

**7.07 DECITABINE with CEDAZURIDINE,
Tablet containing decitabine 35 mg with
cedazuridine 100 mg,
Inqovi[®],
Otsuka Australia Pharmaceutical Pty Ltd.**

1 Purpose

- 1.1 The early re-entry resubmission sought Authority Required listing for decitabine+cedazuridine for the treatment of myelodysplastic syndrome (MDS) and chronic myelomonocytic leukaemia (CMML) in high-risk patients.
- 1.2 The resubmission was based on the PBAC advice from March 2021. The resubmission addressed most of the issues raised by PBAC; see table below.

Table 1: Summary of key matters to be addressed

Matter of concern	Response	Addressed?
<p>A revised cost-minimisation analysis informed by conservative assumptions (paragraph 7.16).</p> <p>The PBAC noted the analysis assumed all patients receive 2 vials of azacitidine, and did not consider dose reductions, which may be substantial given the average age of the patient population. Overall, the PBAC considered that the assumptions used to inform the cost-minimisation analysis were not appropriately conservative in the context of the limited clinical data.</p>	<p>The requested AEMP was revised to \$ [REDACTED] based on a 10% price reduction on the cost-minimised AEMP. The submission stated this accounted for the additional mark-ups and dispensing fees associated with decitabine+cedazuridine and dose reductions with azacitidine.</p>	<p>Y</p>
<p>Revised financial estimates which account for the revised lower cost-minimised price and reduced growth rates (paragraph 7.16)</p> <p>The PBAC considered the assumed market growth (4.24% declining to 3.63% over 5 years) to be overestimated given lower growth rates in 2019 (2%) and 2020 (-2%) (paragraph 7.12).</p>	<p>The market growth rate was unchanged from the March 2021 submission.</p>	<p>N</p>
<p>A proposed RSA which include expenditure caps and rebate for use in excess of these caps (paragraph 7.16).</p> <p>The PBAC agreed with ESC that there may be an increase in the number of patients treated if decitabine+cedazuridine was listed due to the treatment of patients who are currently not on therapy because of the administration requirements for azacitidine. The PBAC noted that the sponsor was willing to consider a Risk Sharing Arrangement (RSA), and considered that such an agreement could address the risk of use in a broader patient population compared with azacitidine (paragraph 7.13)</p>	<p>The resubmission proposed an RSA with caps based on estimated financial implications and a rebate of [REDACTED]% for use in excess of these caps (although the submission stated that the Sponsor would like to have a final negotiation during the post-recommendation listing phase).</p>	<p>Y</p>

Source: Compiled during the development of the minor overview. Paragraph references refer to the March 2021 decitabine with cedazuridine Public Summary Document.

2 Background

- 2.1 Decitabine+cedazuridine was TGA registered on 2 November 2020 for the treatment of adult patients with myelodysplastic syndromes (MDS) intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups, and patients with chronic myelomonocytic leukaemia (CMML).

3 Requested listing

- 3.1 The resubmission agreed with the March 2021 PBAC advice that the restrictions for decitabine+cedazuridine should align with the existing azacitidine restrictions (i.e. restrictions for MDS, AML and CMML) and that the restriction for MDS should specify

an upper threshold of 20% for bone marrow blasts consistent with the WHO classification system. The submission did not request any further changes to the proposed restrictions from the March 2021 submission.

- 3.2 The resubmission requested a Special Pricing Arrangement. As per the March 2021 submission, the requested published DPMQ (\$4,861.16) is based on a published ex-manufacturer price of \$4,700.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted and welcomed the input from the Leukaemia Foundation via the Consumer Comments facility on the PBS website. The Leukaemia Foundation reiterated its support for a PBS listing of decitabine+cedazuridine, noting there are few treatment options for patients with MDS and CMML. The Leukaemia Foundation again provided feedback it previously received from patients and a carer of a patient with MDS or CMML, which emphasised the side effects and travel burden associated with azacitidine treatment.

Economic analysis

- 4.3 The resubmission proposed an effective AEMP of \$ [REDACTED] that is a 10% price reduction on the ex-manufacturer price (\$ [REDACTED]) derived from the cost-minimisation analysis presented in the sponsor's March 2021 pre-PBAC Response, which accounted for the difference in supply chain costs (mark-ups and fees) between azacitidine and decitabine+cedazuridine. The 10% price reduction is achieved from a reduction in the number of azacitidine vials per administration from 2 to 1.74 (13.17% reduction) in the cost-minimisation analysis. Table 2 presents the revised cost-minimisation analysis that accounted for the difference in supply chain costs and assumed 1.74 vials of azacitidine per patient.

