or failure and/or resistance" or intolerance to first-line TKIs suggested that treatment with asciminib was associated with a clinically meaningful proportion of patients achieving MMR at 9 months ([redacted]), as well as for other molecular response (MR) outcomes. However, pERC emphasized that the available results were associated with considerable uncertainty given the limitations of the evidence including the noncomparative design, short follow-up duration based on interim analyses, and small sample size where only 1 patient enrolled in the ASC2ESCALATE study had results at the prespecified primary end point of 12 months. Results for other clinically important outcomes including duration of response, overall survival (OS), and quality of life were also not available at the interim analysis, precluding any assessment of the impact of asciminib on these outcomes in second line. Furthermore, there was no direct or indirect comparative evidence provided, precluding pERC from drawing any conclusions about comparative effectiveness or safety where multiple other treatment options are available.

Patients and clinicians identified the need for additional effective treatments that improve symptom control, reduce side effects, and enhance quality of life. They also underscored the importance of having multiple treatment options given current rates of treatment resistance or intolerance for some patients to current TKIs available in Canada. pERC acknowledged the needs of patients and clinicians; however, given the limitations with the available evidence, the committee was unable to conclude that asciminib would meet the clinical needs of patients including an effective treatment with improved symptom control and quality of life, or superiority in efficacy relative to other treatments in Ph+ CML in second line.

Discussion Points

- **Request for reconsideration from the sponsor:** The sponsor requested a reconsideration of the initial draft recommendation to not reimburse asciminib for Ph+ CML in chronic phase in patients who have previously received 1 TKI. There were 2 issues outlined by the sponsor in the request for reconsideration related to how asciminib addresses the unmet needs in the second-line CML chronic phase setting, which were discussed by pERC. First, the sponsor highlighted that the use of asciminib in second-line treatment of Ph+ CML is supported by the findings from the ASC2ESCALATE study, real-world evidence from Canada and the US, feedback from both patients and leading physicians, as well as the 2025 European LeukemiaNet (ELN) and the National Comprehensive Cancer Network (NCCN) guidelines. Second, the sponsor highlights that although a randomized controlled trial (RCT)

was not conducted for asciminib in the second-line setting, asciminib has already been compared to first-generation and second-generation TKIs in RCTs conducted in first-line and third-line therapies, and other second-line therapies were supported by similar evidence.

- **Unmet needs:** pERC discussed patient input highlighting the physical and emotional burden associated with Ph+ CML in chronic phase, including fatigue, stress, pain, and sleep disturbances that disrupt daily functioning, work, and social activities. Patients noted difficulties with finding effective treatments that are also tolerable and emphasized the desire to discontinue therapy while remaining in remission, given that treatment is often lifelong. pERC acknowledged that both patients and clinicians identified effective disease control with minimal toxicity, improvements in health-related quality of life (HRQoL), and the potential to achieve treatment-free remission (TFR) as highly valued outcomes. However, during the initial and reconsideration meetings, pERC was unable to substantiate that asciminib meets these needs given the limitations of the available evidence including the phase II single-arm design of the ASC2ESCALATE study, immaturity of the study results at the time of the review, and a lack of comparisons to currently available treatment options for the patient population under review.
- **Certainty and quality of evidence:** pERC discussed the results of the ASC2ESCALATE study, which evaluated asciminib in patients with Ph+ CML in chronic phase who had "warning or failure and/or resistance" according to 2020 ELN recommendations, or intolerance to 1 prior TKI therapy. The primary end point of the ASC2ESCALATE study was the proportion of patients achieving MMR at 12 months. pERC emphasized the small sample size and immaturity of the results as only 1 patient in the trial had 12-months of follow-up, and 9-month data were only available for 42% of patients at the time of review. At 9 months, [redacted] of patients ([redacted]) achieved MMR, defined as a 3.0 log reduction in *BCR-ABL1* transcripts (*BCR-ABL1* on the international scale [IS] ≤ 0.1). Similar improvements were observed for other MRs (MR2 [redacted], MR4 [redacted], and MR4.5 [redacted]). The clinical experts noted that MR2 is generally equivalent to a complete cytogenetic response and represents a robust treatment outcome. The certainty of evidence for molecular outcomes was rated as low, rather than very low (given the study design of the ASC2ESCALATE trial), due to the improbability of spontaneous MR in the absence of treatment. pERC discussed the results of the study with the clinical experts who noted that the early MRs observed with asciminib is consistent with expectations for second-generation TKIs used in the second-line setting, although the long-term durability of these responses is currently unknown. pERC noted that the ASC2ESCALATE study did not provide data on OS or other time to event outcomes (e.g., time to MMR or duration of response), or HRQoL, all of which were identified as important outcomes by both patients and clinicians. pERC discussed the limitations of the evidence, which included the noncomparative and open-label design, the small sample size and short duration of follow-up resulting in a small information fraction, and lack of data for clinically important outcomes. During the initial and reconsideration meetings, pERC also discussed the availability of asciminib in the third-line setting, as well as the indication in first-line setting, noting the biological plausibility that asciminib may function similarly in the second-line setting. However, pERC upheld their initial conclusions, determining that the current evidence was inadequate to support a positive recommendation in the second line.

