6.20 DASATINIB

Tablet 100 mg, 30
Tablet 70 mg, 60
Tablet 50 mg, 60
Tablet 20 mg, 60
Sprycel®, Bristol-Myers Squibb Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission sought an extension to the existing listing of dasatinib in combination with chemotherapy or corticosteroids for Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) to include patients who are newly diagnosed.

1.2 During consideration of a restriction change for ponatinib for Ph+ALL in November 2017, the PBAC advised the dasatinib and ponatinib restrictions should be updated to align with current treatment guidelines and advice was sought from the Haematology Society of Australia and New Zealand (HSANZ).

1.3 The advice from the HSANZ was considered in April 2018 and a summary of the HSANZ proposals and PBAC recommendations are summarised in Table 1. The purpose of this application was to address the fourth proposal in Table 1.

Table 1: HSANZ proposed changes to Ph+ALL restriction criteria

	HSANZ proposal	PBAC recommendation
1.	That the restriction of imatinib to be in combination with intensive chemotherapy be broadened to chemotherapy or corticosteroid therapy	Recommended. The restriction now states that 'The treatment must be in combination with chemotherapy or corticosteroids'
2.	That the limit of 2 years for continuing treatment with imatinib be removed.	The PBAC did not agree to the requested removal of the limit of 2 years for continuing treatment with a TKI as first line therapy for ALL, but would welcome evidence that could inform further consideration of its cost-effectiveness.
3.	The requirement for second line TKI therapy to be the sole-PBS therapy be removed.	The PBAC did not agree to the removal of the requirement for second line TKI to be the sole-PBS therapy.
4.	That consideration be given to allow the use of a second generation TKI in the setting of initial therapy for Ph+ALL, depending on comparative drug cost.	The PBAC considered that the evidence did support the use of dasatinib in combination with chemotherapy as an alternative to the use of imatinib plus chemotherapy. In this setting, a price reduction for dasatinib would be required for it to be cost effective. The PBAC requested that the Department write to the sponsor of dasatinib to invite a submission with a proposal on dosing and price for first line therapy in Ph+ ALL, in combination with chemotherapy or corticosteroid therapy.

Source: ponatinib PSD, November 2017 with addendum

2 Requested listing

2.1 The submission requested the following proposed new listing.

2.2 Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough. The pre-PBAC response agreed with the proposed changes to the criteria and suggested deleted of 'dasatinib' in the Prescriber Instructions.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
DASATINIB			
20mg tablets	**60**	2	SPRYCEL
50mg tablets	**60**		
70mg tablets	**60**		Bristol-Myers Squibb Australia Pty Ltd
100mg tablets	**30**		

Initial Treatment:

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	Newly diagnosed
Condition:	Ph+ Acute Lymphoblastic Leukaemia
PBS Indication:	Newly diagnosed Ph+ ALL
Treatment phase:	Initial treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-
Clinical criteria:	Patient must be newly diagnosed, AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL AND The treatment must be for induction and consolidation therapy AND The treatment must be in combination with chemotherapy or corticosteroids. *AND* Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR

	Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.
Prescriber Instructions	The authority application must be made in writing and must include: (a) A completed authority prescription form; and (b) A completed Acute Lymphoblastic Leukaemia ~~Dasatinib~~ PBS Authority Application – Supporting Information Form; and (c) A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and (d) A signed patient acknowledgement.
Administrative advice	*Note* *Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.* *Note* *No applications for increased repeats will be authorised*

Continuing Treatment:

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	Newly diagnosed
Condition:	Ph+ Acute Lymphoblastic Leukaemia
PBS Indication:	Newly diagnosed Ph+ ALL
Treatment phase:	Continuing treatment
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☒ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☐ Streamlined
Treatment criteria:	-
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition; *OR* Patients must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; OR

	The condition must have the transcript BCR-ABL AND The treatment must be for maintenance of first complete remission; AND The treatment must be in combination with chemotherapy or corticosteroids.
Prescriber Instructions	Dasatinib *and imatinib* are ~~is~~ available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS *in this treatment setting*. Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270.
Administrative advice	*Note* *Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.* *Note* *No applications for increased repeats will be authorised*

2.3 The requested listing is consistent with the current listing for imatinib for newly diagnosed Ph+ ALL with the addition of wording to allow patients intolerant to imatinib to switch to dasatinib.

