6.15 ASCIMINIB, Tablet 20 mg, Tablet 40 mg, Scemblix®, Novartis Pharmaceuticals Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested to add nurse practitioners (NPs) to the prescriber type of Pharmaceutical Benefits Scheme (PBS)-listed asciminib 20 mg, 40 mg for all current indications, both in initiation and continuation phases of treatment. Currently, only Medical Practitioners can prescribe asciminib under the PBS.

2 Background

2.1 Asciminib is currently listed on the PBS as a General Schedule (Authority Required) listing for the treatment of:

- patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) or accelerated phase (AP), who had been previously treated with two or more tyrosine kinase inhibitors (TKIs). This is in the third-line setting or beyond.
- patients with Ph+ CML in CP or AP, who had been previously treated with one or more TKIs and harbouring the T315I mutation. This is in the second-line setting or beyond.

Registration status

2.2 Asciminib was TGA registered on 31 August 2022 for:

- the treatment of patients 18 years of age and above with newly diagnosed Ph+ CML in CP
- the treatment of patients 18 years of age and above with Ph+ CML in CP previously treated with two or more tyrosine kinase inhibitors.

2.3 Asciminib was TGA registered on 1 July 2025 for the treatment of patients 18 years of age and above with Ph+ CML in CP with the T315I mutation.

Previous PBAC consideration

2.4 Initially, the PBAC did not recommend asciminib for listing at its July 2022 meeting for patients with Ph+ CML in CP, who had been previously treated with two or more TKIs.

2.5 In its decision, the PBAC stated it would consider recommending a resubmission that provided:

- expanded restrictions to include a second indication for patients with the T315I mutation
- additional clinical data showing asciminib to be non-inferior to ponatinib in this population.

The sponsor did not request nurse practitioner prescribing nor discuss nurse practitioner prescribing in its submission (July 2022 Public Summary Document).

2.6 At its November 2022 meeting, the PBAC considered that the resubmission for asciminib addressed these issues and recommended its listing for both indications. PBS listing became effective from 1 May 2023.

2.7 In its decision, the PBAC advised that asciminib is not suitable for prescribing by nurse practitioners, noting that existing tyrosine kinase inhibitors listed at the time were not available for nurse practitioner prescribing (November 2022 Public Summary Document [PSD]). No further elaboration on this unsuitability is provided in the November 2022 meeting minutes or PSD.

2.8 At its March 2026 meeting, the PBAC was to consider a Category 2 submission requesting a change of indication for asciminib for its use as a first-line therapy. However, this submission was withdrawn prior to the meeting.

Updates to Line-Agnostic listing of TKI medicines for CML

2.9 At its December 2023 meeting, the PBAC reviewed some proposed updates to the restrictions for tyrosine kinase inhibitors (TKI) for the treatment of CML. In its advice, the PBAC recommended updating the listings for TKI medicines imatinib, dasatinib and nilotinib for CML, regardless of line of therapy or phase (accelerated/chronic/blast):

- to list initial treatment as telephone/online with Streamlined listings for Continuing treatment
- to remove prescribing/administrative advice around diagnosis, and definitions of response/non-response from restrictions.

This recommendation has not yet been implemented.

2.10 The PBAC considered that these changes should not be extended to asciminib, as the evidence base for asciminib was not as mature as that for imatinib, dasatinib or nilotinib at the time of recommendation. For asciminib (3L setting or beyond; 2L

setting or beyond with T315I mutation), the PBAC advised that the restriction criteria should continue to specify "CML not blast phase (BP)". Also, the PBAC advised that treatment with asciminib should not be line agnostic.

PBS Review of Prescribing by Nurse Practitioners

2.11 The PBAC recalled from its March 2024 meeting its General Principles for Prescriber Type Determination. Under these Principles, the PBAC is to consider whether prescriber groups (e.g., optometrists, nurse practitioners, endorsed midwives) are to be excluded from prescribing. This consideration is to be cited in minutes and PSDs for PBAC items.

2.12 The department has recently completed a review of PBS prescribing by NPs and endorsed midwives. This is in response to Item 4.1.2 of the Nurse Practitioner Workforce Plan released by the Australian Government in May 2023. In early 2024, the then-PBAC Chair consulted with health professional groups (nurse practitioner, midwifery, medical and rural/remote medicine) in the development of general principles for determining prescriber types for PBS listings. While the draft guidance principles were developed in the context of this PBS Review, the guidance principles were intended to be applicable to all PBS prescribers. The PBAC endorsed the guidance principles for determining PBS prescriber type eligibility at its March 2024 meeting. An abridged version is shown in Table 1.

