# 5.19 ARIPIPRAZOLE,
# Powder for injection 300 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe,
# Powder for injection 400 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe,
# Abilify Maintena,
# Lundbeck Australia Pty Ltd

## 1 Purpose of Submission

1.1 The Category 4 submission requested a General Schedule Authority Required (STREAMLINED) listing of a new pre-filled syringe (PFS) dose form of aripiprazole long-acting injectable (LAI) in both 300 mg and 400 mg (once-monthly) strengths (hereafter referred to as AOM PFS) for the treatment of schizophrenia.

1.2 The listing of AOM PFS was requested on cost-minimisation basis versus AOM modified release injection and inert substance diluent packs (therapeutic vial kits) (hereafter referred to as AOM vial kit).

## 2 Background

2.1 AOM vial kit is currently listed on the PBS as an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.

2.2 The PBAC first recommended the AOM vial kit on a cost-minimisation basis to paliperidone long-acting injection (LAI) at its July 2014 meeting. The PBAC considered paliperidone LAI was the most appropriate clinical comparator to AOM vial kit accepting that 390 mg aripiprazole LAI every 28 days is equi-effective to 83 mg paliperidone LAI every 28 days.

### *Registration status*

2.3 AOM PFS was TGA registered on 7 May 2018 for the acute and maintenance treatment of schizophrenia in adults and for maintenance treatment to prevent the recurrence of manic or mixed episodes of bipolar I disorder in adult patients as monotherapy.

### *Previous PBAC consideration*

2.4 The PBAC first considered and recommended the 400 mg strength of AOM PFS at its July 2018 meeting. At the time, the 300 mg strength of AOM PFS was not requested for listing as the submission stated that the 300 mg strength would only be used for dose adjustment while the 400 mg was intended to list as a steady state dose.

2.5 Post-recommendation, the department reached an in-principle pricing agreement for PBS listing of the AOM PFS at an equivalent price to the AOM vial kit. However, upon being made aware that a first brand Statutory Price Reduction may apply to all listed strengths of injectable aripiprazole with the listing of the PFS dose form, the sponsor withdrew the pricing offer package and did not progress the recommendation to listing.

2.6 The AOM PFS recommendation was subsequently rescinded at the March 2023 PBAC meeting.

2.7 Due to the application of a price reduction under 99ACN of the Act on 1 April 2023, listing both strengths of Abilify Maintena PFS would no longer trigger a first brand Statutory Price Reduction.

# 3 Requested listing

3.1 This submission requested listings of both the 300 and 400 mg strengths of AOM PFS unlike its July 2018 submission which excluded the 300 mg strength. The submission justified this noting that approximately 30% of patients consistently used the 300 mg strength of AOM vial kit (that is, as a steady state dose rather than for dose adjustment) and stated that listing a PFS dose form would allow those patients the same administration convenience.

3.2 The submission requested the same listing conditions as the currently listed AOM vial kit.

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| ARIPIPRAZOLE | | | | | |
| aripiprazole 300 mg modified release injection [1 chamber] (&) inert substance diluent [1.2 mL chamber], 1 dual chamber syringe | NEW | 1 | 1 | 5 | Abilify Maintena |
| aripiprazole 400 mg modified release injection [1 chamber] (&) inert substance diluent [ 1.6 mL chamber], 1 dual chamber syringe | NEW | 1 | 1 | 5 | Abilify Maintena |
| | | | | | |
| **Restriction Summary / Treatment of Concept** | | | | | |
| **Category / Program:**<br>☒ GENERAL - General Schedule (Code GE) | | | | | |
| **Prescriber type:**<br>☒Medical Practitioners ☒Nurse practitioners | | | | | |
| **Benefit type:**<br>☒Authority Required (Streamlined) | | | | | |
| **Indication:** Schizophrenia | | | | | |

3.3 In its previous consideration of the 400 mg AOM PFS, the PBAC considered that the vial kit and PFS should not be considered equivalent for the purposes of substitution.