2.4 Any flow-on changes to the restriction criteria for imatinib, dasatinib and ponatinib will need to be reviewed prior to the listing of dasatinib for first-line Ph+ALL.

For more detail on the PBAC's view, see Section 6 PBAC Outcome.

3 Background

3.1 Dasatinib was included on the Australian Register of Therapeutic Goods (ARTG) for the treatment of adults aged 18 years and over with newly diagnosed Ph+ ALL integrated with chemotherapy on the 10 March 2018.

3.2 Dasatinib is also registered for the treatment of adults aged 18 years or over with newly diagnosed Ph+ CML in the chronic phase, chronic, accelerated or myeloid or lymphoid blast phase CML with resistance or intolerance to prior therapy including imatinib, and Ph+ ALL with resistance or intolerance to prior therapy.

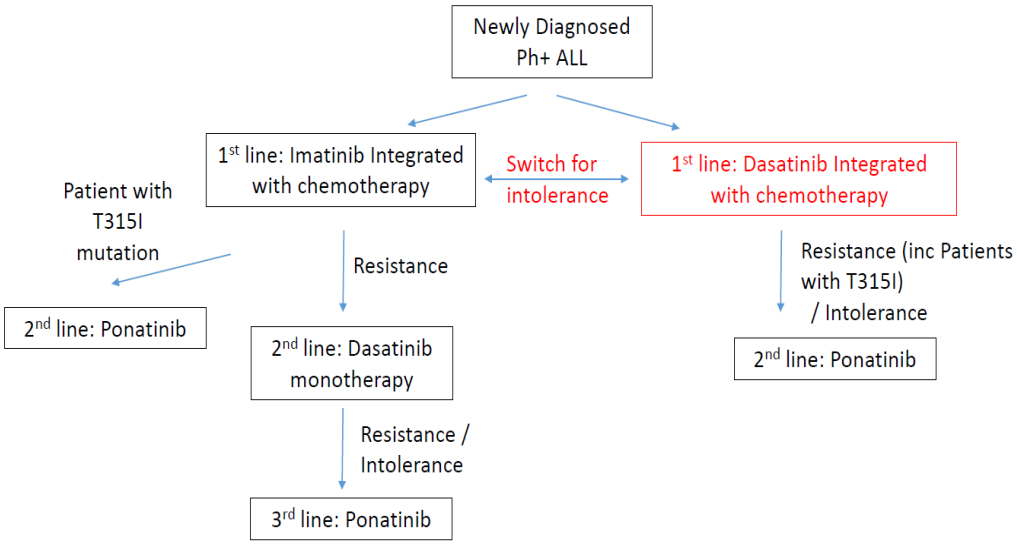
3.3 Dasatinib is listed on the PBS for the treatment of newly diagnosed and relapsed/ refractory Ph+CML and for relapsed/ refractory Ph+ALL. This is the first time the PBAC has considered dasatinib for the treatment of newly diagnosed Ph+ALL.

4 Proposed treatment algorithm

4.1 The proposed future clinical management algorithm (Figure 1) for the treatment of patients with Ph+ALL is consistent with the National Comprehensive Cancer Network (NCCN) treatment guidelines and advice previously provided by the HSANZ. Dasatinib will be an alternative first-line treatment for patients with newly diagnosed Ph+ALL

and will continue to be used as a second-line treatment in patients who have previously received imatinib as a first-line treatment.

Figure 1: Future clinical management algorithm for patients with Ph+ ALL.



Source: Figure 2, pg 10, minor submission

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

5.2 The PBAC noted and welcomed the input from health care professionals (3) and organisations (1) via the Consumer Comments facility on the PBS website. The health care professionals were supportive of listing dasatinib for newly diagnosed Ph+ALL and considered it a better treatment option for most patients due to its ability to penetrate the central nervous system and better tolerability profile compared to imatinib. The Leukaemia Foundation was supportive of listing dasatinib for newly diagnosed Ph+ALL as it would align access with current treatment guidelines.

