Technology Guidance

Asciminib

for Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase after two or more tyrosine kinase inhibitors

Technology Guidance from the MOH Drug Advisory Committee

Guidance Recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ Asciminib 20 mg and 40 mg tablets as monotherapy for the treatment of patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase whose disease is resistant and/or who are intolerant to two or more tyrosine kinase inhibitors.

  Asciminib is not recommended for patients with T315I mutation.

Funding status

Asciminib 20 mg and 40 mg tablets are recommended for inclusion on the Medication Assistance Fund (MAF) for the abovementioned indication from 1 April 2026.

MAF assistance **does not** apply to asciminib 100 mg tablet.

Clinical indication, subsidy class and MediShield Life claim limit for asciminib are provided in the Annex.

Updated: 6 February 2026

Technology evaluation

1.1. At the March 2025 meeting, the MOH Drug Advisory Committee ("the Committee") considered the technology evaluation of asciminib for treating Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) in patients previously treated with two or more tyrosine kinase inhibitors (TKIs). The evaluation comprised the evidence submission for asciminib (Scemblix) by Novartis, and a review conducted by one of ACE's evidence review centres.

1.2. Expert opinion obtained from clinicians from public healthcare institutions and the MOH Cancer Drug Subcommittee assisted ACE in ascertaining the clinical value of asciminib. Local patient and voluntary organisations were invited to provide their lived experiences to inform the evaluation, however, no submissions were received.

1.3. The evidence was used to inform the Committee's deliberations around four core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
- Estimated annual technology cost and the number of patients likely to benefit from the technology.

1.4. Additional factors, including social and value judgments, may also inform the Committee's funding considerations.

Clinical need

2.1. CML is a myeloproliferative disorder that accounts for 15% to 20% of all cases of leukaemia in adults. For patients with Ph+ CML in CP, TKI monotherapy remains the standard of care across different lines of therapy, with the choice of TKI dependent on patients' experiences in prior lines of therapy and BCR::ABL1 kinase domain mutation status (e.g. T315I mutation).

2.2. The Committee heard that each year approximately 43 local patients with Ph+ CML in CP and without the T315I mutation require subsequent treatment after receiving two or more TKIs. Asciminib is most likely to replace current treatment options for these patients (comparator TKIs: dasatinib, nilotinib and ponatinib).

2.3. The Committee noted that asciminib is also approved by the HSA for treating adult patients with Ph+ CML in CP who have the T315I mutation. The Committee considered it was reasonable that the clinical criteria for funding should specify that asciminib be used only in patients without the T315I mutation, in line with the data presented in the submission.

Clinical effectiveness and safety

3.1. The Committee noted that there was no direct clinical trial evidence comparing asciminib with the comparator TKIs. The submission was based on one phase III, open-label randomised controlled trial (RCT) comparing asciminib with bosutinib (ASCEMBL), and five single-arm or non-randomised studies investigating the comparator TKIs for treating CML in CP in patients previously treated with two or more TKIs (Rossi et al. 2013, Tan et al. 2019, Ibrahim et al. 2010, Giles et al. 2010 and PACE). The Committee considered that bosutinib was not a relevant comparator as it was not registered by HSA and not used in local clinical practice.

3.2. The Committee reviewed a series of unanchored matching-adjusted indirect comparisons (MAICs) that estimated the relative efficacy of asciminib versus the comparator TKIs. The efficacy outcomes included time-to-treatment discontinuation (TTD), major molecular response (MMR) and complete cytogenetic response (CCyR) rates.

3.3. The ASCEMBL trial was considered to have a moderate risk of bias due to its open-label nature. The studies investigating the comparator TKIs were considered to have a high risk of bias as they were either single-arm or non-randomised.

3.4. The Committee noted significant transitivity issues in the included studies due to cross-study heterogeneity for various patient characteristics. Adjustment was not possible for some known prognostic factors of CML in CP (e.g. T315I mutation status), or for unknown or unmeasured confounders. In some analyses, convergence of all baseline characteristics that impacted outcomes was not plausible, and selected characteristics were removed in the MAIC models. The resultant effective sample size across the MAICs was small (15% to 39% of the ASCEMBL population), with data weighted heavily on a small number of patients.