Table 2: Results of the cost-minimisation analysis

	Cost per day	Cost per treatment cycle
Azacitidine cost (7 treatment days in each cycle)		
Azacitidine: 1.74 vials at \$156.61 (AEMP) per vial	\$271.96	\$1,961.76
Granisetron: 1 tablet per day (AEMP)	\$8.29	
Azacitidine administration: MBS item 13950	\$111.40	\$779.80
Total cost	\$391.66	\$2,741.56
Cost-minimisation		
Per cycle cost of decitabine+cedazuridine to match azacitidine		\$2,741.56
Adjustment for azacitidine mean supply chain costs (an additional \$18.85) ^a	–	\$2,760.41
Decitabine+cedazuridine administration days	5	–
Daily cost at cost neutrality (in terms of DPMQ)	\$552.08	
Cost-minimised price		
DPMQ	\$	
Wholesale mark-up		\$54.14
PTP ^b	\$	
AHI mark-up		\$99.28
Preparation fee		\$7.74
AEMP ^c	\$	

Source: Table 3 of the resubmission

AEMP=approved ex-manufacturer price; AHI=Administration, Handling and Infrastructure DPMQ=dispensed price maximum quantity; PTP=price to pharmacy

^a Based on a public/private hospital split of 60.55%/39.45% for azacitidine. The private/public hospital split was derived from Medicare statistics (PBS items 6100C, 6138C, 9597D and 9598E processed from August 2019 to June 2020). The mean supply chain cost for azacitidine (\$18.85) is calculated by multiplying the proportion of azacitidine PBS items from the private hospital setting (39.45%) by the mark-ups and fees associated with the Section 100 Highly Specialised Drugs (HSD) listing (\$47.74 in total, comprising of \$40.00 AHI mark-up and \$7.74 preparation fee)

^b AEMP (\$) plus wholesale mark-up (\$54.14)

^c DPMQ (\$) minus wholesale mark-up (\$54.14), AHI mark-up (\$99.28) and preparation fee (\$7.74)

- 4.4 Based on the AEMP for azacitidine and granisetron, and the administration cost for azacitidine, the cost per cycle is \$2,741.56. Based on the proposed AEMP for decitabine+cedazuridine, the cost per cycle is \$.
- 4.5 The resubmission stated that it is difficult to obtain reliable real-world data to determine actual dose adjustments for azacitidine. Based on the 10% PBS sample, the resubmission estimated that the mean number of vials per administration is 1.9 (9% of claims for one vial; 82% for two vials; 9% data unavailable). The resubmission noted that under the extremely conservative assumption that claims in the PBS dataset for which dosing data could not be determined equated to zero vials per administration, that the mean number of vials per administration is 1.73, and that this estimate is consistent with the vial number implied in the cost-minimisation analysis.
- 4.6 Based on the revised requested price, the estimated drug cost/patient/cycle (28 days) is \$ (DPMQ).

Estimated PBS usage & financial implications

- 4.7 The resubmission estimated (Table 3):

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- a net cost to the PBS/RPBS of \$0 to < \$10 million in Year 6 of listing, with a total net cost to the PBS/RPBS of \$10 million to < \$20 million over the first 6 years of listing; and
- a net cost to the PBS/RPBS/MBS of \$0 to < \$10 million in Year 6 of listing, with a total net cost to the PBS/RPBS/MBS of \$0 to < \$10 million over the first 6 years of listing.

Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	█ ¹	█ ¹	█ ¹	█ ¹	█ ²	█ ²
Initiation scripts	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Continuation scripts	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Estimated financial implications						
Cost to PBS/RPBS less copayments	\$█ ³	\$█ ³	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Cost offsets for substituted azacitidine and granisetron ^a	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ⁴	-\$█ ⁴
Net financial implications						
Net cost to PBS/RPBS	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³
Net cost to MBS ^b	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³
Net cost to PBS/RPBS/MBS	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³
March 2021 submission						
Net cost to PBS/RPBS/MBS ^c	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³

^a one script of granisetron (to manage nausea and vomiting) is assumed to accompany each script of azacitidine. Includes assumption that patients use 12.16 vials of azacitidine per cycle.