Clinical evidence

5.3 Four Phase II studies were provided in the TGA registration dossier as the pivotal clinical data supporting the indication for patients with newly diagnosed Ph+ ALL. These studies collectively represent 247 adult patients treated with dasatinib as part of their first-line treatment. The minor submission does not present any clinical data, noting the PBAC has previously acknowledged the available information supports the use of dasatinib in the first-line setting. The TGA Clinical Evaluation Report (CER) was provided to support dasatinib's place in clinical therapy.

5.4 The TGA CER concluded:

- In terms of hierarchy of evidence, the data in the submission are of level III evidence or lower.
- First-line treatment regimens for Ph+ ALL that incorporate a TKI have been shown to result in very high initial complete response success, with or without chemotherapy.
- Dasatinib has already been approved for treatment of this disease, in cases of resistance or intolerance to prior therapy.
- Comparative data for dasatinib versus use of other TKIs for the same indication suggest similar efficacy but the true quantification of benefit in this regard in terms of comparison between different TKIs is not fully circumscribed and would need phase III trial data.
- The treatment regimens using dasatinib in this submission have varied considerably. The use of chemotherapy, dosage of dasatinib, and continuous or intermittent dosing, all vary across studies.
- Use of the drug is limited by haematological toxicity and the PI contains information on dose modification in such instances.
- It is noted that the most robust data are in combination with hyper CVAD.
- The adverse events that are apparent are known adverse drug reactions for dasatinib and there do not appear to be additional serious adverse events revealed by the studies.

Clinical claim

5.5 The submission claimed it is reasonable to conclude that dasatinib in combination with chemotherapy or corticosteroids is comparable in both efficacy and safety to imatinib in combination with chemotherapy or corticosteroids in the first-line setting for patients with Ph+ ALL. The PBAC noted it had previously considered the evidence supported this claim (see Table 1).

Economic analysis

5.6 Based on a claim of comparable efficacy and safety to imatinib, the submission presented a cost-minimisation analysis (CMA). The key assumptions and components of the CMA are presented in Table 2.

Table 2: Key assumptions and components of the cost-minimisation approach

	Claim or assumption
Therapeutic claim: effectiveness	Dasatinib in combination with chemotherapy and imatinib combined with chemotherapy are assumed to have comparable effectiveness.
Therapeutic claim: safety	Dasatinib in combination with chemotherapy and imatinib combined with chemotherapy are assumed to have comparable safety.
Evidence base	Clinical Evaluation Report forming the basis of the TGA registration for this indication, NCCN Guidelines supporting first-line use of dasatinib and HSANZ and PBAC support for the first-line use of dasatinib.
Equi-effective dose	100mg/day dasatinib = 600mg/day imatinib
Duration of Therapy	Assumed equivalent to imatinib with a maximum duration of therapy of 24 months

Source: Table 3, pg 19 minor submission.

5.7 The recommended dose for newly diagnosed Ph+ ALL patients for dasatinib is 100mg per day (with an increase to 140mg if needed) and for imatinib is 600mg per day. The PBAC noted the proposed equi-effective doses are consistent with the recommended doses and considered they were reasonable. A trial-based estimation of equi-effective doses is unlikely to be informative given the nature of the clinical data.

5.8 The submission assumed the daily cost of dasatinib is equivalent to the daily cost of imatinib based on the proposed equi-effective doses (Table 3).

Table 3: Cost-minimisation calculations for dasatinib in newly diagnosed Ph+ ALL

Imatinib	**$ per pack (AEMP)**	**$ per mg**
100mg tablet/ capsule, 60	$851.25	$0.1419
400mg tablet/ capsule, 30	$1,702.50	$0.1419
Dose per day	600mg	
Cost per day	$85.1250	
Dasatinib		
Cost per day	$85.1250	
Dose per day	100mg	
100mg tablet, 30	$2,533.75	

AEMP approved ex-manufacturer price
Source: Table 5, pg 21, minor submission

5.9 The submission noted the proposed effective price for newly diagnosed Ph+ ALL is significantly lower than the current effective price ($4,153.11) for other indications. The Sponsor would be willing to enter into a Special Pricing Arrangement (SPA) to achieve the proposed effective price whilst maintaining the current list price for dasatinib for all currently listed indications. However, the Sponsor acknowledges the SPA criteria may not be met in this circumstance and implementing a new weighted price for dasatinib for all PBS indications would reduce administrative burden on the Department.

