6.15 RUXOLITINIB, Tablet 5 mg, Tablet 10 mg, Tablet 15 mg, Tablet 20 mg, Jakavi®, 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 PBS-listed ruxolitinib 5 mg, 10 mg, 15 mg and 20 mg for the treatment of myelofibrosis (MF), polycythemia vera (PV) and acute and chronic graft versus host disease (aGVHD, cGVHD) both in initiation and continuation phases of treatment. Currently, only Medical Practitioners can prescribe ruxolitinib under the PBS. The submission proposed that any NP prescribing would be in consultation with a specialist physician.

2 Background

2.1 Ruxolitinib is currently listed on the PBS as:

- A General Schedule (Authority Required) listing for the treatment of Intermediate-1 risk, High risk and Intermediate-2 risk myelofibrosis (MF)
- A Section 100 – Highly Specialised Drugs Program listing for the treatment of Grade II to IV acute graft vs host disease (aGVHD)
- A General Schedule (Authority Required) listing for the treatment of moderate to severe chronic graft vs host disease (cGHVD)
- A General Schedule (Authority Required) listing for the treatment of polycythemia vera.

Registration status

2.2 Ruxolitinib was originally registered on the Australian Register of Therapeutic Goods (ARTG) on 3 July 2013 for its 5 mg, 15 mg and 20 mg strengths. Its 10 mg strength was subsequently ARTG registered on 16 December 2015. As of 10 November 2023, ruxolitinib is TGA registered for the treatment of:

- disease-related splenomegaly or symptoms in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis

- adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea
- patients aged 12 years and older with acute graft-versus-host disease who have inadequate response to corticosteroids
- patients aged 12 years and older with chronic graft-versus-host disease who have inadequate response to corticosteroids.

Previous PBAC consideration

2.3 Previous PBAC recommendations of ruxolitinib for the treatment of myelofibrosis, polycythemia vera, acute graft-vs-host disease and chronic graft-vs-host disease all restricted prescribing to medical practitioners only.

Myelofibrosis

2.4 The PBAC did not recommend ruxolitinib for MF for high risk and intermediate-2 risk patients at its July 2013 meeting due to its unacceptably high price, where its benefits were not commensurate with its costs.

2.5 The PBAC deferred its decision on the resubmission at its July 2014 meeting due to a lack of clarity around its clinical place, concerns around proposed restrictions, and an unacceptably high price.

2.6 At its March 2015 meeting, the PBAC recommended listing for MF based on a lowered cost and a broadened population to include intermediate-1 risk patients, alongside high risk and intermediate-2 risk patients. The PBAC advised that ruxolitinib was not suitable for prescribing by Nurse Practitioners.

2.7 At its November 2025 meeting, PBAC recommended listing fedratinib for patients with intermediate/high-risk primary MF, post-PV MF, or post-essential thrombocythaemia MF.

2.8 The PBAC considered that NPs should be permitted to prescribe fedratinib for continuing existing treatment, where the patient's care is shared with a medical practitioner. The PBAC considered this should flow on to the listings for momelotinib and ruxolitinib for the intermediate-1, intermediate-2 and high-risk myelofibrosis populations. The flow-on for the listing comprised adding NPs as a prescriber type to all strengths of ruxolitinib, as well as the addition of the following treatment criteria (paragraph 8.4, fedratinib Public Summary Document, November 2025 meeting):

> **[34120] Treatment criteria:**
>
> [33255] Must be treated by a medical practitioner; or
>
> [34119] 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

Polycythemia Vera

2.9 The PBAC did not recommend ruxolitinib for PV at its July 2013 meeting due to its unacceptably high price, where its benefits were not commensurate with its costs.

2.10 The PBAC did not recommend ruxolitinib for PV at its November 2019 meeting. The PBAC considered that clinical benefit was not supported by evidence, and that the economic model was not sound.

