

12.01 QUETIAPINE Tablet 25 mg (as fumarate), Multiple Brands

1 Purpose of Item

- 1.1 A Request to change the current listing for the 25 mg tablets to allow for up to 5 repeats to be prescribed as an Authority Required listing for maintenance therapy for treatment of acute mania, bipolar 1 disorder and in the treatment of schizophrenia.

2 Background

- 2.1 The request was from Dr Michelle Atchison the Chair of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) Section of Private Practice Psychiatry, in response to the recent publication of a series of clinical practice guidelines.
- 2.2 The Drug Utilisation Sub-Committee (DUSC) has previously reviewed the utilisation of antipsychotics in February 2013 which concluded the following:
- High growth in the volume of antipsychotic prescriptions, particularly newer listed products
 - High and inappropriate utilisation of antipsychotics in the elderly
 - Also indicated some use of antipsychotics in very young patients and possible use of antipsychotics for non-PBS subsidised indications in middle-aged adults
- 2.3 The PBAC considered the February report and requested a follow-up review of utilisation to better inform the committee on the extent of this use in practice.
- 2.4 The 2nd stage of the DUSC (June 2013) review concluded that:
- Off-label and non-subsidised use of antipsychotics was most evident with the use of the 25 mg strength of quetiapine,
 - 38% of all patients on a regimen that contained a PBS listed antipsychotic included quetiapine,
 - Main findings relating to 25 mg quetiapine:
 1. 23.3% of all patients taking quetiapine were taking the 25 mg strength alone
 2. 66% of initial prescriptions for quetiapine were written by GPs (suggesting that the indications were not schizophrenia or bipolar disorder)
 - DUSC indicated that quetiapine 25 mg was not a therapeutic dose for any of the PBS listed indications.
 - The report indicated that the most likely use was 'off-label' as an anxiolytic and sedative.

- 2.5 The PBAC considered the information presented by DUSC and recommended that the number of repeats for the listing of the 25 mg strength of quetiapine be reduced from five to zero, that the listing include that “the treatment must be for dose titration purposes” and that the approved indication to be for schizophrenia, acute mania and bipolar I disorder.

3 Current situation

- 3.1 The listing for the 25 mg tablet was updated to reflect the changes in paragraph 2.5 on 1 January 2014.
- 3.2 The DUSC reviewed the impact of the above restriction changes in 2016 and concluded that “The intervention to change the listing of the 25 mg strength of quetiapine to allow no repeats from 1 January 2014 had been effective in supporting its intended use as a titrating dose for PBS-listed indications.”

4 Requested PBAC advice

- 4.1 The RANZCP requested that the current restriction for the 25 mg strength quetiapine tablet be changed to an Authority Required listing and that the number of repeats be increased from zero to 5 for maintenance therapy for treatment of acute mania, bipolar 1 disorder and in the treatment of schizophrenia.
- 4.2 The basis for the request was:
- Concern that the absence of 25 mg tablets for maintenance disadvantages those who fall between the 50 mg dosage steps (e.g. a maintenance dose of 37.5 mg or 52.5 mg).
 - Claim that to go to the higher dose causes intolerable side effects and the lower dose causes inadequate symptom relief.
 - Quetiapine is currently recommended in RANZCP clinical practice guidelines for mood disorders (as monotherapy or adjunctive therapy) and for schizophrenia and related disorders.

5 PBAC outcome

- 5.1 The PBAC recommended that the current listing for the 25 mg strength quetiapine tablets be changed to allow for up to 5 repeats via an Authority Required prescription for maintenance therapy for treatment of acute mania, bipolar 1 disorder and in the treatment of schizophrenia.
- 5.2 The PBAC considered that this could be achieved by removing the note “No increase in the maximum number of repeats may be authorised” in the Administrative Advice and removal of “The treatment must be for dose titration purposes” from the clinical criteria.
- 5.3 The PBAC advised that this submission would not meet the criteria for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands Multiple sponsors

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
Condition:	Schizophrenia
PBS Indication:	Schizophrenia
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
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Clinical criteria	The treatment must be for dose titration purposes.