5.10 The submission calculated a weighted price for dasatinib by estimating the number of dasatinib 100mg (30 tablets) packs that will be dispensed for newly diagnosed Ph+ ALL and the number that are currently dispensed for the listed PBS indications. The submission estimates less than 10,000 packs of dasatinib 100mg (30 tablets) will be dispensed for newly diagnosed Ph+ALL (Table 4).

Table 4: Anticipated number of dasatinib 100mg (30 tablets) packs for first-line Ph+ALL

	First-line Ph+ ALL	Value	Source
	Imatinib		
A.	Total mg dispensed	[redacted]	Calculated from PBS statistics using Ph+ ALL item codes for each strength
B.	Dose per day	600mg	Equi-effective dose
C.	Number of treatment days	[redacted]	A. ÷ B.
	Dasatinib		
D.	% market share (treatment days)	[redacted]%	Calculated based on second generation TKI share of treatment days for CML (see below for description)
E.	Number of treatment days	[redacted]	D. x C.
F.	Dose per day	100mg	Equi-effective dose
G.	Total mg dispensed	[redacted]	E. x F.
H.	100mg (30 tablets) scripts	[redacted]	G.÷ F.

Source: Based on information in Table 6, pg 23, minor submission

5.11 The assumption of [redacted]% market share in the first-line treatment setting is derived from the market share of the second-generation TKIs in the first-line treatment setting for CML. The PBAC considered applying a CML market share to ALL may not be appropriate as they are different conditions and that there are particular reasons clinicians may favour dasatinib in ALL. The submission calculated the number of treatment days for each TKI listed for the first-line treatment of CML (imatinib, nilotinib and dasatinib) by dividing the total milligrams dispensed by the recommended daily doses. These data were then used to calculate the market share of treatment days for the second generation TKIs (dasatinib and nilotinib). This was assumed to be a proxy for the market share of treatment days expected for dasatinib should it be listed for first-line Ph+ ALL.

5.12 Based on the total milligrams of dasatinib dispensed, the submission estimated approximately 10,000 to 50,000 dasatinib 100mg (30 tablets) script equivalents were dispensed in 2017/2018 for indications currently listed on the PBS. Therefore it is expected that if dasatinib is listed for the first-line treatment of Ph+ALL PBS listing, it will account for [redacted]%[1] of all dasatinib PBS scripts.

5.13 The proposed weighted price for dasatinib 100mg (30 tablets) is $[redacted] a [redacted]% reduction on the current price (Table 5). This reduction is applied across all strengths of dasatinib (Table 6).

Table 5: Weighted price calculation

Dasatinib 100mg (30), AEMP	
Proposed price for 1L Ph+ALL	$[redacted]
% weighted price for 1L Ph+ALL	[redacted]%
Current price	$4,153.11
% weighted price for current price	[redacted]%
New weighted dasatinib	$[redacted]
% change	[redacted]%

Source: Table 8, pg 24, minor submission

[1] [redacted] / ([redacted] + [redacted]) = [redacted]%

Table 6: Current and proposed prices

	Current		Proposed	
	AEMP	DPMQ	AEMP	DPMQ
Dasatinib 20mg (60)	$2,521.48	$2,672.52	$[redacted]	$[redacted]
Dasatinib 50mg (60)	$4,153.11	$4,304.15	$[redacted]	$[redacted]
Dasatinib 70mg (60)	$5,141.83	$5,292.87	$[redacted]	$[redacted]
Dasatinib 100mg (30)	$4,153.11	$4,304.15	$[redacted]	$[redacted]

Source: Table 9, pg 25, minor submission

5.14 The submission stated that in the context of recent statutory price reductions, the impact of the proposed price reduction on other dasatinib indications and the uncertainty associated with the volume increase related to the extended listing, no further price reductions can be accepted by the sponsor.

