

24 June 2008

Proposal for Risperdal (risperidone), Topamax (topiramate), Concerta (methylphenidate extended release), Eprex (erythropoietin alpha) and Recormon (erythropoietin beta)

Proposal summary

PHARMAC and Janssen-Cilag have reached an agreement that would enable widening of access to several currently funded medicines as well as funding a new medicine for Attention Deficit Hyperactivity Disorder (ADHD), all effective 1 September 2008. The agreement includes the following components:

- Listing once-daily extended-release methylphenidate (Concerta) for ADHD under Special Authority criteria.
- Removing the Special Authority from topiramate (Topamax), meaning that it could be prescribed for indications other than epilepsy (eg migraine prophylaxis).
- Amending the prescriber restrictions on various risperidone formulations (Risperdal, Risperdal Quicklets, Risperdal Consta), to make subsidised access easier for non-specialists.
- Reducing the price and subsidy for erythropoietin alpha (Eprex), a treatment for anaemia that is not currently fully funded, such that Epex would become fully funded. The Special Authority criteria applying to Epex would be widened.

In conjunction with this agreement, PHARMAC proposes to reduce the subsidy for Recormon from 1 July 2009 through the application of reference pricing in line with the rebated price of Epex. If the price of Recormon remains the same as it is now, this would mean that a manufacturer's surcharge would apply to Recormon, and patients would need to pay a surcharge if they continue on the Recormon brand.

Further details of the proposal can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Tuesday 15 July 2008** to:

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

The details of the proposal

We have entered into a provisional agreement with Janssen-Cilag to list, or amend the prices/subsidies for, risperidone (Risperdal), topiramate (Topamax), methylphenidate extended release (Concerta) and erythropoietin alpha (Eprex), all of which would be listed in both Section B and in Part II of Section H of the Pharmaceutical Schedule, from 1 September 2008 (prices ex-manufacturer, excluding GST) as follows:

Pharmaceutical	Brand	Form and Strength	Pack Size	Current list price (& subsidy, if different)	Proposed list price & subsidy
Risperidone	Risperdal	Tablet 0.5 mg	20	\$10.25	\$5.20
Risperidone	Risperdal	Tablet 1 mg	60	\$61.53	\$30.77
Risperidone	Risperdal	Tablet 2 mg	60	\$123.05	\$61.53
Risperidone	Risperdal	Tablet 3 mg	60	\$184.63	\$92.32
Risperidone	Risperdal	Tablet 4 mg	60	\$246.09	\$123.05
Topiramate	Topamax	Tablet 25 mg	60	\$51.50	\$26.04
Topiramate	Topamax	Tablet 50 mg	60	\$87.54	\$44.26
Topiramate	Topamax	Tablet 100 mg	60	\$148.83	\$75.25
Topiramate	Topamax	Tablet 200 mg	60	\$256.82	\$129.85
Topiramate	Topamax	Sprinkle cap 15 mg	60	\$41.20	\$20.84
Topiramate	Topamax	Sprinkle cap 25 mg	60	\$51.50	\$26.04
Methylphenidate hydrochloride	Concerta	Extended-release tablet 18 mg	30	Not listed	\$58.96
Methylphenidate hydrochloride	Concerta	Extended-release tablet 27 mg	30	Not listed	\$65.44
Methylphenidate hydrochloride	Concerta	Extended-release tablet 36 mg	30	Not listed	\$71.93
Methylphenidate hydrochloride	Concerta	Extended-release tablet 54 mg	30	Not listed	\$86.24
Erythropoietin alpha	Eprex	Inj 1,000 iu, pre-filled syringe	6	\$162.90 (\$60.82)	\$48.68
Erythropoietin alpha	Eprex	Inj 2,000 iu, pre-filled syringe	6	\$325.80 (\$121.63)	\$120.18
Erythropoietin alpha	Eprex	Inj 3,000 iu, pre-filled syringe	6	\$455.34 (\$182.45)	\$166.87
Erythropoietin alpha	Eprex	Inj 4,000 iu, pre-filled syringe	6	\$572.40 (\$243.67)	\$193.13
Erythropoietin alpha	Eprex	Inj 5,000 iu, pre-filled syringe	6	Not listed	\$243.26
Erythropoietin alpha	Eprex	Inj 6,000 iu, pre-filled syringe	6	Not listed	\$291.92
Erythropoietin alpha	Eprex	Inj 10,000 iu, pre-filled syringe	6	\$1,322.82 (\$608.16)	\$395.18

The prices and subsidies for Risperdal Quicklets, Risperdal Consta and Risperdal oral liquid would remain the same as they are now.

Other changes proposed to take effect from 1 September 2008 are as follows:

- Risperidone tablets (Ridal and Risperdal brands) and oral liquid (Risperdal) would no longer be subject to a "Retail pharmacy-Specialist" restriction.
- The Special Authority applying to risperidone orally-disintegrating tablets (Risperdal Quicklets) would be amended to remove the requirement for a psychiatrist to apply for the Special Authorities and to write the first prescription.
- The Special Authority applying to risperidone microspheres for injection (Risperdal Consta) would be amended to remove the requirement for a psychiatrist to make the application.
- The Special Authority for Topamax would be removed.
- Concerta would be subject to the following Special Authority for subsidy:

Initial application only from a paediatrician, psychiatrist or any other medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder); and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
 - 3.1 Applicant is a paediatrician or psychiatrist; or
 - 3.2 Both:
 - 3.2.1 Applicant is a medical practitioner and confirms that a relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient; and
 - 3.2.2 Provide name of the recommending specialist
- 4 Either:
 - 4.1 Current methylphenidate medication has not been effective due to significant administration and/or compliance difficulties; or
 - 4.2 There is significant concern regarding the risk of diversion or abuse of short-acting methylphenidate.