- **Place in therapy and lack of comparative evidence:** pERC discussed the place in therapy of asciminib in second line, highlighting the availability of multiple other comparators (dasatinib, bosutinib, nilotinib, and ponatinib). Given the lack of direct and indirect comparison, pERC and the clinical experts noted that there is no evidence to support choosing 1 TKI over another but highlighted that treatments would be chosen in consultation with the patient considering multiple factors including but not limited to patient preference regarding potential toxicities. During the initial and reconsideration meetings, pERC also acknowledged that similar evidence was reviewed by the committee previously for bosutinib and ponatinib. In the feedback on the draft recommendation, the sponsor, patient groups, clinician groups, and clinical experts highlighted that a similar standard should be applied to asciminib as with other therapies in the second line. However, pERC considered the results for asciminib to be too immature, citing the short follow-up duration (the ASC2ESCALATE trial had not reached the prespecified 12-month primary end point) and incomplete data, with fewer than one-half of patients having response assessments at the 9-month interim analysis. Consequently, the evidence was deemed insufficient to determine any potential clinical benefit. pERC noted that no indirect comparative evidence was provided for asciminib in this patient population, acknowledging the position of the sponsor that there is likely substantial heterogeneity in available data and difficulty conducting a robust analysis; however, pERC noted that this remains a limitation of the evidence. This issue was also discussed at the reconsideration meeting, where pERC upheld their initial conclusions.
- **Safety:** pERC discussed the safety findings of the ASC2ESCALATE study, as well as the known toxicity profile of asciminib, noting that no new safety signals were identified. However, the open-label, single-arm design may introduce subjective bias in reporting adverse events, and the short follow-up limits assessment of long-term harms that may emerge after years of TKI therapy. The clinical experts noted that cumulative toxicities, such as cardiovascular, pulmonary, and vascular events, have been observed with other TKIs, highlighting the importance of long-term monitoring. pERC also noted the absence of direct or indirect comparative evidence; thus, the relative safety of asciminib compared to other TKIs in this patient population remains unknown. However, in discussion with the clinical experts, there are patients with various comorbidities who would not be suitable for treatment or unable to receive other TKIs in second line given their hallmark toxicities (e.g., patients with chronic kidney disease and imatinib, or cardiovascular risk and nilotinib or ponatinib). As such, pERC noted that jurisdictional approval of asciminib in second line on a case by case basis may be an option for patients who have contraindications or comorbidities that prevent them from receiving other TKIs in second line to avoid unnecessary burden on patients.
- **Supportive evidence:** pERC discussed supporting evidence from a retrospective chart review which the sponsor provided to address the gap in long-term data. The results of the chart review suggested similar MR rates to those observed in the ASC2ESCALATE trial, as well as results for harms, which were consistent with the findings from the ASC2ESCALATE study. However, pERC noted methodological limitations of this study, highlighting that the 48-week duration did not provide sufficient long-term evidence in addition to, or beyond, the immature 9-month results of the ASC2ESCALATE trial to support the reimbursement of asciminib in second line.

- **Feedback on the draft recommendation from patient and clinician groups:** During the reconsideration meeting, feedback from the patient and clinician groups was discussed by pERC, where patient groups highlighted the lack of clarity on how the real-world evidence and patient-reported outcomes described in their input were factored into the recommendation. In their feedback, patient groups emphasized that asciminib offered improved quality of life, easier daily management, and a milder side effect profile compared to other TKIs, and clinician groups highlighted individual case reports describing the tolerability and safety profile of asciminib in patients with various comorbidities. pERC acknowledged the patient and clinician group perspectives but determined that the experiences of the patient and clinician groups were not supported by the evidence reviewed by the committee, which was too limited to draw conclusions on the efficacy and safety of asciminib relative to currently available treatments in patients with Ph+ CML in the second line.

Background

CML is a myeloproliferative neoplasm characterized by the aberrant and uncontrolled proliferation of mature and maturing granulocytes. Blood and bone marrow cells in patients with CML usually contain a characteristic chromosomal abnormality, known as the Philadelphia chromosome, resulting from a reciprocal translocation between chromosomes 9 and 22. In this process, a segment of the *ABL1* gene on chromosome 9 detaches and joins the *BCR* gene on chromosome 22, forming the *BCR-ABL1* fusion gene. This results in a shortened chromosome 22 which drives the uncontrolled cell growth associated with CML. The incidence rate of CML across all ages and sexes in Canada, excluding Quebec, ranged from 400 to 665 cases from 2009 to 2019, respectively. This corresponds to an incidence rate of 2.3 per 100,000 population in 2019. It is estimated that about 90% to 95% of patients with CML are in chronic phase at diagnosis which usually manifests as leukocytosis and immature myeloid cells in the blood. The chronic phase is the earliest and most stable stage of the disease, characterized by a high number of mature white blood cells, with limited blast cell proliferation in the bone marrow and peripheral blood. About 50% of patients with CML in chronic phase are asymptomatic at presentation and are often diagnosed upon receiving laboratory abnormalities during a routine examination. Patients with symptoms most commonly present with anemia, fatigue, splenomegaly, and weight loss. Infrequently, patients are initially diagnosed in advanced CML stages: accelerated phase or blast phase.

TKIs are the initial treatment of choice for the majority of patients with CML. Imatinib was the first drug in this class to be approved for patients with CML and is commonly used as the first line of treatment. Some patients with initial response to imatinib ultimately lose their achieved response; 10% to 15% of patients with CML in chronic phase develop resistance to imatinib within 18 months to 2 years of treatment. Dasatinib, nilotinib, and bosutinib are second-generation TKIs approved for treatment of chronic phase or accelerated phase CML in patients with resistance or intolerance to prior therapy with a TKI. Ponatinib is a third-generation TKI used in patients with a *BCR-ABL1* mutation, although it is associated with serious toxicity including cardiovascular, cerebrovascular, and peripheral vascular events.

Asciminib is indicated for the treatment of adult patients with Ph+ CML in chronic phase that is newly diagnosed or has previously been treated with 1 or more TKIs. Asciminib is a TKI. It is available as an oral tablet (20 mg and 40 mg). The recommended total daily dose of asciminib is 80 mg. Asciminib can be taken orally either as 80 mg once daily at approximately the same time each day, or as 40 mg twice daily at approximately 12-hour intervals.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information:

- a review of 1 single-arm, open-label, dose-escalation study (ASC2ESCALATE) of oral asciminib in the treatment of adult patients with CML in chronic phase; and 1 retrospective chart review by Atallah et al
- patients' perspectives gathered by 4 patient groups; the CML Society of Canada, Heal Canada, and a joint submission from the Canadian CML Network and the Leukemia & Lymphoma Society of Canada
- input from public drug plans and cancer agencies that participate in the reimbursement review process
- 2 clinical specialists with expertise diagnosing and treating patients with Ph+ CML in chronic phase
- input from 2 clinician groups: the Canadian CML Physicians Interest Group and the Ontario Health (Cancer Care Ontario) Hematology Drug Advisory Committee
- a review of the pharmacoeconomic model and report submitted by the sponsor
- information submitted as part of the sponsor's request for reconsideration (subsequently described)
- feedback on the draft recommendation.

