CONSULTATION

PHARMAC
Pharmaceutical Management Agency

13 February 2014

Proposal for paliperidone depot injection, risperidone depot injection and olanzapine depot injection

PHARMAC is seeking feedback on 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), both through a provisional agreement with Janssen-Cilag Pty Ltd (Janssen).

Both treatments would be subject to community and hospital restrictions for patients with schizophrenia and related psychoses. Amendments to the community and hospital restrictions for risperidone depot injection and olanzapine depot injection (Zyprexa Relprevv) are also proposed, which would allow patients with an approvals for risperidone depot and olanzapine depot to access paliperidone depot without having to re-meet the initial approval criteria (and vice versa).

Details of the proposal and background information can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm on Friday, 28 February 2014** to:

Geraldine MacGibbon	Email: paliperidoneconsult@pharmac.govt.nz
Senior Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

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Details of the proposal

Paliperidone depot injection

- Paliperidone depot injection (Invega Sustenna) would 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	Proposed 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 would apply to Invega Sustenna from 1 October 2017.

- Paliperidone depot injection would 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 6 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:
> 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 paliperidone depot injection; and
> 1.2 There is no clinical reason to discontinue treatment; or
> 2 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 paliperidone 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 would be listed in the HML subject to the following restrictions:

Restricted
Re-assessment required after 6 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
Either:
1 The patient has had less than 12 months' treatment with paliperidone depot injection and there is no clinical reason to discontinue treatment; or
2 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 paliperidone depot injection.

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

Risperidone depot injection

- The prices and subsidies for risperidone depot injection (Risperdal Consta) would 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	Proposed 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 would be amended in Section B of the Pharmaceutical Schedule from 1 May 2014 as follows (additions in bold):

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 6 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
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 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 would be amended in the HML from 1 May 2014 as follows (additions in bold):

Restricted
Re-assessment required after 6 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
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 depot injection.

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

Olanzapine depot injection

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

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 6 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
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 olanzapine depot injection.

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 would be amended in the HML from 1 May 2014 as follows (additions in bold):

Restricted
Re-assessment required after 6 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 olanzapine depot injection.

Background

Paliperidone is the major active metabolite of risperidone. The key difference between paliperidone depot injection and risperidone depot injection is that paliperidone depot can be given every four weeks (or monthly) and risperidone depot is given fortnightly.

This proposal arose from a funding application from Janssen for paliperidone depot. The funding application has been reviewed by the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Mental Health Subcommittee of PTAC on a number of occasions, most recently by PTAC at its November 2013 meeting.

In summary, while noting that there were some potential advantages of paliperidone depot, PTAC recommended that paliperidone depot be funded only if it was cost-neutral to risperidone depot, on the basis that the available evidence suggests that the two treatments

provide similar efficacy. Minutes of the PTAC and Mental Health Subcommittee reviews of paliperidone depot can be found on PHARMAC's website at:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId_359

Please note that PHARMAC is not intending to progress a proposal to fund paliperidone tablets at this time, taking into account the advice received from PTAC and the price differential between paliperidone tablets and other funded oral antipsychotics. More information about the status of the funding application for paliperidone tablets can be found on PHARMAC's website at:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId_281