For more detail on the PBAC's view, see Section 6 PBAC Outcome.

Estimated PBS usage & financial implications

5.15 The submission presented the financial impact of listing dasatinib for the treatment of newly diagnosed patients with Ph+ ALL over the first six years of PBS listing. A market-based approach was used, with similar methodology to determine script numbers as used to determine the weighted price above. Cost offsets for reduced imatinib scripts and reduced cost of dasatinib in the other listed indications due to the [redacted]% overall price reduction have been included in the estimates.

5.16 The base case financial estimates provided in the submission forecast that extending the listing of dasatinib to include the first line treatment of Ph+ ALL will result in small cost savings to the PBS/RPBS (Table 7). The net increase in cost from substituting dasatinib at a higher weighted price than imatinib is offset by the cost savings generated by the price reduction for dasatinib use in the other indications.

Table 7: Total net cost to the PBS/RPBS for listing dasatinib on the PBS/RPBS for first-line Ph+ALL

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total cost for dasatinib	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Cost offset for reduced imatinib scripts	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]
Total reduced cost to due to lower dasatinib price	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]
Net cost to PBS/RPBS	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]	-$[redacted]

Source: Table 15, pg 33, Table 16, pg 33, minor submission

The redacted table shows that at Year 6, the net cost saving to the PBS/RPBS would be less than $10 million.

5.17 The weighted price calculation and the financial estimates do not account for a reduction in the use of dasatinib in the second line treatment setting. The PBAC noted any impact is likely to be small given the small patient numbers for Ph+ALL relative to the other indications.

For more detail on the PBAC's view, see Section 6 PBAC Outcome.

6 PBAC Outcome

6.1 The PBAC recommended extending the existing listing of dasatinib for the condition of Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) to include the treatment of patients who are newly diagnosed. The PBAC's recommendation for listing was based on, among other matters, its assessment, as described above, that the cost-effectiveness of dasatinib in this indication would be acceptable if it were cost-minimised against imatinib.

6.2 The PBAC considered the claim that dasatinib in combination with chemotherapy or corticosteroids is comparable in both efficacy and safety to imatinib in combination with chemotherapy or corticosteroids for the first-line treatment of patients with Ph+ ALL to be reasonable although based on limited clinical evidence. The PBAC considered dasatinib may be a better treatment option for some patients given its penetration into the central nervous system.

6.3 The PBAC considered the equi-effective doses proposed in the submission to be reasonable: 100mg dasatinib daily: 600mg imatinib daily for up to 24 months.

6.4 The PBAC noted the sponsor's statement that the SPA criteria are unlikely to be met and agreed with the view that a weighted price for dasatinib would be appropriate as proposed in the minor submission.

6.5 The PBAC considered that the restriction as proposed in the submission was appropriate and should be aligned with the restriction for imatinib for newly diagnosed patients, and noted that flow-on changes to existing listings for imatinib would be needed to ensure that patients in the first-line setting could switch between imatinib and dasatinib due to intolerance. Further flow-on changes would be required to the existing second line listing of dasatinib to ensure that patients treated with dasatinib in the first line setting do not receive retreatment in the second line setting.

6.6 The PBAC considered the prices proposed in the submission to be acceptable. The PBAC considered the market share of dasatinib in this treatment setting may be higher than [redacted]% but noted increasing the market share had little impact on the proposed prices because of the small numbers of Ph+ALL patients.

Outcome:

Recommended.

