NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

25 March 2014

Approval of proposal for paliperidone, risperidone and olanzapine depot injections

PHARMAC is pleased to announce the approval of a proposal to:

- fund paliperidone depot injection (Invega Sustenna) from 1 May 2014 in conjunction with a price decrease on risperidone depot injection (Risperdal Consta), through an agreement with Janssen-Cilag Pty Ltd (Janssen); and

- amend the restrictions for risperidone depot injection and olanzapine depot injection (Zyprexa Relprevv) from 1 May 2014.

This proposal was the subject of a consultation letter dated 13 February 2014, available online at http://www.pharmac.health.nz/news/consultation-2014-02-13-palperidone/

Some additional changes were made to the criteria for all three depot injections following consideration of consultation feedback, as outlined below and on the following pages.

Details of the decision

Paliperidone depot injection

- Paliperidone depot injection (Invega Sustenna) will be listed in Section B of the Pharmaceutical Schedule (community listing) and on the Hospital Medicines List (HML; Part II of Section H of the Pharmaceutical Schedule) from 1 May 2014 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Paliperidone	Inj 25 mg syringe	Invega Sustenna	1	$194.25
Paliperidone	Inj 50 mg syringe	Invega Sustenna	1	$271.95
Paliperidone	Inj 75 mg syringe	Invega Sustenna	1	$357.42
Paliperidone	Inj 100 mg syringe	Invega Sustenna	1	$435.12
Paliperidone	Inj 150 mg syringe	Invega Sustenna	1	$435.12

- A confidential rebate will apply to Invega Sustenna from 1 October 2017.

- Paliperidone depot injection will be listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority restrictions:

> **Special Authority for Subsidy**
> **Initial application** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
> Either:
> 1 The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection; or
> 2 All of the following:

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2.1 The patient has schizophrenia or other psychotic disorder; and
2.2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
1 The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Note: Paliperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialling paliperidone depot injection.

- Paliperidone depot injection will be listed in the HML subject to the following restrictions:

Restricted
Re-assessment required after 12 months
Either:
1 The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection; or
2 All of the following:
2.1 The patient has schizophrenia or other psychotic disorder; and
2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Continuation
Re-assessment required after 12 months
1 The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

- Invega Sustenna will have protection from subsidy reduction and delisting until 30 June 2018.

Risperidone depot injection

- The prices and subsidies for risperidone depot injection (Risperdal Consta) will be reduced in Section B of the Pharmaceutical Schedule and on the HML from 1 May 2014 as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	New price and subsidy
Risperidone	Inj 25 mg vial	Risperdal Consta	1	$175.00	$135.98
Risperidone	Inj 37.5 mg vial	Risperdal Consta	1	$230.00	$178.71
Risperidone	Inj 50 mg vial	Risperdal Consta	1	$280.00	$217.56

- The Special Authority criteria currently applying to risperidone depot injection will be amended in Section B of the Pharmaceutical Schedule from 1 May 2014 as follows (additions in bold, deletions in strikethrough):

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for ~~6~~ **12** months for applications meeting the following criteria:
Either:

1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection; or

2 All of the following:
- 2.1 The patient has schizophrenia or other psychotic disorder; and
- 2.2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
~~Either:~~
~~1 Both:~~
- ~~1.1 The patient has had less than 12 months treatment with risperidone depot injection; and~~
- ~~1.2 There is no clinical reason to discontinue treatment; or~~

1~~2~~ The initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of ~~risperidone~~ **an atypical antipsychotic** depot injection.

Note: Risperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialling risperidone depot injection.

- The restrictions currently applying to risperidone depot injection in DHB hospitals will be amended in the HML from 1 May 2014 as follows (additions in bold, deletions in strikethrough):

Restricted
*Re-assessment required after ~~6~~ **12** months*
Either:

1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection; or

2 All of the following:
- 2.1 The patient has schizophrenia or other psychotic disorder; and
- 2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Continuation
Re-assessment required after 12 months
~~Either:~~
~~1 The patient has had less than 12 months' treatment with risperidone depot injection and there is no clinical reason to discontinue treatment; or~~

1~~2~~ The initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of **an atypical antipsychotic** ~~risperidone~~ depot injection.

- Risperdal Consta will have protection from subsidy reduction and delisting until 31 December 2016.

Olanzapine depot injection

- The Special Authority criteria currently applying to olanzapine depot injection will be amended in Section B of the Pharmaceutical Schedule from 1 May 2014 as follows (additions in bold, deletions in strikethrough):

> **Special Authority for Subsidy**
> **Initial application** from any relevant practitioner. Approvals valid for ~~6~~ **12** months for applications meeting the following criteria:
> **Either:**
> **1 The patient has had an initial Special Authority approval for risperidone depot injection or paliperidone depot injection; or**
> 2 All of the following:
> 2.1 The patient has schizophrenia; and
> 2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
> 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.
>
> **Renewal** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
> ~~Either:~~
> ~~1 Both:~~
> ~~1.1 The patient has had less than 12 months treatment with olanzapine depot injection; and~~
> ~~1.2 There is no clinical reason to discontinue treatment; or~~
> **1**~~2~~ The initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of **an atypical antipsychotic** ~~olanzapine~~ depot injection.
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> Note: The patient should be monitored for post-injection syndrome for at least two hours after each injection.

- The restrictions currently applying to olanzapine depot injection in DHB hospitals will be amended in the HML from 1 May 2014 as follows (additions in bold):

> **Restricted**
> *Re-assessment required after 12 months*
> **Either:**
> **1 The patient has had an initial Special Authority approval for risperidone depot injection or paliperidone depot injection; or**
> 2 All of the following:
> 2.1 The patient has schizophrenia; and
> 2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
> 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.
>
> **Continuation**
> *Re-assessment required after 12 months*
> ~~Either:~~
> ~~1 The patient has had less than 12 months' treatment with olanzapine depot injection and there is no clinical reason to discontinue treatment; or~~
> 2 The initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of **an atypical antipsychotic** ~~olanzapine~~ depot injection.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Two responders requested alterations to the criteria and/or approval periods for the atypical antipsychotic depot injections.	Following consideration of this feedback we have made one of the requested changes (to extend the initial approval period from 6 to 12 months) and intend to seek advice on the other requested changes (to reduce the pre-requisite period of hospitalisation time to 10 days and to increase the approval period to two years) from the Mental Health Subcommittee of PTAC next time it meets.
Two responders had concerns that there are ingredients in the paliperidone depot formulation that are not present in the risperidone depot formulation, including ingredients not listed on Medsafe's website, that could cause side effects.	Janssen has confirmed that there are no ingredients in risperidone depot or paliperidone depot that are not listed on the datasheets on Medsafe's website. Anyone who has concerns about the ingredients of paliperidone depot injection should contact Medsafe: http://www.medsafe.govt.nz/other/contact.asp Clinical trial evidence suggests that risperidone depot injection and paliperidone depot injection have similar adverse event profiles. Medsafe assessed the safety of paliperidone depot as part of its registration process in New Zealand, and information about the side effects are included on the datasheet and the consumer medicine information available on Medsafe's website: http://www.medsafe.govt.nz/consumers/cmi/i/invega.pdf We would encourage anyone experiencing side effects from paliperidone depot injection (or any other treatment) to discuss these with their doctor, including the possibility of reporting the side effect to the Centre for Adverse Reactions Monitoring: https://nzphvc-01.otago.ac.nz/carm-adr/reporting.php

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.