^b Based on 80% of fee for MBS item 13950 (\$111.40)

^c Based on 80% of fee for MBS item 13915 (\$67.10) and mark-ups from 1 December 2020.

Source: Table 9 of the resubmission; Table 16 of the March 2021 decitabine+cedazuridine Public Summary Document (PSD).

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

² 5,000 to < 10,000

³ \$0 to < \$10 million

⁴ \$10 million to < \$20 million

4.8 The revised financial estimates account for the revised cost-minimised price for decitabine+cedazuridine based on 1.74 vials of azacitidine per administration. Consistent with the revised cost-minimisation analysis, the cost offsets for substituted azacitidine assume 12.16 vials of azacitidine per cycle (1.7366 x 7). The resubmission also presented financial estimates assuming two vials of azacitidine per administration. The estimated net cost to the PBS/RPBS was \$10 million to < \$20

million over the first 6 years of listing offset by a save of \$10 million to < \$20 million to the MBS.

- 4.9 The PBAC previously considered the assumed market growth (4.24% declining to 3.63% over 5 years) to be overestimated given lower growth rates in 2019 (2%) and 2020 (-2%) (paragraph 7.12, decitabine+cedazuridine Public Summary Document (PSD), March 2021). The revised financial estimates applied the same market growth rates as per the March 2021 submission. The resubmission indicated that the azacitidine PBS statistics that the market growth rates have been based on reflect the adherence and compliance issues associated with azacitidine observed in clinical practice. The resubmission indicated that given the growth rates were based on azacitidine data, they are conservative and argued that a positive market growth is required to capture the improved adherence and compliance of decitabine+cedazuridine versus azacitidine. The pre-PBAC Response maintained that the assumed market growth applied in the March 2021 submission and current resubmission noting that total usage of azacitidine in the last 12-month period (May 2020 to April 2021; 5,000 to < 10,000 scripts) grew by 3.4% from the preceding 12-month period (May 2019 to April 2020; 5,000 to < 10,000 scripts). The pre-PBAC Response considered that the decrease in the azacitidine usage observed was attributable to access issues due to the COVID-19 pandemic.
- 4.10 The PBAC previously noted the listing of decitabine+cedazuridine resulted in additional cost to the Government due to (i) the additional supply chain costs for decitabine+cedazuridine, (ii) the patient copayments for the administration of azacitidine and (iii) the patient copayments for granisetron being incorporated into the price of decitabine+cedazuridine (paragraph 7.11, decitabine+cedazuridine PSD, March 2021). The estimated cost to the Government (PBS/RPBS/MBS) in the March 2021 submission was \$0 to < \$10 million over the first 6 years of listing. The estimated cost to the Government in the resubmission was \$0 to < \$10 million over the first 6 years of listing.