3.5. The Committee also noted that the MAIC results were not consistent. While some analyses favoured asciminib over the comparator TKIs, others showed either similar results or favoured the comparator TKIs over asciminib.

3.6. Regarding safety, the Committee noted that the submitted naïve indirect treatment comparisons were informed by single-arm data from different studies, each with different follow-up durations. Moreover, the adverse event data presented for dasatinib and nilotinib were limited.

3.7. Based on the available evidence, the Committee considered that the submission's clinical claim of superior effectiveness and safety for asciminib compared with the comparator TKIs was not adequately supported. The Committee concluded that it was more reasonable to consider asciminib non-inferior to the comparator TKIs in this setting.

Cost effectiveness

4.1. The Committee noted that the submission included a cost-utility analysis comparing asciminib with the comparator TKIs, based on results of the MAICs. However, the Committee considered the submission's economic model inappropriate for decision-making, given a lack of evidence to support a claim of superiority for asciminib over the comparator TKIs. The Committee considered that a cost-minimisation analysis (CMA) was more appropriate.

4.2. The evidence review centre conducted a CMA using equi-effective doses of: asciminib 79.8 mg/day ≡ dasatinib 109.7 mg/day ≡ nilotinib 782.5 mg/day ≡ ponatinib 27.2 mg/day. These were based on equi-effective doses accepted by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) and the median dose intensity reported in PACE for ponatinib. Based on the CMA, the Committee noted that the total treatment cost of asciminib was higher than that of dasatinib, nilotinib or ponatinib.

4.3. The Committee therefore considered that, at the proposed price, asciminib did not represent a cost-effective use of healthcare resources for treating Ph+ CML in CP in patients previously treated with two or more TKIs.

Estimated annual technology cost

5.1. Using an epidemiological approach, the submission estimated that the annual cost impact to the public healthcare system would increase from less than SG$1 million in the first year, to between SG$3 million and SG$5 million in the fifth year of listing asciminib on the MOH List of Subsidised Drugs for treating Ph+ CML in CP in patients previously treated with two or more TKIs.

5.2. The Committee considered that the submission's estimates and price-volume agreement (PVA) caps were overestimated, due primarily to double-counting of patients in the budget impact model and inappropriate inclusion of patients with the T315I mutation. Based on the revised budget impact model, the annual cost impact to the public healthcare system was estimated to be less than SG$1 million in the first five years of listing.

Recommendations (March 2025)

6.1. Based on the evidence submitted, the Committee recommended not listing asciminib on the MOH List of Subsidised Drugs for treating Ph+ CML in CP in patients previously treated with two or more TKIs. The decision was based on the unfavourable cost-effectiveness of asciminib compared with dasatinib, nilotinib and ponatinib, and the unacceptable PVA proposed by the company.

Updated recommendations (November 2025)

7.1. Following a negative recommendation at the March 2025 meeting, the company of asciminib submitted a revised proposal for funding consideration.

7.2. Overall, the Committee considered the revised proposal acceptable, taking into account cost-effectiveness and budget certainty considerations. Hence, the Committee recommended asciminib 20 mg and 40 mg tablets be listed on the Medication Assistance Fund (MAF) as monotherapy for the treatment of patients with Ph+ CML in CP whose disease is resistant and/or who are intolerant to two or more TKIs. Asciminib was not recommended for treating patients with T315I mutation.

ANNEX

Recommendations by the MOH Drug Advisory Committee

Drug preparation	Approved clinical indication	Subsidy class (implementation date)	MediShield Life claim limit per month (implementation date)
Asciminib 20 mg and 40 mg tablets	Monotherapy for the treatment of patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase whose disease is resistant and/or who are intolerant to two or more tyrosine kinase inhibitors. Asciminib is not recommended for patients with T315I mutation.	MAF (1 Apr 2026)	$1,600 (1 Apr 2026)

Abbreviations: MAF, Medication Assistance Fund.

VERSION HISTORY

Guidance on asciminib for Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase after two or more tyrosine kinase inhibitors

This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance**

   Date of Publication 4 Jun 2025

2. **Guidance updated to reflect the inclusion of asciminib on the MAF and its MediShield Life claim limit**

   Date of Publication 6 Feb 2026