2.11 At its March 2025 meeting, the PBAC recommended ruxolitinib for PV, where patients were resistant to or intolerant of hydroxycarbamide. The PBAC considered that the cost-per-overall response and the revised economic model demonstrated cost-effectiveness. The PBAC restricted prescribing to medical practitioners only, but did not advise on whether ruxolitinib was unsuitable for NP prescribing.

Acute Graft vs Host Disease

2.12 Ruxolitinib was recommended for aGVHD at its July 2022 PBAC meeting. The PBAC restricted prescribing to medical practitioners only, but did not advise on whether ruxolitinib was unsuitable for NP prescribing.

Chronic Graft vs Host Disease

2.13 Initially, at its July 2022 meeting, the PBAC did not recommend ruxolitinib for moderate to severe cGVHD. The PBAC considered the economic modelling unacceptable and the financial estimates overestimated.

2.14 The PBAC did not consider these issues adequately resolved by the resubmission to its September 2022 meeting, and did not recommend ruxolitinib at that time.

2.15 The PBAC recommended ruxolitinib for cGVHD at its November 2022 PBAC meeting. The PBAC considered ruxolitinib cost-effective at the price proposed, and changes to the financial estimates acceptable. The PBAC restricted prescribing to medical practitioners only, but did not advise on whether ruxolitinib was unsuitable for NP prescribing.

PBS Review of Prescribing by Nurse Practitioners

2.16 The department 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 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.

2.17 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.

2.18 Between 1 March – 1 April 2024, the Department of Health, Disability and Ageing 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

2.19 Under its 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 Highly Specialised Drug (HSD) medicines. Ruxolitinib was not considered at this meeting as it had not been identified for review by stakeholders.

2.20 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 (Nurse Practitioners, Minutes, July 2025 meeting).

2.21 Most of the identified General Schedule oncology and haematology medicines were recommended to allow NPs to continue existing therapy, where patient care is being shared with a medical practitioner. These July 2025 PBAC recommendations for oncology and haematology General Schedule medicines were implemented on 1 February 2026.

2.22 For the General Schedule oncology and haematology medicines referred to above, the PBAC advised to add the prescriber type 'nurse practitioner' and the following

Treatment Criterion to any treatment phase listing described as 'Continuing treatment' or 'Maintenance treatment' or equivalent (where there are at least two treatment phase listings) as well as to any listing where no treatment phase exists (Nurse Practitioners, Minutes, July 2025 meeting):

[34120] Treatment criteria:

[33255] Must be treated by a medical practitioner; or

[34119] 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

2.23 Several medicines on the S100 HSD program were recommended by the PBAC at its July 2025 meeting to be suitable for prescribing by NPs for continuing treatment, with agreement from the treating specialist medical practitioner. The PBAC noted that amendments to the S100 HSD program legislative instrument would be required to facilitate nurse practitioner prescribing for these medicines. At the time of this March 2026 meeting, the department had yet to implement the PBAC's S100 HSD recommendations from July 2025, but advised that it was progressing the necessary amendments to the legislated Section 100 arrangements.

2.24 For the s100 HSD medicines referred to above, the PBAC advised to add the prescriber type 'nurse practitioner' and the following Treatment Criterion in the same manner as described in paragraph 2.21 above: (Nurse Practitioners, Minutes, July 2025 meeting):

[New TC1] Treatment criteria:

[33255] Must be treated by a specialist medical practitioner; or

[New TC1.1] Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner

3 Requested listing

3.1 The sponsor proposed adding NP prescribing to all indications, for both initiating and continuing phases.

3.2 The Secretariat proposed to add NP prescribing to the continuing phase only. For PV, the Secretariat proposed NP prescribing for subsequent continuing treatment only.