Table 1: PBAC general principles for guiding PBS prescriber type eligibility (abridged)

Principle		Considerations may include (but are not limited to):
1	Scope of practice of the health practitioner group	Consider if the prescriber group is likely to be required to treat patients with this medicine.
2	Scope of practice of individual health practitioners	Consider whether a subset of prescribers within the health practitioner group have an extended or specialised scope of practice. Consider what education, training or experience may be required, how this is recognised, and the context of practice for these health practitioners.
3	Medicine specific considerations	Consider any medicine-specific risks for prescribing e.g. narrow therapeutic index, addiction/diversion risks, dosing error risks, severe side effects, medicine scheduling. Consider medicine cost/overall Government budget impact.
4	Health condition specific considerations	Consider the complexity of the condition the medicine is used for, risk and implications of misdiagnosis or mismanagement, and consequences of possible treatment delay.

2.13 Between 1 March – 1 April 2024, the department published a consultation survey to inform the PBS Review, to collect data on which medicines are frequently being prescribed privately by nurse practitioners and endorsed midwives that are subsidised through the PBS when prescribed by another prescriber type, and the settings in which this is occurring. The survey received feedback from consumers, carers, health professionals, consumer groups and peak representative organisations

2.14 Under this review, at its July 2025 meeting, the PBAC considered a tranche of identified medicines for the Review consisting of General Schedule oncology, haematology, and S100 HSD medicines. The PBAC considered whether stakeholder-identified medicines should be eligible for NP prescribing. Asciminib was

not considered at this meeting as it had not been identified for review by stakeholders. Given that asciminib was first listed on 1 May 2023 and the NP/MW online consultation survey only opened in March 2024, NP experience and awareness of asciminib on the PBS may have been low and therefore not identified widely by nurse practitioners in the responses to the survey. Instead, long-standing CML treatments such as imatinib, dasatinib and nilotinib, as well as others, were identified by nurse practitioner survey respondents.

2.15 For oncological or haematological conditions in general, the PBAC considered that the clinical work up required for a diagnosis and differential diagnosis may be complex and likely require that a patient's care be overseen by an oncologist or haematologist. As such, the PBAC was of a view that limiting nurse practitioner prescribing to continuing therapy with a specific medicine, and where patient care is shared with a medical practitioner, would assist in mitigating potential risks. These considerations applied to the TKIs treating CML that were specifically identified by nurse practitioners from the online consultation survey open throughout March 2024 (imatinib, dasatinib, nilotinib, and ponatinib).

2.16 These July 2025 PBAC recommendations for oncology and haematology General Schedule medicines were implemented on 1 February 2026. The following treatment criterion was added:

Treatment criteria:

Must be treated by a medical practitioner; or

Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine

3 Requested listing

3.1 The sponsor requested the addition of NPs as a prescriber type to all existing asciminib listings for both initial and continuing treatment phases.

The Secretariat proposed to add 'NP – nurse practitioner' prescriber type to the existing continuing treatment phase listings as follows:

Table 2: PBS items and treatment phases for which NPs are to be added as a prescriber type

PBS item codes	Restriction summary	Treatment of concept	Treatment phase
13268H	13923	13923	Continuing treatment for patients without T315I mutation
13259W	13923	13923	Continuing treatment for patients without T315I mutation
13260X	13987	14008	Continuing treatment for patients with T315I mutation

To the concepts above, the Secretariat proposed that the following treatment criteria be applied:

Treatment criteria:

Must be treated by a medical practitioner; or

Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer inputs

4.2 The PBAC noted and welcomed the input from individuals (2) via the Office of Health Technology Assessment Consultation Hub. The PBAC acknowledged CML as an insidious disease that brings emotional and physical pain to both patients and families. It noted consumer input describing asciminib as offering treatment with milder side effects and the possibility of a longer life. The input described asciminib as unaffordable without PBS listing.

Basis of the request

4.3 The submission presented a narrative of the role of NPs in the clinical management algorithm for CML and thus proposes a new prescribing model. This was based on anecdotal evidence from the sponsor's conversations with current haematology NPs.

4.4 The submission presented NPs as key members of multidisciplinary teams, where treatment decisions are made collaboratively. While the clinical haematologist diagnoses, the NP carries out and interprets tests under their direction. These tests can determine the phase of disease. The patient would also regularly attend follow-up appointments with the NP to monitor disease progression and manage any symptoms resulting from disease or treatment.

4.5 Asciminib is currently prescribed as a third-line therapy for CML for patients without the T315I mutation. The submission argued that where a patient has failed first and second line TKIs, the NP would have already been extensively involved in their care. With this experience, the NP would be able to identify changes in disease progression and the need to initiate asciminib.