Renewal only from a paediatrician, psychiatrist or any other medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Both:
 - 2.2.1 Applicant is a medical practitioner and confirms that a relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient; and
 - 2.2.2 Provide name of the recommending specialist

- Eprex would continue to be subject to a Special Authority for subsidy, with new criteria as follows:

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Both:
 - 1.1 patient in chronic renal failure; and
 - 1.2 Haemoglobin \leq 100g/L; and
- 2 Any of the following:
 - 2.1 Both:
 - 2.1.1 patient is not diabetic; and
 - 2.1.2 glomerular filtration rate \leq 30ml/min; or

- 2.2 Both:
- 2.2.1 patient is diabetic; and
- 2.2.2 glomerular filtration rate \leq 45ml/min; or
- 2.3 patient is on haemodialysis or peritoneal dialysis.

Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Notes: The Cockcroft-Gault Formula may be used to estimate glomerular filtration rate (GFR) in persons 18 years and over:

GFR (ml/min) (male) = $(140 - \text{age}) \times \text{Ideal Body Weight (kg)} / 814 \times \text{serum creatinine (mmol/l)}$

GFR (ml/min) (female) = Estimated GFR (male) \times 0.85

- The subsidised dosage delivery form for Eprex would change from the current form to the Protecs needle system.

Other relevant terms of the agreement are as follows:

- Risperdal tablets and oral liquid, Topamax and Concerta would have protection from delisting and subsidy reduction until 1 July 2012.
- Risperdal Quicklets and Risperdal Consta would have protection from delisting and subsidy reduction until 1 July 2013.
- Eprex would have protection from delisting and subsidy reduction until 1 July 2011.
- The currently subsidised dosage delivery form of Risperdal Consta would be replaced by an Alaris "two-needle" system, subject to Medsafe approval.
- Concerta and Eprex would be subject to a confidential rebate, reducing the net subsidy paid for these products.

From 1 July 2009 the subsidy for Recormon would be reduced through the application of reference pricing as follows:

Pharmaceutical	Brand	Form and Strength	Pack Size	Current list price and subsidy	Proposed subsidy
Erythropoietin beta	Recormon	Inj 1,000 iu, pre-filled syringe	6	\$76.02	\$31.20
Erythropoietin beta	Recormon	Inj 2,000 iu, pre-filled syringe	6	\$152.04	\$62.40
Erythropoietin beta	Recormon	Inj 3,000 iu, pre-filled syringe	6	\$228.06	\$93.60
Erythropoietin beta	Recormon	Inj 4,000 iu, pre-filled syringe	6	\$304.08	\$125.00
Erythropoietin beta	Recormon	Inj 5,000 iu, pre-filled syringe	6	\$380.10	\$156.00
Erythropoietin beta	Recormon	Inj 6,000 iu, pre-filled syringe	6	\$456.12	\$187.20
Erythropoietin beta	Recormon	Inj 10,000 iu, pre-filled syringe	6	\$760.20	\$312.10

Background information

Topamax

An application to widen access to Topamax (topiramate) for prophylaxis of migraine has been reviewed by the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC considered that topiramate would most benefit patients who could not tolerate or were unresponsive to other funded alternatives. PTAC recommended that access to topiramate be widened for migraine prophylaxis with a low priority, and noted the financial risk associated with widening access to topiramate at the current prices. This pricing concern has been addressed as part of this multi-product proposal.

Concerta

PTAC has reviewed an application to list Concerta (once-daily extended-release methylphenidate) for the treatment of ADHD. The Committee recommended that a once-daily methylphenidate preparation be listed in the Pharmaceutical Schedule with a medium priority subject to the Special Authority criteria outlined earlier in this consultation letter.

If the Board approves this proposal there would be no current funding applications under consideration by PHARMAC with regard to Concerta; however, we would remain open to receiving future applications for changes to the access criteria.

Eprex and Recormon

Recormon (erythropoietin beta) was listed in the Pharmaceutical Schedule in April 2002, following a positive recommendation from PTAC. At the time, the subsidy for Eprex (erythropoietin alpha), which was already listed in the Schedule, was reduced to match the subsidy for Recormon (this is known as reference pricing), based on advice from PTAC that these two forms of erythropoietin have the same or similar effect in treating the same or similar conditions. PTAC considered that a 1:1 dose equivalence ratio could be used for reference pricing purposes. Over time the cost of Recormon continued to decrease, and the subsidy for Eprex was re-reference priced each time. The current proposal would result in reference pricing of Recormon to Eprex, in the same manner as has occurred previously when Eprex was reference priced to Recormon.

We note that the current Medsafe datasheet for Eprex does not include the 5,000 iu and 6,000 iu strengths. However, these strengths have been approved for use in New Zealand and the datasheet is in the process of being updated to include them. Under this proposal these additional strengths would be available and subsidised from 1 September 2008.

Risperdal, Risperdal Quicklets and Risperdal Consta

As part of this multi-product agreement the 'Specialist' prescriber restrictions would be removed from all formulations of risperidone listed in the Pharmaceutical Schedule. This is similar to most other funded atypical antipsychotics. Risperdal Quicklets and Risperdal Consta would remain subject to a requirement for Special Authority for subsidy.