3.3 As such, the Secretariat proposed to add 'NP – nurse practitioner' prescriber type to the existing PBS item codes as follows:

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

PBS item codes	Indication	Restriction summary	Treatment of concept	Treatment phase
14990Y 14991B 15014F 15002N	PV	17051	17019	Subsequent continuing treatment
10616R 10927D 10619X 10618W	Intermediate-1 risk MF	167373	167373	Continuing treatment
10616R 10927D 10619X 10618W	High-risk and intermediate-2 risk MF	13637	13637	Continuing treatment

To the above concepts, 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

The Secretariat also proposed to add the 'NP – nurse practitioner' prescriber type to these PBS item codes as follows, under different treatment criteria:

Table 3: PBS items and treatment phases for which NPs are to be added as a prescriber type

PBS item codes	Indication	Restriction summary	Treatment of concept	Treatment phase
13241X 13235N	Moderate to severe cGVHD	13867	13867	Continuing treatment
13238R/Public 13245D/Public	Grade II to IV aGVHD	13892	13892	Continuing treatment
13244C/Private 13231J/Private	Grade II to IV aGVHD	13908	13876	Continuing treatment

3.4 The Secretariat noted that for the concepts in Table 3, the sponsor had not requested changes to the existing treatment criteria. However, this treatment criteria would not allow for the proposed NP prescribing.

3.5 As such, the Secretariat proposed that to the following changes be applied to the PBS restriction criteria pertaining to prescriber types:

Remove:

[28311] Existing treatment criterion:

[26077] Must be treated by a haematologist; or

[28309] Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or

[28310] Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

And replace with:

[New TC1] **Treatment criteria:**

[33255] Must be treated by a specialist medical practitioner; or

[New TC1.1] Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner

3.6 This is in line with the July 2025 advice from PBAC on the role of nurse practitioners in prescribing haematology medicines (see paragraph 2.19) as applied in the context of the PBAC's July 2025 recommendations for NP prescribing of s100 HSD medicines(see paragraph 2.22).

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 one health professional via the Office of Health Technology Assessment Consultation Hub. The input highlighted the role of nurse practitioners in patient care, and their current inability to provide ongoing prescriptions, when assessed as required within their scope. It noted the potential for them to be able to support clients and reduce demand on colleagues if NP prescribing were permitted.

Basis of the request

4.3 The submission requested the expansion of prescribing abilities for Nurse Practitioners who specialise in haematological disorders to both initiate and continue ruxolitinib for the treatment of intermediate 1, 2 and High Risk MF, PV, aGVHD and cGVHD.

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

4.5 The submission presented NPs as key members of multidisciplinary teams, where treatment decisions are made collaboratively. Once the clinical haematologist has

diagnosed and the MDT has agreed on the best treatment, the NP is responsible for most ongoing patient care. The patient regularly attends follow-up appointments with the NP to monitor disease progression and manage any symptoms resulting from disease or treatment.

4.6 The PBAC previously noted that Principle 4 of the 'General guidance principles for PBS prescriber type determination' asks that consideration be given to the complexity of the condition for which a medicine is being prescribed. (Nurse Practitioners, Minutes, July 2025 meeting).

4.7 For oncological or haematological conditions, the PBAC previously 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. The PBAC was of the view that it would be reasonable to expect initial treatment for these complex conditions to be authorised by a medical practitioner (Nurse Practitioners, Minutes, July 2025 meeting) (also see paragraph 2.10).

Basis of request for initiation phase

4.8 For PV, the submission noted that ruxolitinib is a second-line treatment. NPs are currently able to prescribe continuation of first-line treatment hydroxycarbamide. NPs also can initiate and continue treatment with alternative first-line treatment (peg)interferon.

4.9 Therefore, the submission argued that where a patient has failed first line therapy, the NP would have already been extensively involved in their care. With this experience and knowledge of the disease, the NP would be able to identify changes in disease progression and the need to initiate ruxolitinib to treat PV.

4.10 The submission argued that for all indications, delays in initiating treatment would result in potential serious harm for the patient. For MF and PV, the submission claimed that delays would result in disease progression and/or cardiovascular related complications. For aGVHD & cGVHD, the submission claimed that delays are life threatening due to the high mortality and morbidity of GVHD. The submission argued that such delays would be avoidable if NPs were given the power to initiate prescribing.