Basis of request for Initiation Phase

4.6 During the initial appointment, the NP would spend time running tests to confirm a diagnosis as well as understand the patient holistically. All results from these tests, as well as any other necessary information would be taken to discussion with the haematologist and other members of the multidisciplinary team to determine the best treatment for the patient. Based on this treatment algorithm, the submission argued for NPs to be able to initiate prescription of asciminib.

4.7 The submission argued that allowing haematology NPs to initiate asciminib would not change the current treatment decision processes, but it would just allow NPs to see their patients as soon as a multidisciplinary team treatment decision is made. Rather than sending their patient back to a haematologist for a script, the NP, after consultation with the MDT, would be able to write the initiation script in clinic. This would lower the administrative burden for the haematologist.

4.8 However, the proposed NP-initiated, multidisciplinary team treatment decision process may be incongruous with PBAC's July 2025 recommendations for other TKI medicines (see paragraph 2.15), that limits NP prescribing to continuing therapy. Additionally, NPs may not be an appropriate proxy for the haematologist in prescribing and providing patient advice on the new asciminib treatment.

Basis of request for Continuing Phase

4.9 The submission argued that NPs already have prescribing power for other therapies for CML, as well as medications to manage patients' disease, such as anti-nausea, pain medications and anti-hypertensives. The submission argued that prescribing these additional agents require a high working knowledge of the disease and asciminib to ensure the avoidance of any drug interactions.

4.10 It is also in line with the PBAC's July 2025 decision for similar General Schedule oncology and haematology medicines. These were recommended to allow NPs to continue existing therapy, where patient care is being shared with a medical practitioner (see paragraph 2.15).

Estimated financial implications

4.11 The submission stated that it is not expected that the requested change will result in an increase in asciminib utilisation. This was due to:

- No change to size of patient population (no change in market size)
- No change to the current treatment algorithm (no change in annual packs consumed)
- No change to the price per unit of existing medications (no change in total cost)
- No change to the service delivery arrangements (no flow-on change to Services Australia)
- No change to the utilisation of testing or medical imaging (no flow-on change to Medical Benefits Schedule).

As such, the submission estimated that there will be no additional cost to the PBS.

5 PBAC Outcome

5.1 The PBAC recommended amending asciminib's listing to add nurse practitioners as eligible prescribers, but for the continuing phase only for both indications.

5.2 Consistent with its July 2025 consideration, the PBAC gave particular attention to the General Guidance Principle 4 and the specific considerations in the diagnosis and management of chronic myeloid leukaemia.

5.3 The PBAC considered that the clinical expertise required in determining whether a patient is in the blast phase or not, as well as assessing for a haematological or cytogenetic response or disease progression to prior tyrosine kinase inhibitor treatment as all required in the initial treatment restriction, likely requires that a patient's care be overseen by a haematologist.

5.4 As such, the PBAC was of a view that limiting nurse practitioner prescribing to continuing therapy with asciminib and where patient care is shared with a medical practitioner (haematologist), would assist in mitigating potential risks of non-compliance with the initial treatment restriction requirements.

5.5 The PBAC advised that listing for asciminib should follow precedent for other NP prescribing items for other drugs in the same class, recalling its June 2025 decision for other CML medicines.

5.6 The PBAC considered that there would be no additional cost to the PBS.

5.7 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically, the PBAC found that in the circumstances of its recommendation for amendment to the NP prescribing arrangements, it is not expected to address a high and urgent unmet clinical need.

5.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

6 Recommended listing

6.1 Add Nurse Practitioner (NP) prescriber type to the Continuing treatment phases only.

6.2 Add Treatment criteria as described below to the Continuing treatment phases only – only the added treatment criteria are shown below; all other existing eligibility criteria are to remain:

Continuing treatment for patients *without* T315I mutation

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ASCMINIB						
asciminib 20 mg tablet, 60		13268H	1	60	5	SCEMBLIX
asciminib 40 mg tablet, 60		13259W	1	60	5	SCEMBLIX
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒Medical Practitioners ☒*Nurse Practitioners*					
	Restriction type: ☒ Authority Required (Streamlined)					
	Indication: Chronic myeloid leukemia					
	Treatment phase: Continuing treatment for patients without T315I mutation					
	Treatment criteria:					
	Must be treated by a medical practitioner; or					
	Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine					

Continuing treatment for patients *with* T315I mutation

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ASCMINIB					
asciminib 40 mg tablet, 60	13260X	5	300	5	SCEMBLIX
	Category / Program: ☒GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒*Nurse Practitioners*				
	Restriction type: ☒ Authority Required				
	Indication: Chronic myeloid leukemia				
	Treatment Phase: Continuing PBS-subsidised treatment for patients with T315I mutation				
	Treatment criteria:				
	Must be treated by a medical practitioner; or				
	Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine				

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.