Perspectives of Patients, Clinicians, and Drug Programs

Patient Input

Four organizations provided input for this review including the CML Society of Canada, Heal Canada, and a joint submission from the Canadian CML Network and the Leukemia & Lymphoma Society of Canada. The CML Society of Canada collected insights through surveys and phone interviews with more than 20 patients from Canada, France, the US, and the UK who had experience with asciminib after at least 1 prior therapy. Heal Canada conducted a survey of 15 patients in Canada living with CML and interviewed 16 patients who were not from Canada who had experience with asciminib, most of whom accessed the treatment upon TKI failure. The joint submission gathered responses from an online survey of 70 patients from Canada with Ph+ CML in chronic phase, all of whom had at least 1 prior therapy and 20 patients provided details on their experience with asciminib treatment. Additional input from the Leukemia & Lymphoma Society of Canada included in-person interviews with 2 patients living with CML and a round table discussion with 3 patients

receiving treatment with asciminib. Across submissions, details on the proportion of patients with Ph+ CML in chronic phase were not consistently identified.

All submissions highlighted the significant physical and emotional burden of CML, including stress, fatigue, pain, and sleep disturbances, which affect daily activities, work, and social life. Heal Canada noted that most patients were asymptomatic before diagnosis and that lifelong medication is often undesirable, as many hope to discontinue treatment while maintaining remission. The joint submission emphasized the emotional toll of CML and the challenge of finding an effective treatment with manageable side effects. Many patients undergo a study and error process with their health care providers to identify the most suitable therapy. Patients reported experience with various TKIs (e.g., bosutinib, dasatinib, imatinib), as well as other treatments such as allopurinol, bone marrow or stem cell transplant, chemotherapy, hydroxyurea, and radiation. Commonly reported TKI side effects across submissions included bone, joint, or muscle pain, diarrhea, fatigue, headache, nausea, and vomiting.

Across submissions, patients and caregivers prioritize treatments that improve symptom control, reduce side effects, and enhance quality of life, even if some side effects must be managed. The joint submission emphasized the importance of having multiple treatment options for CML. Key considerations when evaluating new therapies included quality of life during treatment, the number and severity of side effects, and treatment convenience.

Side effects experienced by patients treated with asciminib varied across submissions and included cold-like symptoms, bone, joint, or muscle pain, brain fog, fatigue, headache, low blood cell count, and skin rash. Across submissions, patients who had experience with asciminib reported various benefits including improved blood counts, reduced fatigue, and enhanced quality of life, with milder side effects compared to other TKIs. Patients found asciminib easy to use, with fewer disruptions to their daily lives, with those resistant or intolerant to other TKIs experiencing notable benefits. The CML Society of Canada highlighted the ability of asciminib to target a broader range of mutations, increasing the likelihood of achieving deep MR (commonly defined as a 4 or 4.5 log reduction in *BCR-ABL1* gene levels) and improving patients' quality of life. The joint submission reported that more than one-half of those who responded who were receiving asciminib experienced moderate to significant improvements in daily routines and mental health, with nearly one-half also noting benefits in their personal life and work life compared to other treatments.

Clinician Input

Input From Clinical Experts Consulted for This Review

The clinical experts shared that therapy goals for patients with Ph+ CML in chronic phase include achieving the best MR possible with the fewest side effects. For some patients, their goal is TFR and for others it is improved HRQoL. The clinical experts emphasized that these goals are particularly important for patients receiving second-line treatment, as it indicates prior TKI therapy was unsuccessful due to resistance or intolerance, highlighting the need for alternative therapeutic options. The clinical experts noted that although in most cases the disease responds to treatment when managed appropriately and with patient adherence, there are instances where the disease does not respond to treatment or becomes refractory over time. The

clinical experts noted that nonadherence may occur due to a variety of reasons including side effects that are not being addressed, patient age, and personal beliefs. The clinical experts stated that some patients feel worse while receiving treatment than before diagnosis, making it essential to minimize side effects and optimize quality of life, especially given the long term, often lifelong nature of therapy. The experts stated that this is particularly relevant for patients starting a second-generation TKI, which are known to have more side effects than imatinib. The experts stated that individual responses and side effects experienced by patients can vary, and as such, having a broad range of therapeutic options is essential.

Although the clinical experts noted that the treatment under review is for first-line or second-line therapy, they would reserve asciminib for cases where treatment with a second-generation TKI was unsuccessful, whether due to resistance, including mutation-driven resistance, or less commonly, intolerance. The clinical experts added that resistance or intolerance to a treatment can only be confirmed after trying at least 1 other therapy for comparison. The choice of treatment options in second-line would be determined by patients and clinicians; however, 1 clinical expert noted that it would be appropriate to recommend that patients try other treatments before initiating asciminib as the long-term safety profile of asciminib is not yet available, which may be a concern for many patients given its current higher cost relative to other available treatments. The clinical experts shared that subsequent TKIs, including asciminib, may be slightly more effective in patients with high Sokal scores. They also noted that patients with multiple comorbid conditions would be most in need of intervention, as some options may be safer than others based on individual health conditions.

The experts stated that most provinces and territories use the 2020 ELN recommendations in clinical practice to assess response to treatment. The clinical experts noted that in both clinical trials and clinical practice, objective MR to treatment corresponding to a reduction in *BCR-ABL* transcript levels are clinically relevant outcomes. One clinical expert noted that newer TKIs have not been able to improve TFR or survival beyond improvements made with first-generation TKIs; emphasizing that patients may still achieve long-term survival even if all treatment milestones are not met. As such, attempting TFR may become less important in the case of treatment resistance. One expert noted that many other factors can influence how a patient improves including coping mechanisms, mental outlook, and available support systems.