4.11 During an 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.

4.12 As such, the submission argued that allowing haematology NPs to initiate ruxolitinib would not change the current treatment decision processes. Instead, it would allow the NP to immediately write an initiation script in clinic after the multidisciplinary team decision had been made. This would avoid the delays of patient back to a

haematologist for a script and save the haematologist time (section 1.5.5, ruxolitinib submission).

4.13 However, the proposed NP-initiated, multidisciplinary team treatment decision process may be incongruous with PBAC's July 2025 recommendations (see paragraph 2.10 and the complexity of the diseases (see paragraph 4.5). Additionally, NPs may not be an appropriate proxy for the haematologist in prescribing and providing patient advice on the new ruxolitinib treatment.

Basis of request for the continuation phase

4.14 The submission argued that NPs already have prescribing power for other therapies for all indications, as well as medications to manage patients' disease, such as anti-nausea, pain and anti-hypertensive medications. The submission argued that prescribing these additional agents requires a high working knowledge of the disease and ruxolitinib to ensure the avoidance of any drug interactions.

4.15 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 2.16).

Estimated financial implications

4.16 The submission stated that it is not expected that the requested change will result in an increase in ruxolitinib utilisation.

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

However, it should be noted that ruxolitinib will be subject to a 19-year anniversary price reduction of 5% on 1 April 2026.

5 PBAC Outcome

5.1 The PBAC recommended listing ruxolitinib for NP prescribing for continuing treatment only for all indications. The PBAC advised that ruxolitinib would not be suitable for initiation by NPs.

5.2 The PBAC advised that listing for ruxolitinib should follow precedent for other NP prescribing items for similar haematological drugs. The PBAC recalled its July 2025 recommendations with regards to medicines prescribed for haematology indications and considered that limiting NP prescribing of ruxolitinb to continuing treatment where patient care is shared would be consistent with the PBAC's most recent recommendation in the context of haematology medicines.

5.3 The PBAC further recalled its November 2025 consideration of fedratinib and its recommendation to permit NP prescribing of continuing treatment of MF, which had the flow-on change to ruxolitinib and NP prescribing (see paragraph 2.7).

5.4 For PV, the PBAC advised NP prescribing was suitable for subsequent continuing treatment only. Under General Guidance Principle 4, the PBAC considered the complexity of each indication was such that in its view, a nurse practitioner, whether in consultation with a multidisciplinary team or practicing independently, would not ordinarily establish the diagnosis.

5.5 Whilst nurse practitioners are acknowledged to be multidisciplinary team members in some practice settings with important, defined clinical roles, it was the PBAC's view that the treating haematologist in the multidisciplinary team would be the prescriber with ultimate responsibility and expertise in establishing a diagnosis and declaring compliance with PBS restriction criteria.

5.6 In PV specifically, the First Continuing treatment restriction requires that a response be achieved and maintained, including palpable splenomegaly being excluded - the PBAC's view was that the absence of palpable splenomegaly is a clinical finding most accurately made by medical practitioner.

5.7 The PBAC noted that amendments to the S100 HSD program legislative instrument would be required to facilitate nurse practitioner prescribing for ruxolitinib for the continuing treatment of aGVHD.

4.17 As no changes were requested to the patient population eligibility requirements the PBAC considered that this amendment was not anticipated to result in a change in utilisation of ruxolitinib and that there would be no financial impact to the PBS and RPBS.

5.8 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.

5.9 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 prescriber type 'nurse practitioner' and treatment criterion 34120 to the restrictions for PV, MF and flow-on restrictions for momelotinib as follows. Full restrictions are not displayed and existing eligibility criteria are unchanged:

Polycythemia vera

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
RUXOLITINIB					
ruxolitinib 5mg tablet, 56	14990Y	1	56	5	Jakavi
ruxolitinib 10 mg tablet, 56	14991B	1	56	5	Jakavi
ruxolitinib 15mg tablet, 56	15014F	1	56	5	Jakavi
ruxolitinib 20mg tablet, 56	15002N	1	56	5	Jakavi

	Category / Program: GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: Authority Required (telephone/online PBS Authorities system)
	Indication: Polycythemia vera
	Treatment Phase: Subsequent continuing treatment
	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

