

6.20 RISPERIDONE tablets, oral solution, orally disintegrating tablets, Janssen-Cilag Pty Ltd

1 Purpose of Application

- 1.1 To request an amendment made to the current risperidone restriction for the treatment of dementia to be consistent with TGA's recent approved changes to the indication.

2 Requested listing

- 2.1 The submission requested an inclusion of moderate to severe dementia for the Alzheimer's type and limiting duration of treatment to 12 weeks be incorporated into the current restriction for dementia for the following items:

Table 1: PBS item codes proposed to be amended

PBS item code	Dose form and strength
1842Y	Risperidone 500 mcg tablet, 20 pack
8787L	Risperidone 500 mcg tablet, 60 pack
8788M	Risperidone 500 mcg, orally disintegrating, 28 pack
8789N	Risperidone 1 mg tablet, 60 pack
8790P	Risperidone 1 mg, orally disintegrating, 28 pack
9293D	Risperidone 1 mg/ml oral liquid, 100 ml

Source: Minor submission

- 2.2 The PBAC noted that subsequent to submitting the minor submission, the sponsor requested that risperidone orally-disintegrating tablets (8788M and 8790P) be delisted from the PBS from 1 May 2016.

3 Background

- 3.1 Risperidone tablets, 1 mg, 2 mg, 3 mg and 4 mg; oral disintegrating tablets, 1 mg and 2 mg; oral solution, 1 mg per mL, 100 mL, were recommended for listing at the November 2005 PBAC meeting for:
- schizophrenia and related psychoses;
 - acute mania associated with bipolar I disorder;
 - behavioural disturbances in dementia;
 - conduct and other disruptive disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviours (e.g. aggression, impulsivity and self-injurious behaviours) are prominent; and
 - behavioural disorders associated with autism in children and adolescents.
- 3.2 The requested change was based on a review of the original company-sponsored clinical studies. The review showed that the benefit/risk profile was favourable with regard to the use of risperidone in dementia of the Alzheimer's type (DAT), but was unfavourable for vascular dementia or mixed dementia.
- 3.3 The highlighted features included in the company-sponsored clinical studies were:
- Generally patients with DAT of moderate to severe intensity (severity) were included
 - Duration of treatment was up to 12 weeks
 - Specific target symptoms included were agitation, aggression or psychotic symptoms.
- 3.4 Revised TGA approved indication is as below:
Risperdal is indicated for the treatment (up to 12 weeks) of psychotic symptoms, or persistent agitation or aggression unresponsive to non-pharmacological approaches in patients with moderate to severe dementia of the Alzheimer type.
- 3.5 The submission stated that these changes do not impact the intramuscular injection formulation of risperidone. Risperidone injections are not currently PBS listed for dementia indication.

4 PBAC consideration of the evidence

Sponsor hearing

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

Consumer comments

- 4.2 The PBAC noted and welcomed the input from a health care professional via the Consumer Comments facility on the PBS website. The comment described the possible negative unintended consequences of the change to listing, including the increased prescribing of alternative antipsychotics, benzodiazepines or anticonvulsants, and increased off label use of risperidone.

Estimated PBS usage & financial implications

- 4.3 The minor submission stated it is difficult to quantify the financial implications as the

[REDACTED]

5 PBAC Outcome

- 5.1 The PBAC recommended an amendment be made to the current risperidone's restriction for the treatment of dementia to align with the revised TGA indication, restricting use to moderate to severe dementia of the Alzheimer's type and limiting duration of treatment to 12 weeks.
- 5.2 The PBAC also recommended the change be flowed on to generic formulations of risperidone.
- 5.3 The PBAC noted the issues raised by the Secretariat concerning existing patients who are being treated with risperidone for dementia for longer than 12 weeks.
- 5.4 The PBAC also noted there may be a potential for use outside the PBS restriction.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend existing listing as follows:

Item numbers 1842Y, 8787L, 8789N, 9293D and generic formulations of risperidone

Public Summary Document – November 2015 PBAC Meeting

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	-
Severity:	-
Condition:	Behaviour disturbances
PBS Indication:	Behaviour disturbances
Treatment phase:	-
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Treatment criteria:	-
Clinical criteria:	The condition must be characterised by psychotic symptoms and aggression; AND Patient must have dementia of the Alzheimer type AND Patient must have failed to respond to non-pharmacological methods of treatment AND The treatment must not be more than 12 weeks under this restriction.
Population criteria:	-
Foreword	-
Definitions	-
Prescriber Instructions	-
Administrative Advice	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and a medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Cautions	In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attack, in patients treated with risperidone compared with patients treated with placebo.

Delete item numbers: 8788M, 8790P

7 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.

8 Sponsor's Comment

The sponsor had no comment.