The clinical experts noted that asciminib may be discontinued due to disease progression, treatment resistance or intolerance, a suboptimal response to treatment, or a deep and sustained MR allowing for TFR. Other reasons to discontinue treatment include undergoing a stem cell transplant or the development of a separate terminal illness where treating CML is no longer appropriate. The clinical experts highlighted the importance of having CML experts or hematologists in consultation with CML experts diagnosing and monitoring the disease due to its rarity and the expense of the drugs involved.

Clinician Group Input

Two clinician groups (43 clinicians in total) provided input: the Canadian CML Physicians Interest Group and the Ontario Health (Cancer Care Ontario) Hematology Drug Advisory Committee. Input was gathered via virtual discussions with information gathered from literature reviews and collective clinical experiences.

The Canadian CML Physicians Interest Group noted that the introduction of TKIs transformed CML from a fatal disease into a manageable chronic condition. Both submissions noted that in Canada, standard first-line

treatment for CML in chronic phase includes imatinib, dasatinib, nilotinib, or bosutinib, although access varies by province and territory. Additional TKIs like asciminib and ponatinib are both approved for later lines of therapy, including for patients with the *T315I* mutation, which presents resistance to first-line options. Across submissions, the main treatment goals for patients with CML in chronic phase include prolonging survival, preventing disease progression to accelerated phase or blast phase CML, achieving response milestones such as an MMR, improve or maintain quality of life, improvement in blood counts, minimize treatment-related toxicities, reduction in splenomegaly and other disease symptoms, and offer eligible patients the opportunity to attempt TFR. For individual patients, treatment goals evolve over time and across lines of therapy but are based on patient desires and disease-specific characteristics. Both submissions noted that despite the transformative impact of TKI therapy in CML, treatment failure remains a persistent issue across all lines of therapy, leading to continued CML-related mortality. As such, the clinician groups noted that there is a need for treatments that are better tolerated and have superior efficacy.

The input noted that patients best suited for treatment with asciminib in the second-line setting are those that fit the ASC2ESCALTE trial inclusion criteria regardless of whether their disease progression was caused by resistance, intolerance, or lack of response.

The Canadian CML Physicians Interest Group stated that most clinicians from Canada follow the 2020 ELN recommendations for treating CML as guidelines for treatment decisions. Response assessments begin with a baseline quantitative polymerase chain reaction and mutation testing if resistance is suspected. During the first 12 months of treatment, quantitative polymerase chain reaction is performed every 3 months, with treatment changes recommended for intolerance or unmet molecular milestones. After 12 months, *BCR-ABL1* levels are monitored every 3 to 6 months, with increased monitoring and mutation testing if response is lost. The input noted that *BCR-ABL1* transcript levels serve as a surrogate marker for treatment efficacy and long-term survival, with lower levels linked to reduced progression risk and improved outcomes. Patients who sustain MR4 or deeper for at least 2 years may be eligible for TFR.

Both inputs agreed that asciminib should be discontinued in cases of treatment response failure (*BCR-ABL1* on the IS > 10% at 3 or 6 months or > 1% at 12 months or later) or if toxicity persists despite dose changes. Experienced hematologists should oversee initial treatment and early monitoring, while pharmacy and nursing teams can support oral medication management, adverse event monitoring, and treatment adherence.

Drug Program Input

Input was obtained from the drug programs that participate in the reimbursement review process. The following were identified as key factors that could potentially impact the implementation of a recommendation for asciminib:

- considerations for initiation of therapy
- considerations for prescribing of therapy
- generalizability of trial populations to the broader populations in the jurisdictions
- care provision issues

- system and economic issues
- potential need for a Provisional Funding Algorithm.

The clinical experts consulted for the review provided advice on the potential implementation issues raised by the drug programs.

Clinical Evidence

Systematic Review

Description of Studies

One single-arm study, ongoing, phase II, open-label, dose-escalation study (ASC2ESCALATE) of oral asciminib in first-line and second-line treatment of adult patients with CML in chronic phase was included in this review. This report will focus on the second-line cohort only. The primary objective of the ASC2ESCALATE study was to evaluate the efficacy, safety, and tolerability of asciminib (starting dose of 80 mg once daily) for the treatment of adult patients with CML in chronic phase previously treated with 1 TKI. Dose escalations were guided by patients' *BCR-ABL1* results at 6 and 12 months. Patients with *BCR-ABL1* on the IS of 1% or less at 6 months remained on their current dose, while those above this threshold increased their dose to 200 mg once daily. At 12 months, patients who did not achieve MMR, defined as a 3.0 log reduction in *BCR-ABL1* transcripts (*BCR-ABL1* on the IS ≤ 0.1%) increased their dose from 80 mg once daily to 200 mg once daily, or from 200 mg once daily to 200 mg twice daily. If MMR was still not achieved and it was deemed in the patient's best interest, the investigator could discontinue the study treatment and switch to an alternative therapy.

The ASC2ESCALATE trial includes a 28-day screening period, a 36-month treatment period, and a 30-day safety follow-up phase. As of the November 15, 2024, clinical cut-off date for interim analysis 4 (IA4), a preliminary assessment was conducted on 101 evaluable patients in the second-line cohort. Of these, 63 patients (62.4%) had reached the 6-month follow-up, with additional data available for 42 patients (41.6%) who reached the 9-month time point. Efficacy end points of interest for this review included the proportion of patients who achieved an MMR, the proportion of patients who achieved MRs (MR2, MR4, MR4.5), defined as 2.0, 4.0, and 4.5 log reductions in *BCR-ABL1* transcripts (≤ 1%, ≤ 0.01%, and ≤ 0.0032%, respectively), duration of and time to MMR, HRQoL as measured by the MD Anderson Symptom Inventory Questionnaire for Chronic Myeloid Leukemia (MDASI-CML), OS, as well as safety outcomes including adverse events (AEs), serious adverse events (SAEs), and notable harms such as pancreatitis and ischemic heart conditions.