Financial Management – Risk Sharing Arrangements

- 4.11 The resubmission proposed a Risk Sharing Arrangement with financial caps based on the revised financial estimates. The sponsor indicated it is willing to accept [REDACTED] % rebate for any use above the caps however requested a final negotiation during the post-recommendation listing phase.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of decitabine+cedazuridine for the treatment of patients with myelodysplastic syndrome (MDS) classified as intermediate-2 or high-risk according to the International Prognostic Scoring System (IPSS) and patients with chronic myelomonocytic leukaemia (CMML). The PBAC's recommendation for listing was based on, among other matters, its assessment, that the cost-effectiveness of decitabine+cedazuridine would be acceptable if it were cost-minimised against azacitidine. The PBAC considered that the more conservative cost-minimisation analysis presented in the resubmission largely addressed the uncertainty around the claim of non-inferiority versus azacitidine. Further, the PBAC considered that the Risk Sharing Arrangement proposed by the sponsor would address its previous concerns around use in a broader patient population compared with azacitidine.
- 5.2 The PBAC again acknowledged the advantages of an oral treatment, particularly for patients in rural and remote areas, given the administration of azacitidine requires attendance at an outpatient clinic for seven days each month. The PBAC reiterated there would be a substantially reduced treatment burden with oral therapy and that this may make treatment available to more patients.
- 5.3 The PBAC recalled its March 2021 consideration that the claim of non-inferior effectiveness versus azacitidine was uncertain due to heterogeneous results across the trials and the wide confidence intervals for the indirect estimates. The PBAC also recalled its previous advice that conservative assumptions would need to inform any economic evaluation versus azacitidine, in the context that further data might not be available to increase the certainty for the non-inferiority claim. The PBAC further recalled that the cost-minimisation analysis in the March 2021 submission assumed all patients receive two vials of azacitidine, and did not consider dose reductions, which may be substantial given the average age of the patient population. The PBAC noted that the revised cost-minimisation analysis accounted for differences in supply chain costs (mark-ups and fees) between azacitidine and decitabine+cedazuridine, used the updated cost for the MBS item for azacitidine administration and reduced the number of vials of azacitidine per administration from 2 to 1.74. The PBAC considered the revised cost-minimisation analysis sufficiently conservative to address the uncertainty regarding the non-inferiority claim versus azacitidine.
- 5.4 The PBAC noted the resubmission proposed an RSA with financial caps based on the revised financial estimates, which account for the lower cost-minimised price of decitabine+cedazuridine. The PBAC noted the revised financial estimates did not incorporate a reduced market growth rate compared to the March 2021 submission, as previously advised by the Committee. The PBAC considered the growth rate used in the resubmission's estimates to be reasonable given the proposed [REDACTED] % rebate for any utilisation exceeding the financial caps.
- 5.5 The PBAC noted the reduction in the estimated cost to Government associated with listing decitabine+cedazuridine from \$0 to < \$10 million to \$0 to < \$10 million over 6

years. The PBAC noted that the cost to Government was due to the full MBS schedule fee for item 13950 being included in the cost-minimised price while lower cost offsets at 80% of the MBS schedule fee for item 13950 were included in the financial estimates and the patient copayment for granisetron being included in the cost-minimised price. The PBAC considered that the proposed RSA would adequately manage the risk of additional cost to the Government due to the treatment of a broader patient population compared with azacitidine.

- 5.6 The PBAC considered the equi-effective doses to be: decitabine 35 mg+cedazuridine 100 mg tablet daily × 5 days every 28 days and azacitidine 75mg/m² IV or SC daily × 7 days every 28 days, with an average of 1.74 vials of azacitidine per dose.
- 5.7 The PBAC recalled that at its November 2020 meeting, as part of its consideration of PBS Authority Required (Written) listings, it recommended reducing the level of the azacitidine initial treatment restriction for AML from Authority Required (Written) to Authority Required (Telephone) and Authority Required (STREAMLINED) for continuing treatment. The PBAC also recalled that at its March 2021 meeting, it recommended that the initial treatment authority requirements for azacitidine for MDS indication be amended from Authority Required (Written) to Authority Required (Telephone) for consistency with its November 2020 recommendation. The PBAC considered that consistent with its November 2020 and March 2021 recommendations, the initial treatment authority level for decitabine+cedazuridine should be Authority Required (Telephone) for the AML and MDS indications and the authority level for the decitabine+cedazuridine AML continuing treatment should be Authority Required (STREAMLINED).
- 5.8 The PBAC considered that treatment with decitabine+cedazuridine for MDS and CML should be limited to 3 cycles for initial treatment and 6 cycles for continuing treatment consistent with the current azacitidine listing. The PBAC noted that at the same meeting, it recommended removing the limit on the number of treatment cycles from the azacitidine restriction for AML, and considered that this should also apply to the AML restriction for decitabine+cedazuridine.
- 5.9 The PBAC recommended that under Section 101(3BA) of the *National Health Act, 1953* that decitabine+cedazuridine should not be treated as interchangeable on an individual patient basis with any other drugs.
- 5.10 The PBAC advised that decitabine+cedazuridine is not suitable for prescribing by nurse practitioners.
- 5.11 The PBAC advised that the Early Supply Rule should apply to decitabine+cedazuridine.
- 5.12 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because decitabine+cedazuridine is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over azacitidine, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the National

Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.