# 4 Comparator

4.1 The submission nominated AOM vial kit as the main comparator consistent with the 2018 July submission.

# 5 Consideration of the evidence

## *Sponsor hearing*

5.1 There was no hearing for this item.

## *Consumer comments*

5.2 The PBAC noted that no consumer comments were received for this item.

## *Justification of the request*

5.3 The submission stated that in clinical practice, a PFS would be intuitively simpler, easier, and therefore more convenient to administer than a vial kit as both the powder and solvent are supplied within the syringe, eliminating the need to transfer them from vial to syringe. Both AOM vial kit and AOM PFS are to be administered by a healthcare professional, monthly, as a single injection.

5.4 The submission indicated that there was no intention to delist the current PBS listings of AOM vial kit because the PFS form does not support dose titration where the vial kit does.

## *Clinical claim*

5.5 The submission claimed non-inferior comparative effectiveness and safety of AOM PFS to AOM vial kit. No clinical evidence was provided to support this claim. The submission appears to rely on the notion that the PBAC had previously accepted the 400 mg AOM PFS as a suitable alternative to the AOM vial kit of the same strength.

5.6 The PBAC advised that this clinical claim is appropriate.

## *Economic analysis*

5.7 As a Category 4 submission, the economic analysis was not independently evaluated.

5.8 The submission presented a cost-minimisation approach of AOM PFS to AOM vial kit, assuming a 1:1 substitution of the vial kit with the PFS and requesting the same price across the respective strengths. The submission estimated the equi-effective doses as 300 mg AOM PFS and 300 mg AOM vial kit, and 400 mg AOM PFS and 400 mg AOM vial kit.

5.9 The requested prices were based on the approved ex-manufacturer prices (AEMP) of the listed AOM vial kits, consistent with the pricing approach recommended by the PBAC at its July 2018 meeting.

5.10 The proposed price sought for the 300 mg and 400 mg AOM PFS is shown in Table 1: Current and proposed prices for the AOM PFS, 300 mg and 400 mg. No price premium was requested.

**Table 1: Current and proposed prices for the AOM PFS, 300 mg and 400 mg**

| Price level | Current* price AOM vial kit, 300 mg | Proposed price AOM PFS, 300 mg | Current price AOM vial kit, 400 mg | Proposed price AOM PFS, 400 mg |
|---|---|---|---|---|
| DPMQ | $293.37 | $293.37 | $364.60 | $364.60 |
| PTP | $271.34 | $271.34 | $339.18 | $339.18 |
| AEMP | $252.36 | $252.36 | $315.46 | $315.46 |

Source: Table 3 of the submission (p.8)
* Current as of 1 June 2025
AEMP: approved ex-manufacturer price; AOM: Aripiprazole once monthly; DPMQ: dispensed price for maximum quantity; PFS: pre-filled syringe; PTP: price to pharmacy

5.11 The PBAC advised that this approach to the pricing remained appropriate.

## *Estimated PBS usage and financial implications*

5.12 Table 2 presents the estimated extent of use, cost of AOM PFS to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.13 The submission estimated that 400,000 to < 500,000 scripts would be supplied over the first six years of listing (10,000 to < 20,000 in Year 1 to 100,457 in Year 6).

5.14 The submission estimated the net financial impact to the PBS/RPBS for the listing of AOM PFS to be nil over six years assuming no change to patient numbers, utilisation or uptake.

**Table 2: Estimated use and financial implications**

| | Year 1 (2026) | Year 2 (2027) | Year 3 (2028) | Year 4 (2029) | Year 5 (2030) | Year 6 (2031) |
|---|---|---|---|---|---|---|
| **Estimated extent of use** | | | | | | |
| Number of scripts dispensed | [redacted][1] | [redacted][2] | [redacted][3] | [redacted][4] | [redacted][4] | [redacted][4] |
| **Estimated financial implications of AOM PFS*** | | | | | | |
| Cost to PBS/RPBS less co-payment | $[redacted][2] | $[redacted][3] | $[redacted][7] | $[redacted][7] | $[redacted][7] | $[redacted][7] |
| **Estimated financial implications of AOM vial kit*** | | | | | | |
| Cost to PBS/RPBS less co-payment | -$[redacted][2] | -$[redacted][3] | -$[redacted][7] | -$[redacted][7] | -$[redacted][7] | -$[redacted][7] |
| **Net financial implications** | | | | | | |
| Net cost to PBS/RPBS | $[redacted][5] | $[redacted][5] | $[redacted][5] | $[redacted][5] | $[redacted][5] | $[redacted][5] |