The mean age of patients enrolled was 51.2 years (range, 18 years to 89 years), and most patients had an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 (98.0%). All patients had received a prior TKI, the most common of which were dasatinib (45 [44.6%]) and imatinib (43 [42.6%]). The reasons for discontinuing the prior TKI were due to lack of efficacy (57 [56.4%]) and lack of tolerability (44 [43.6%]).

Efficacy Results

Major Molecular Response

The proportion of patients with an MMR was measured at 1 month, 3 months, 6 months, and 9 months in 101 patients with adequate follow-up. At 1 month, MMR was observed in 1.1% of patients (1 of 94; 95% confidence interval [CI], 0.0% to 5.8%). At 3 months, the MMR rate was 39.5% (34 of 86; 95% CI, 29.2% to 50.7%). By 6 months, 44.4% of patients (28 of 63; 95% CI, 31.9% to 57.5%) had an MMR. At 9 months, [redacted]

Results for subgroup analyses by reason for prior TKI discontinuation (lack of efficacy or intolerance) were generally consistent with the primary analysis at the 9-month time point ([redacted]).

Molecular Response 2

The proportion of patients with MR2 was 46.8% ([redacted]) at 1 month, 84.9% (73 of 86; [redacted]) at 3 months, 82.5% ([redacted]) at 6 months, and [redacted] at 9 months.

Molecular Response 4

The proportion of patients with MR4 was 0% (0 of 94; 95% CI, 0.0% to 3.9%) at 1 month, 11.6% (10 of 86; 95% CI, 5.7% to 20.4%) at 3 months, 25.4% (16 of 63; 95% CI, 15.3% to 37.9%) at 6 months, and [redacted] at 9 months.

Molecular Response 4.5

The proportion of patients with MR4.5 was 0% (0 of 94; 95% CI, 0.0% to 3.9%) at 1 month, 2.3% (2 of 86; 95% CI, 0.3% to 8.2%) at 3 months, 9.5% (6 of 63; 95% CI, 3.6% to 19.6%) at 6 months, and [redacted] at 9 months.

Duration of MMR

Results for this outcome were not available as of IA4.

Time to MMR

Results for this outcome were not available as of IA4.

Overall Survival

Results for this outcome were not available as of IA4.

MD Anderson Symptom Inventory Questionnaire for Chronic Myeloid Leukemia

Results for this outcome were not available as of IA4.

Harms Results

Adverse Events

At the time of IA4, most patients (95.0%) experienced at least 1 AE. Headaches and nausea were the most frequently reported AEs experienced by 22.8% and 20.8% of patients, respectively. Cough, diarrhea, fatigue,

and hypertension were each reported as AEs by 16 patients (15.8%). About one-third (31.7%) of patients experienced AEs of grade 3 or higher, the most common of which was hypertension (8.9%).

Serious Adverse Events

Three patients (3.0%) experienced SAEs of grade 3 or higher due to cardiac disorders, gastrointestinal disorders, general disorders, and administration site conditions.

Withdrawals Due to Adverse Events

Three patients (3.0%) discontinued treatment due to AEs, with 1 patient reporting nausea and vomiting of grade 3 or higher.

Mortality

There were no deaths reported as of IA4.

Notable Harms

AEs of special interest in the ASC2ESCALATE study included gastrointestinal toxicity, experienced by 51.5% of patients, followed by hypersensitivity (21.8%), acute pancreatitis including isolated pancreatic enzyme elevations (16.8%), and myelosuppression (11.9%).

Critical Appraisal

There were notable issues with the study design of ASC2ESCALATE, specifically related to the single-arm and open-label nature, as well as the dose-escalation design. Considering the nature of Ph+ CML in the chronic phase (which does not spontaneously reverse), the single-arm, noncomparative design was not deemed inappropriate; however, the lack of comparative evidence versus other second-line treatments (e.g., bosutinib, dasatinib, nilotinib, and imatinib) remains a concern and precludes the ability to assess the comparative effectiveness and safety relative to other available TKIs in clinical practice in Canada. The ASC2ESCALATE study was also open label, potentially increasing the risk of detection bias and performance bias. The reported AEs in the study were consistent with the known and documented profile for asciminib; thus, it is unlikely that the results for harms were biased by the open-label design. Finally, the ASC2ESCALATE study used a dose-escalation design primarily to evaluate the safety and tolerability of increasing doses of asciminib in patients with an inadequate response to the standard dose. This type of design is not usually intended to establish the overall effectiveness or comparative harms of the treatment but rather to identify whether higher doses can be administered safely and was intended to achieve deeper responses with dose escalation. However, the escalated dose of 200 mg is not within the Health Canada–approved dosage of asciminib. Furthermore, only 7 patients received an escalated dose of asciminib as of IA4. According to the FDA, MMR is a surrogate end point used for traditional approval for therapies in CML. According to the 2020 ELN and 2024 NCCN guidelines, sustained MMR (and deep MR) are strong indicators of long-term outcomes including long-term cytogenetic remission and a reduced rate of disease progression. However, the sustainability of MMR observed in patients treated with asciminib in the ASC2ESCALATE study could not be assessed from the interim analysis. Formal statistical tests for efficacy outcomes were not conducted for the ASC2ESCALATE study, and as such, no P values were calculated. The threshold for a positive study outcome was observing a 95% CI for MMR rate at 12 months with a lower limit larger than

30% to reject the null hypothesis. As of the most recent IA4, descriptive results were provided for molecular outcomes (MMR, MR4.5, MR4, and MR2) through to 9 months and harms outcomes (AEs and SAEs) at 6 months. At 6-month and 9-month time points, the proportion of patients with MMR was suggestive of benefit according to the hypothesis previously outlined. However, a limited number of patients were included in the primary efficacy population (n = 101), and only 63 patients and [redacted] patients had MR data available at 6-months and 9-months, respectively, which limits the generalizability of the findings. The evidence provided for the ASC2ESCALATE study at IA4 was considered immature and there was no data available for OS, time to event (time to or duration of MMR), and HRQoL (MDASI-CML). Improvements in quality of life were considered important to patients, clinician groups, and clinical experts consulted for this review, and as such, the lack of such results as of the most recent interim analysis is a notable limitation.