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
DASATINIB			
20mg tablets	60	2	SPRYCEL
50mg tablets	60		
70mg tablets	60		Bristol-Myers Squibb Australia Pty Ltd
100mg tablets	30		

Initial Treatment:

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	
Condition:	Acute Lymphoblastic Leukaemia
PBS Indication:	Acute Lymphoblastic Leukaemia
Treatment phase:	Initial treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-
Clinical criteria:	Patient must be newly diagnosed, AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL AND The treatment must be for induction and consolidation therapy AND The treatment must be in combination with chemotherapy or corticosteroids. *AND* Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.
Prescriber Instructions	The authority application must be made in writing and must include: (a) A completed authority prescription form; and (b) A completed Acute Lymphoblastic Leukaemia PBS Authority Application – Supporting Information Form; and (c) A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome,

	or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and ~~(d) A signed patient acknowledgement.~~
Administrative advice	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Service on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservice.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001 <u>Note</u> Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia. <u>Note</u> No applications for increased repeats will be authorised

Continuing Treatment:

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	
Condition:	Acute Lymphoblastic Leukaemia
PBS Indication:	Acute Lymphoblastic Leukaemia
Treatment phase:	Continuing treatment
Restriction Level / Method:	☐Restricted benefit ☐Authority Required - In Writing ☒Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition; *OR* Patients must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL

	AND The treatment must be for maintenance of first complete remission; AND The treatment must be in combination with chemotherapy or corticosteroids.
Prescriber Instructions	Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting. Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270.
Administrative advice	Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia. Note No applications for increased repeats will be authorised

7.2 Amend items 10917N, 10924Y, 9123E, 9124F

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
IMATINIB			
100mg tablets	**60**	2	Multiple brands
400mg tablets	**30**		
100mg capsules	**60**		Various
400mg capsules	**30**		

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	-
Condition:	Acute Lymphoblastic Leukaemia
PBS Indication:	Acute Lymphoblastic Leukaemia
Treatment phase:	Initial treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-
Clinical criteria:	Patient must be newly diagnosed, AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL AND The treatment must be for induction and consolidation therapy AND The treatment must be in combination with chemotherapy or corticosteroids. *AND* *Patient must not have previously experienced a failure to respond to PBS-subsidised first line treatment with this drug for this condition; OR* *Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.*
Prescriber Instructions	The authority application must be made in writing and must include: (a) A completed authority prescription form; and (b) A completed Acute Lymphoblastic Leukaemia PBS Authority Application – Supporting Information Form; and

	(c) A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and ~~(d) A signed patient acknowledgement.~~
Administrative advice	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Service on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservice.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001 <u>Note</u> Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia. <u>Note</u> No applications for increased repeats will be authorised Note Pharmaceutical benefits that have the form imatinib tablet 400mg and imatinib capsule 400mg are equivalent for the purposes of substitution.

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	-
Condition:	Acute Lymphoblastic Leukaemia
PBS Indication:	Acute Lymphoblastic Leukaemia
Treatment phase:	Continuing treatment
Restriction Level / Method:	☐Restricted benefit ☐Authority Required - In Writing ☒Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-

Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition; *OR* Patients must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL AND The treatment must be for maintenance of first complete remission; AND The treatment must be in combination with chemotherapy or corticosteroids.
Prescriber Instructions	*Dasatinib and* imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting. Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270.
Administrative advice	Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia. Note No applications for increased repeats will be authorised

7.3 Amend items 9125G, 9126H, 9127J, 9343R

Name, Restriction, Manner of administration and form	**Max. Qty**	**№.of Rpts**	**Proprietary Name and Manufacturer**
DASATINIB			
20mg tablets	**60**	2	SPRYCEL
50mg tablets	**60**		
70mg tablets	**60**		Bristol-Myers Squibb Australia Pty Ltd
100mg tablets	**30**		

Category / Program	General Schedule – Authority Required
Prescriber type	Medical Practitioners
Severity:	
Condition:	Acute Lymphoblastic Leukaemia
PBS Indication:	Acute Lymphoblastic Leukaemia
Treatment phase:	Continuing treatment
Restriction Level / Method:	☐Restricted benefit ☐Authority Required - In Writing ☒Authority Required - Telephone

	☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	-
Clinical criteria:	The condition must be expressing the Philadelphia chromosome; OR The condition must have the transcript BCR-ABL AND Patient must have previously received PBS-subsidised treatment with this drug for this condition *as second-line therapy following treatment with imatinib* AND The condition must not have progressed AND The treatment must be the sole PBS-subsidised therapy for this condition
Prescriber Instructions	Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.