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

Outcome:

Recommended

6 Recommended listing

Add new medicinal product as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Manufacturer	Name and
DECITABINE + CEDAZURIDINE decitabine 35 mg + cedazuridine 100 mg tablet, 5	NEW	1	5	2	INQOVI®	Otsuka Australia

Restriction Summary [new] / Treatment of Concept: [new]

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction Type: <input checked="" type="checkbox"/> Authority Required – Telephone/Online PBS Authorities immediate assessment
Caution: This drug is a category x drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special pricing arrangements apply
Condition: Myelodysplastic syndrome
Indication: Myelodysplastic syndrome
Treatment Phase: Initial treatment
Clinical criteria: The condition must be myelodysplastic syndrome confirmed through a recent bone marrow biopsy report and full blood examination
AND
The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); or
The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).
AND
Clinical criteria: The condition must have up to 20% marrow according to World Health Organisation (WHO) Classification.

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	<p>Prescribing Instructions: Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations: a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR, b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR, c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR, d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR, e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR, f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.</p>
	<p>Prescribing Instructions: Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations: a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR, b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR, c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR, d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.</p>
	<p>The following pathology reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and, (b) full blood examination report; and (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS).</p>
	<p>Prescribing Instructions: No more than 3 cycles will be authorised.</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p>

Restriction Summary [new] / Treatment of Concept: [new]

	<p>Category / Program: GENERAL – General Schedule (Code GE)</p>
	<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
	<p>Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required) <input checked="" type="checkbox"/> Authority Required – Telephone/Online PBS Authorities immediate assessment</p>
	<p>Condition: Acute Myeloid Leukaemia</p>
	<p>Indication: Acute Myeloid Leukaemia</p>
	<p>Treatment Phase: Initial treatment</p>
	<p>Clinical criteria:</p>
	<p>The condition must be acute myeloid leukaemia confirmed through a recent bone marrow biopsy report and full blood examination</p>
	<p>AND</p>
	<p>The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification</p>
	<p>The following pathology reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and, (b) full blood examination report.</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p>

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Proprietary Manufacturer	Name and
DECITABINE + CEDAZURIDINE decitabine 35 mg + cedazuridine 100 mg tablet, 5	NEW	1	5	2	INQOVI®	Otsuka Australia

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required) <input checked="" type="checkbox"/> Authority Required – Authority Required (in writing) - Postal/HPOS upload
Caution: This drug is a category x drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special pricing arrangements apply
Condition: Chronic Myelomonocytic Leukaemia
Indication: Chronic Myelomonocytic Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.
No more than 3 cycles will be authorised.
Prescribing Instructions: The first authority application must be made in writing and must include; (a) a completed authority prescription for; and, (b) a completed Decitabine + Cedazuridine PBS Authority Application – Supporting information Form; and, (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and, (d) a copy of the full blood examination report; and, (e) a signed patient acknowledgment form.
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary Manufacturer	Name and
DECITABINE + CEDAZURIDINE decitabine 35 mg + cedazuridine 100 mg tablet, 5	NEW	1	5	5	INQOV [®]	Otsuka Australia

Restriction Summary [new] / Treatment of Concept: [new]

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required) <input checked="" type="checkbox"/> Authority Required – Telephone/Online PBS Authorities immediate assessment
Caution: This drug is a category x drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special pricing arrangements apply
Condition: Myelodysplastic syndrome
Indication: Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria: The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); or The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).
AND
Clinical criteria: Patient must have previously received PBS-subsidised treatment with this drug for this condition.
AND
Clinical criteria: Patient must not have progressive disease.
Prescribing Instructions: Up to 6 cycles will be authorised.
Prescribing Instructions: Applications for continuing therapy may be made by telephone.

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required) <input checked="" type="checkbox"/> Authority Required – Telephone/Online PBS Authorities immediate assessment
Condition: Chronic Myelomonocytic Leukaemia
Indication: Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:

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The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.
AND
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition.
AND
Clinical criteria:
Patient must not have progressive disease.
Prescribing Instructions: Up to 6 cycles will be authorised.
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Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction Type – assessment time by Services Australia – Method of obtaining authority approval (if Authority Required) <input checked="" type="checkbox"/> Authority Required – Streamlined [new code]
Condition: Acute Myeloid Leukaemia
Indication: Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification
AND
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition.
AND
Clinical criteria:
Patient must not have progressive disease.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Special pricing arrangements apply
Caution: This drug is a category x drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

These restrictions may be subject to further review. Should there be any changes made to the restrictions 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

Otsuka welcomes the PBAC's positive recommendation and will keep working with the Department of Health to ensure affordable access to this treatment for Australian patients.