The ASC2ESCALTE trial was conducted exclusively in the US; however, the clinical experts consulted by CDA-AMC noted that the study population was generally consistent with the population expected to receive treatment in Canada. The clinical experts noted that some eligibility criteria such as ECOG PS may have been restrictive, selecting for ideal, less severe patients (e.g., 98% of patients had an ECOG PS score ≤ 1), which may not reflect the general patient population but are typical of clinical trials. The clinical experts also stated that patients with an ECOG PS score of 2 or higher, as well as those with CML in accelerated phase or blast phase — who were excluded from the ASC2ESCALATE trial — could receive asciminib if deemed the best treatment option. The clinical experts also highlighted that there was an overrepresentation of patients who were white (82.2%) in the ASC2ESCALATE study, which is not representative of what would be seen in the population in Canada. The absence of data beyond 9 months limits the ability to assess the durability of treatment responses and long-term safety. Although asciminib has been available in the third-line setting, this is particularly important for this therapeutic class, as AEs may emerge only after prolonged use, with cumulative incidence increasing over time. One clinical expert highlighted the example of nilotinib, where cardiovascular risks became apparent only after a decade on the market.

GRADE Summary of Findings and Certainty of the Evidence

For the pivotal study identified in the sponsor's systematic review, Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to assess the certainty of the evidence for outcomes considered most relevant to inform expert committee deliberations, and a final certainty rating was determined as outlined by the GRADE Working Group. Although GRADE guidance is not available for noncomparative studies, the CDA-AMC review team assessed a pivotal single-arm study for study limitations (which refers to internal validity or risk of bias), inconsistency across studies, indirectness, imprecision of effects, and publication bias to present these important considerations. Because the lack of a comparator arm does not allow for a conclusion to be drawn on the effect of the intervention versus any comparator, the certainty of evidence for single-arm studies starts at very low certainty with no opportunity for rating up.

Table 1 presents the GRADE summary of findings for asciminib for the treatment of patients with CML in chronic phase in the second-line setting. The selection of outcomes for GRADE assessment was based on the sponsor's Summary of Clinical Evidence, consultation with clinical experts, and input received

from patient and clinician groups and public drug plans. The following list of outcomes was finalized in consultation with expert committee members:

- MR (MMR and MR2)
- survival (OS)
- quality of life (MDASI-CML)
- notable harms (pancreatitis and ischemic heart disease).

Table 1: Summary of Findings for Asciminib in Patients With CML in Chronic Phase (Second Line)

Outcome and follow-up (months)	Patients (studies), N	Effect	Certainty[a]	What happens
Molecular response				
Proportion of patients with MMR, defined as a 3.0 log reduction in *BCR-ABL1* transcripts (*BCR-ABL1* on the IS ≤ 0.1%) at 12 months Follow-up: NA	NA (1 single-arm trial)	NA	NA[b]	There is no evidence about the effect of asciminib on the proportion of patients with MMR at 12 months compared to any active comparator.
Proportion of patients with MMR, defined as a 3.0 log reduction in *BCR-ABL1* transcripts (*BCR-ABL1* on the IS ≤ 0.1%) at visit, n (%) Follow-up: 9 months	[redacted]	[redacted]	Low[c,d,e]	The evidence is very uncertain about the effect of asciminib on the proportion of patients with MMR when compared with any comparator.
Proportion of patients with MR2, defined as a 2.0 log reduction in *BCR-ABL1* transcripts (*BCR-ABL1* on the IS ≤ 1.0%) at visit, n (%) Follow-up: 9 months	[redacted]	[redacted]	Low[c,d,e]	The evidence is very uncertain about the effect of asciminib on the proportion of patients with MR2 when compared with any comparator.
OS				
OS Follow-up: NA	NA (1 single-arm trial)	NA	NA[b]	There is no evidence about the effect of asciminib on OS.
Health-related quality of life				
MDASI-CML Follow-up: NA	NA (1 single-arm trial)	NA	NA[b]	There is no evidence about the effect of asciminib on quality of life.
Harms				
Notable harm: Pancreatitis (clinical) Follow-up: 6 months	101 (1 single-arm trial)	0 per 1,000	Very low[c,f]	The evidence is very uncertain about the effect of asciminib on pancreatitis when compared with any comparator.

Outcome and follow-up (months)	Patients (studies), N	Effect	Certainty[a]	What happens
Notable harm: Ischemic heart disease Follow-up: 6 months	101 (1 single-arm trial)	10 per 1,000	Very low[c,f]	The evidence is very uncertain about the effect of asciminib on ischemic heart disease when compared with any comparator.

CDA-AMC = Canada's Drug Agency; CML = chronic myeloid leukemia; IS = international scale; MDASI-CML = MD Anderson Symptom Inventory for Chronic Myeloid Leukemia; MMR = major molecular response; MR = molecular response; NA = not applicable; OS = overall survival.

Note: All serious concerns with study limitations (which refers to internal validity or risk of bias), indirectness, imprecision of effects, and publication bias are documented in the table footnotes.

[a]In the absence of a comparator group, conclusions about efficacy relative to any comparator cannot be drawn and the certainty of evidence is started at very low and cannot be rated up.

[b]The ASC2ESCALATE trial is still ongoing. Data for the primary end point (the proportion of patients with MMR) and secondary end points (OS, MDASI-CML) at 12 months were not reported as of the most recent interim analysis.

[c]Rated down 1 level for serious study limitations as results are based on the most recent interim analysis. Although not necessarily due to bias, interim analyses can overestimate treatment effects.

[d]Rated down 1 level for serious imprecision; evidence from 1 single-arm trial with small sample size (N = 42 patients at 9 months).