* Assuming combined totals of 300mg and 400mg strength AOM-PFS use
Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Table 5, p11 of the submission.
*The redacted values correspond to the following ranges:*
*[1] 10,000 to < 20,000*
*[2] 50,000 to < 60,000*
*[3] 90,000 to < 100,000*
*[4] 100,000 to < 200,000*
*[5] $0 to < $10 million*
*[6] $10 million to < $20 million*
*[7] $30 million to < $40 million*

5.15 The PBAC advised that the assumptions made to derive the nil estimates were reasonable.

# 6 PBAC Outcome

6.1 The PBAC recommended the listing of AOM 300 mg and 400 mg PFS as an Authority Required (STREAMLINED) benefit for the treatment of schizophrenia under the same listing circumstances as the currently listed AOM vial kit form.

6.2 The PBAC advised the equi-effective doses as AOM PFS 300 mg = AOM vial kit 300 mg, and AOM PFS 400 mg = AOM vial kit 400 mg.

6.3 The PBAC considered that the vial kit and PFS should not be considered equivalent for the purposes of substitution, consistent with its previous recommendation at the July 2018 meeting where the PBAC noted that the 400 mg PFS cannot be titrated to a lower dose as there are no graduated markers on the syringe.

6.4 The PBAC noted its July 2014 acceptance of paliperidone LAI as the most appropriate clinical comparator to AOM vial kit. The PBAC noted that the clinical guidelines for the treatment of schizophrenia have changed such that aripiprazole LAI is now considered a first line treatment, while paliperidone LAI is now second line. The PBAC therefore considered that paliperidone is no longer a suitable clinical comparator for LAI forms of aripiprazole.

6.5 The PBAC considered that there should be no net financial implications to the PBS/RPBS as AOM PFS is expected to list at the same price as the AOM vial kit with direct 1:1 substitution. The PBAC therefore did not anticipate listing the PFS would increase the overall market utilisation.

6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because AOM PFS is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over AOM vial kit, and 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 2022 for Pricing Pathway A were not met.

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

**Outcome:**
Recommended

# 7 Recommended listing

7.1 *Add new medicinal product packs as follows:*

| MEDICINAL PRODUCT<br>medicinal product pack | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---|---|---|---|
| ARIPIPRAZOLE | | | | | |
| aripiprazole 300 mg modified release injection [1 chamber] (&) inert substance diluent [1.2 mL chamber], 1 dual chamber syringe | NEW | 1 | 1 | 5 | Abilify Maintena |
| aripiprazole 400 mg modified release injection [1 chamber] (&) inert substance diluent [ 1.6 mL chamber], 1 dual chamber syringe | NEW | 1 | 1 | 5 | Abilify Maintena |
| | | | | | |
| **Restriction Summary 16004 / Treatment of Concept: 4246** | | | | | |
| **Concept ID** (for internal Dept. use) | **Category / Program:**<br>☒ GENERAL - General Schedule (Code GE) | | | | |
| | **Prescriber type:**<br>☒Medical Practitioners ☒Nurse practitioners | | | | |
| | **Benefit type:**<br>☒Authority Required (Streamlined) [existing code] | | | | |
| | **Indication:** Schizophrenia | | | | |

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

# 9 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.

# 10 Sponsor's Comment

Lundbeck Australia welcomes the decision of the PBAC which recognises the need for reimbursed access to treatments for Australians living with serious mental illness.