Myelofibrosis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
RUXOLITINIB					
ruxolitinib 5mg tablet, 56	10616R	2	112	5	Jakavi®
ruxolitinib 10 mg tablet, 56	10927D	1	56	5	Jakavi®
ruxolitinib 15mg tablet, 56	10619X	1	56	0	Jakavi®
ruxolitinib 20mg tablet, 56	10618W	1	56	0	Jakavi®

	Category / Program: ☒GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: ☒ Authority Required (STREAMLINED)
	Indication: Intermediate-1 risk myelofibrosis
	Treatment Phase: Continuing treatment
	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
	Category / Program: ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: ☒ Authority Required (STREAMLINED)
	Indication: High-risk and Intermediate-2 risk myelofibrosis
	Treatment Phase: Continuing treatment
	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

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
MOMELOTINIB						
momelotinib 100mg tablet, 30		14743Y	1	30	5	omjarra®
momelotinib 150mg tablet, 30		14744B	1	30	5	omjarra®
momelotinib 200mg tablet, 30		14770J	1	30	5	omjarra®
	Category / Program: ☒GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: Intermediate-1 risk myelofibrosis					
	Treatment Phase: Continuing treatment					
	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					
	Category / Program: ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: High-risk and Intermediate-2 risk myelofibrosis					
	Treatment Phase: Continuing treatment					
	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					

6.2 Add TC1 to the restrictions for cGVHD (General Schedule) and aGVHD (S100 HSD Public/Private Hospital) (full restrictions not displayed). Full restrictions are not displayed and existing eligibility criteria are unchanged:

Moderate to severe Chronic Graft vs Host Disease (cGVHD)

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
RUXOLITINIB					
ruxolitinib 5mg tablet, 56	13241X	1	56	5	Jakavi®
ruxolitinib 10 mg tablet, 56	13235N	1	56	5	Jakavi®

	Category / Program: ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: ☒ Authority Required (STREAMLINED)
	Indication: Moderate to severe chronic graft versus host disease (cGVHD)
	Treatment Phase: Continuing treatment
	~~**Treatment criteria:**~~ ~~Must be treated by a haematologist; OR~~
	~~Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR~~
	~~Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.~~
	Treatment criteria:
	Must be treated by a specialist medical practitioner; OR
	Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner

Acute Graft vs Host Disease, S100 HSD Public

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
RUXOLITINIB					
ruxolitinib 5mg tablet, 56	13238R /Public	1	56	5	Jakavi®
ruxolitinib 10 mg tablet, 56	13245D /Public	1	56	5	Jakavi®

	Category / Program: ☒ GENERAL - Section 100 – Highly Specialised Drugs Program Public
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: ☒ Authority Required (STREAMLINED)
	Indication: Grade II to IV acute graft versus host disease (aGVHD)
	Treatment Phase: Continuing treatment
	~~**Treatment criteria:**~~
	~~Must be treated by a haematologist;~~ ~~OR~~
	~~Must be treated by an oncologist with allogeneic bone marrow transplantation experience;~~ ~~OR~~
	~~Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.~~
	Treatment criteria:
	Must be treated by a specialist medical practitioner; or
	Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner

Acute Graft vs Host Disease, S100 HSD Private

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
RUXOLITINIB					
ruxolitinib 5mg tablet, 56	13244C /Private	1	56	5	Jakavi®
ruxolitinib 10 mg tablet, 56	13231J/ Private	1	56	5	Jakavi®

	Category / Program: GENERAL – Section 100 – Highly Specialised Drugs Program Private
	Prescriber type: ☒ Medical Practitioners ☒ *Nurse Practitioners*
	Restriction type: ☒ Authority Required (STREAMLINED)
	Indication: Grade II to IV acute graft versus host disease (aGVHD)
	Treatment Phase: Continuing treatment
	~~**Treatment Criteria:**~~
	~~Must be treated by a haematologist; OR~~
	~~Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR~~
	~~Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.~~
	Treatment criteria:
	Must be treated by a specialist medical practitioner; or
	Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner

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.