[e]Despite the study limitations resulting in the certainty of evidence starting as "very low," the outcomes of MMR and MR2 are demonstrative of an antitumour effect, which is supported by the FDA and the proportion of patients with MR was considered clinically meaningful by the clinical experts consulted for this review. As such, given the effect size, which was believed to be large and clinically important, the CDA-AMC review team considered the certainty of this evidence to be higher.

[f]Rated down 1 level for serious risk of bias due to potential bias arising from the open-label nature of the study and the subjective nature of the outcome.

Long-Term Extension Studies

No long-term extension studies were submitted by the sponsor for this review.

Indirect Comparisons

The sponsor determined that it was infeasible to conduct an indirect treatment comparison for asciminib in the second line; thus, no indirect evidence was submitted for this review.

Studies Addressing Gaps in the Evidence From the Systematic Review

Description of Studies

One retrospective chart review study (Atallah et al.) conducted in the US in adult patients living with Ph+ CML in chronic phase (N = 255) was submitted by the sponsor. Eligible patients did not have a *T315I* mutation and were treated with asciminib after treatment with 1 prior TKI. Time to achieving or maintaining MMR, MR2, and MR4.5 were evaluated using Kaplan-Meier analyses. Subgroup analyses were conducted based on the reason for first TKI discontinuation (intolerance versus resistance) and by TKI generation (first-generation versus second-generation).

The mean age of patients was 60.5 years (standard deviation = 9.5 years) and 43.5% were female and 56.5% were male. A total of 20.8% of patients identified as Black or African American, 16.5% as Hispanic or Latino, 56.1% as white, and 6.7% as other [from original source]. At CML chronic phase diagnosis, 22.0% had low-risk Sokal scores, 57.6% intermediate-risk Sokal scores, and 18.4% high-risk Sokal scores (2.0% unknown). A total of 23.1%, 59.6%, and 17.3% had an ECOG PS score of 0, 1 or at least 2, respectively. For initial treatment, 49.8% of patients received imatinib, while 34.5%, 10.6%, and 5.1% received dasatinib, nilotinib, and bosutinib, respectively. First-line treatment had a mean duration of [redacted] (standard deviation = 17.3 months), during which, [redacted] of patients had an MMR or better. Among subgroups, 43.5% discontinued their first-line TKI due to intolerance and 23.5% due to treatment resistance.

Efficacy Results

Patients Continuing Treatment

Based on Kaplan-Meier analysis, the estimated probability of patients continuing asciminib treatment at 48 weeks was 95.0% (95% CI, 91.3% to 97.1%). The probability of continuing treatment with asciminib at 48 weeks among those who discontinued their first TKI due to intolerance (N = 111) or treatment failure (N = 60) was 97.2% (95% CI, 91.5% to 99.1%) and 92.2% (95% CI, 80.1% to 97.1%), respectively. By initial TKI type, the probability of continuing treatment with asciminib at 48 weeks was 93.4% (95% CI, 87.2% to 96.6%) in patients previously receiving a first-generation TKI (N = 127) and 96.4% (95% CI, 91.0% to 98.7%) in those previously receiving a second-generation TKI (N = 128).

Molecular Outcomes

MMR or Better

At week 48, MMR or better was achieved or maintained by 68.3% of patients (95% CI, 61.8% to 74.5%). The median time to MMR or better was 30.7 weeks. At week 48, the proportion of patients that achieved or maintained MMR or better was 68.4% (95% CI, 58.9% to 77.5%) in patients with intolerance to prior TKI therapy, and 55.8% (95% CI, 42.9% to 69.7%) in patients with prior treatment failure. A total of 73.6% (95% CI, 65.4% to 81.3%) of patients initially treated with a second-generation TKI, and 61.5% (95% CI, 51.7% to 71.5%) with a first-generation TKI had achieved or maintained an MMR or better.

Molecular Response 2

At week 48, 84.0% of patients ( ) achieved or maintained MR2, and the median time to MR2 was . At week 48, the proportion of patients that achieved or maintained MR2 was 90.7% ( ) among those who discontinued their first TKI due to treatment failure and 79.5%; ( ) in those who discontinued due to intolerance. A total of 86.7% ( ) of patients initially treated with a second-generation TKI, and 80.4% (of patients who received a first-generation TKI had achieved or maintained MR2.

Molecular Response 4

At week 48, MR4 was achieved or maintained in 40.6% of patients ( ). At week 48, the proportion of patients that achieved or maintained MR4 was 44.9% ( ) in patients with prior TKI intolerance and 15.9% ( ) with prior TKI failure. MR4 was achieved or maintained by 43.2% ( ) of patients who received a second-generation TKI in first-line and 37.3% ( ) of patients who received a first-generation TKI in first-line.

Harms Results

While receiving treatment with asciminib, the most reported AEs were fatigue (8.6%), headache (7.1%), rash (4.3%), and abdominal pain (2.4%). Gastrointestinal AEs included nausea (11.8%), vomiting (6.7%), and diarrhea (4.7%). Cytopenia occurred in 2.4% of patients. No cases of stroke, myocardial infarction, or heart failure were reported.

Critical Appraisal

The sponsor submitted data on a retrospective chart review study of the efficacy and safety of asciminib in the real-world setting. However, the absence of study protocols and statistical analysis plans limited the ability to fully assess the study design, outcome measurements, and analytical methods. Chart reviews rely on the accuracy and completeness of clinical documentation. The evaluation of real-world MR may have been based on heterogeneous criteria and inconsistent assessment schedules. As such, dates of diagnosis, progression, or death may have been inconsistently recorded, potentially leading to inaccurate results.

By week 48, [redacted] in the overall cohort had either experienced an event or were censored. As censoring could have resulted from various factors including loss to follow-up or disease progression, the potential for biased response estimates cannot be excluded, particularly as the specific reasons and timing for censoring were not reported.