Public Summary Document – March 2018 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

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
Condition:	Acute mania
PBS Indication:	Acute mania
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
Clinical criteria	The condition must be associated with bipolar I disorder, AND The treatment must be as monotherapy, AND The treatment must be for dose titration purposes.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

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
Condition:	Bipolar I disorder
PBS Indication:	Bipolar I disorder
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
Clinical criteria	The treatment must be as monotherapy, AND The treatment must be for dose titration purposes.
Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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.

Addendum to the March 2018 PBAC Minutes:

**4.03 QUETIAPINE
Tablet 25 mg (as fumarate),
Multiple Brands**

8 Purpose of Item

8.1 Subsequent to recommendation by the PBAC, the Department advised that implementation of the recommended change to quetiapine would not provide an adequate criterion for providing an authority for increased maximum repeats for dose optimisation purposes. The PBAC Secretariat has proposed an additional criterion to specify the conditions under which increased maximum repeats would be granted.

9 Requested listing

Additions to the PBAC recommended restriction are indicated in *italics*.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Schizophrenia
PBS Indication:	Schizophrenia
Restriction Level / Method:	Restricted benefit Authority Required - In Writing Authority Required - Telephone Authority Required – Emergency Authority Required - Electronic Streamlined

Public Summary Document – July2018 PBAC Meeting

Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>
Clinical criteria	The treatment must be for dose titration purposes.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Acute mania
PBS Indication:	Acute mania
Restriction Level / Method:	<p>Restricted benefit</p> <p>Authority Required - In Writing</p> <p>Authority Required - Telephone</p> <p>Authority Required – Emergency</p> <p>Authority Required - Electronic</p> <p>Streamlined</p>
Clinical criteria	<p>The condition must be associated with bipolar I disorder,</p> <p>AND</p> <p>The treatment must be as monotherapy,</p> <p>AND</p> <p>The treatment must be for dose titration purposes.</p>

Public Summary Document – July2018 PBAC Meeting

Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>
------------------------------	--

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Bipolar I disorder
PBS Indication:	Bipolar I disorder
Restriction Level / Method:	<p>Restricted benefit</p> <p>Authority Required - In Writing</p> <p>Authority Required - Telephone</p> <p>Authority Required – Emergency</p> <p>Authority Required - Electronic</p> <p>Streamlined</p>
Clinical criteria	<p>The treatment must be as monotherapy,</p> <p>AND</p> <p>The treatment must be for dose titration purposes.</p>
Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>

10 PBAC outcome

10.1 The PBAC recommended amending its recommended restriction to facilitate Department of Human Services (DHS) implementation and administration of authority requests for increased maximum repeats for the 25 mg strength of quetiapine. The PBAC noted this amendment will facilitate verification of the reasons for which an authority request is being made.

Outcome:

Recommended

11 Recommended listing

11.1 Amend recommended listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Schizophrenia
PBS Indication:	Schizophrenia
Restriction Level / Method:	Restricted benefit Authority Required - In Writing Authority Required - Telephone Authority Required – Emergency Authority Required - Electronic Streamlined

Public Summary Document – July2018 PBAC Meeting

Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>
Clinical criteria	The treatment must be for dose titration purposes.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Acute mania
PBS Indication:	Acute mania
Restriction Level / Method:	<p>Restricted benefit</p> <p>Authority Required - In Writing</p> <p>Authority Required - Telephone</p> <p>Authority Required – Emergency</p> <p>Authority Required - Electronic</p> <p>Streamlined</p>
Clinical criteria	<p>The condition must be associated with bipolar I disorder,</p> <p>AND</p> <p>The treatment must be as monotherapy,</p> <p>AND</p> <p>The treatment must be for dose titration purposes.</p>

Public Summary Document – July2018 PBAC Meeting

Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>
------------------------------	--

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
QUETIAPINE 25 mg tablet, 60	1	0	Multiple brands	Multiple sponsors

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Condition:	Bipolar I disorder
PBS Indication:	Bipolar I disorder
Restriction Level / Method:	Restricted benefit Authority Required - In Writing Authority Required - Telephone Authority Required – Emergency Authority Required - Electronic Streamlined
Clinical criteria	The treatment must be as monotherapy, AND The treatment must be for dose titration purposes.
Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><i>Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.</i></p> <p>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</p>

12 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.