Although the sponsor defined treatment failure based on existing clinical guidelines, physicians may have applied their own criteria when identifying resistance to first-line TKI therapy. Differences in clinical decision-making and patient management across institutions could have confounded results. AEs were recorded during treatment with asciminib, but because physicians may only document AEs that lead to treatment changes (e.g., dose adjustments), underreporting is likely.

The retrospective chart review was conducted exclusively in the US with patients selected by physicians participating in a panel which may limit the generalizability of the findings to clinical practice in Canada. Clinical experts noted that in clinical practice in Canada, in the first-line setting, patients are more likely to receive dasatinib and less likely to receive nilotinib or bosutinib compared to the patients included in the chart review. Despite these differences in treatment patterns, the results suggested that asciminib was associated with consistent benefit in MR across all subgroups, regardless of whether patients initially received a first-generation or second-generation TKI.

Economic Evidence

Economic Evaluation and Budget Impact

- Asciminib is available as 20 mg and 40 mg tablets. At the submitted price of $63.00 per 20 mg tablet and $85.00 per 40 mg tablet, the 28-day cost of asciminib is expected to be $4,760 per patient, based on the Health Canada–recommended dosage.[2]
- Based on the CDA-AMC base-case results, asciminib is expected to be associated with lower drug acquisition costs to health care systems compared to ponatinib (incremental savings = -$66,120) and expected to have higher drug acquisition costs compared to other TKIs ranging from $6,487 (versus bosutinib) to $54,484 (versus imatinib). Due to the absence of evidence, it is uncertain whether there will be differences in nondrug costs related to management of AEs and disease monitoring.
- CDA-AMC estimates that the budget impact of reimbursing asciminib for the treatment of adult patients with Ph+ CML in chronic phase previously treated with at least 1 TKI will be approximately $8

million for the first 3 years of reimbursement compared to the amount currently spent on comparators, with an estimated expenditure of $65 million on asciminib for this period. The actual budget impact of reimbursing asciminib will depend on the percentage of patients covered by public drug plans and the eligible patient population.

Request for Reconsideration

The sponsor filed a request for reconsideration of the draft recommendation for asciminib for the treatment of adult patients with Ph+ CML in chronic phase previously treated with 1 TKI. In their request, the sponsor identified the following issues:

- The sponsor stated that the use of asciminib in the second-line treatment of Ph+ CML in chronic phase is strongly supported by the consistent and robust findings from the ASC2ESCALATE study, real-world evidence from Canada and the US, and feedback from both patients and leading physicians including the ELN and NCCN guidelines. Additionally, the sponsor noted that many patients have comorbidities that limit the use of existing TKI therapies; thus, asciminib represents an additional option for achieving durable disease control. Furthermore, real-world evidence suggests that asciminib is already being used as second-line therapy through private means. As such, the sponsor requested that CDA-AMC revise the draft recommendation and acknowledge that asciminib addresses the well-documented unmet needs in second-line CML in chronic phase by changing the wording from “pERC was unable to substantiate that asciminib meets these needs” to “pERC was able to substantiate that asciminib meets these needs.”
- The sponsor highlighted that although a comparative RCT was not conducted for asciminib in the second-line setting, the same evidence supported the use of other TKIs in the second-line setting, and asciminib has already been compared to first-generation and second-generation TKIs in RCTs conducted in first-line and third-line populations. As such, given the established efficacy in first-line and third-line CML versus standard of care comparators, and the similar disease biology and TKI landscape across first-line, second-line, and third-line settings, the sponsor stated that a comparable response trend could be expected in second line. Thus, the sponsor requested that CDA-AMC acknowledges that asciminib meets the well-documented unmet needs in second-line CML in chronic phase.

In the meeting to discuss the sponsor’s request for reconsideration, pERC considered the following information:

- information from the initial submission related to the issues identified by the sponsor
- feedback from 2 clinical specialists with expertise in diagnosing and treating patients with Ph+ CML in chronic phase
- feedback on the draft recommendation from 2 patient groups: a joint submission from the Leukemia & Lymphoma Society of Canada and the Canadian CML Network, and the CML Society of Canada
- feedback on the draft recommendation from 2 clinician groups: Ontario Health (Cancer Care Ontario) Hematology Cancer Drug Advisory Committee and the Canadian CML Physicians Interest Group

- feedback on the draft recommendation from the public drug plans and cancer agencies that participate in the reimbursement review process
- feedback on the draft recommendation from the sponsor.

All feedback received in response to the draft recommendation is available on the CDA-AMC website.

pERC Information

Members of the Committee (Initial Meeting)

Dr. Catherine Moltzan (Chair), Dr. Philip Blanchette, Dr. Kelvin Chan, Dr. Matthew Cheung, Dr. Michael Crump, Annette Cyr, Dr. Jennifer Fishman, Dr. Jason Hart, Terry Hawrysh, Dr. Yoo-Joung Ko, Dr. Aly-Khan Lalani, Amy Peasgood, Dr. Anca Prica, Dr. Adam Raymakers, Dr. Patricia Tang, Dr. Pierre Villneuve, and Danica Wasney.

Meeting date: August 13, 2025

Regrets: Six expert committee members did not attend.

Conflicts of interest: None.

Members of the Committee (Reconsideration Meeting)

Dr. Catherine Moltzan (Chair), Dr. Kelvin Chan (Vice Chair), Dr. Philip Blanchette, Dr. Matthew Cheung, Dr. Michael Crump, Annette Cyr, Dr. Jennifer Fishman, Dr. Jason Hart, Terry Hawrysh, Dr. Yoo-Joung Ko, Dr. Aly-Khan Lalani, Amy Peasgood, Dr. Anca Prica, Dr. Adam Raymakers, Dr. Patricia Tang, Dr. Pierre Villneuve, Dr. Michael Raphael, and Danica Wasney.

Reconsideration meeting date: February 10, 2026

Regrets: Three expert committee members did not attend.

Conflicts of interest: None.

Canada's Drug Agency
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Questions or requests for information about this report can be directed to Requests@CDA-AMC.ca.