CONSULTATION

PHARMAC
Pharmaceutical Management Agency

20 June 2014

Proposal for sole supply of erythropoietin

PHARMAC is seeking feedback on a proposal, resulting from a provisional agreement with Janssen-Cilag Pty Ltd, to:

- award Sole Subsidised Supply Status (the only funded brand in the community) and Hospital Supply Status (the only available brand in DHB hospitals, subject to a 5% discretionary variance (DV) limit) to Eprex (erythropoietin alfa) from 1 March 2015 to 28 February 2018; and
- widen access to erythropoietin to include:
    - patients with myelodysplasia; and
    - patients for whom blood transfusion is not a viable treatment option (in hospital only).

Further details of this proposal, including how to provide feedback and background information including proposed transition timelines and how a change to erythropoietin alfa would be managed, can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 4 July 2014** to:

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Fax: 04 460 4995

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

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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.

Details of the proposal

- Janssen's brand of erythropoietin alfa prefilled syringes (Eprex) would continue to be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the current subsidies and prices (ex-manufacturer and excluding GST) as follows (additions in bold, deletions in strikethrough):

Chemical	Presentation	Strength	Brand	Pack size	Price and subsidy
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	1,000 iu in 0.5ml	Eprex	6	$48.68
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	2,000 iu in 0.5ml	Eprex	6	$120.18
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	3,000 iu in 0.3ml	Eprex	6	$166.87
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	4,000 iu in 0.4ml	Eprex	6	$193.13
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	5,000 iu in 0.5ml	Eprex	6	$243.26
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	6,000 iu in 0.6ml	Eprex	6	$291.92
Erythropoietin ~~alpha~~**alfa**	Prefilled syringe	10,000 iu in 1ml	Eprex	6	$395.18

- Eprex would be subject to a confidential rebate.

- There would be a 6-month transition period between 1 September 2014 and 28 February 2015 where both erythropoietin alfa (Eprex) and Roche's brand of erythropoietin beta (NeoRecormon) would both be listed, fully funded, on the Pharmaceutical Schedule.

- Eprex would be awarded Sole Subsidised Supply Status (the only funded brand of erythropoietin in the community) and Hospital Supply Status (the only available brand of erythropoietin in DHB hospitals, subject to a 5% DV limit) from 1 March 2015 to 28 February 2018.

- The NeoRecormon brand of erythropoietin beta would be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule from 1 March 2015.

- A note would be added to the listing of Eprex (erythropoietin alfa) in Part II of Section H to make it clear that other types of erythropoietin could be used by hospitals as a DV pharmaceutical.

- Funded access to erythropoietin would be widened from 1 September 2014 and the access criteria would be amended in Section B and Part II of Section H as follows (additions in bold, deletions in strikethrough):

Section B

Initial application – (chronic renal failure) from ~~a relevant~~ any 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 ≤ 100 g/L; and
2. Any of the following:
   2.1 Both:
      2.1.1 patient is not diabetic; and
      2.1.2 glomerular filtration rate ≤ 30 ml/min; or
   2.2 Both:
      2.2.1 patient is diabetic; and
      2.2.2 glomerular filtration rate ≤ 45 ml/min; or
   2.3 patient is on haemodialysis or peritoneal dialysis.

Note
Erythropoietin ~~beta/alpha~~**alfa** is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.
The Cockroft-Gault Formula may be used to estimate glomerular filtration rate (GFR) in persons 18 years and over:
GFR (ml/min) (male) = (140 - age) x Ideal Body Weight (kg) / 814 x serum creatinine (mmol/l)
GFR (ml/min) (female) = Estimated GFR (male) x 0.85

Initial application – (myelodysplasia) from any Specialist. Approvals valid for 2 months for applications meeting the following criteria:
All of the following:
1. Patient has a confirmed diagnosis of myelodysplasia (MDS);
2. Has had symptomatic anaemia with haemoglobin <100g/L and is red cell transfusion-dependent*;
3. Patient has very low or low risk MDS based on the WHO classification based prognostic scoring system for myelodysplastic syndrome (WPSS);
4. Other causes of anaemia such as B12 and folate deficiency have been excluded;
5. Patient has a serum erythropoietin level of <500 IU/mL; and
6. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

***Transfusion dependence is defined as a transfusion requirement of at least 4 units of red cells per month over a period of 4 months.**

Renewal – (chronic renal failure) from ~~a relevant~~ any Specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note
Erythropoietin ~~beta/alpha~~**alfa** is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.
The Cockroft-Gault Formula may be used to estimate glomerular filtration rate (GFR) in persons 18 years and over:
GFR (ml/min) (male) = (140 - age) x Ideal Body Weight (kg) / 814 x serum creatinine (mmol/l)

GFR (ml/min) (female) = Estimated GFR (male) x 0.85

Renewal application – (myelodysplasia) from any Specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. The patient's transfusion requirement continues to be reduced with erythropoietin treatment;
2. Transformation to acute myeloid leukaemia has not occurred; and
3. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

Part II of Section H

Restricted (chronic renal failure)
Both:
1 Both:
- 1.1 Patient in chronic renal failure; and
- 1.2 Haemoglobin ≤ 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 ≤ 30ml/min; or
- 2.2 Both:
  - 2.2.1 Patient is diabetic; and
  - 2.2.2 Glomerular filtration rate ≤ 45ml/min; or
- 2.3 Patient is on haemodialysis or peritoneal dialysis.

Initiation (myelodysplasia)
Re-assessment required after 2 months
All of the following:
1. Patient has a confirmed diagnosis of myelodysplasia (MDS);
2. Has had symptomatic anaemia with haemoglobin <100g/L and is red cell transfusion-dependent*;
3. Patient has very low or low risk MDS based on the WHO classification based prognostic scoring system for myelodysplastic syndrome (WPSS);
4. Other causes of anaemia such as B12 and folate deficiency have been excluded;
5. Patient has a serum erythropoietin level of <500 IU/mL; and
6. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

***Transfusion dependence is defined as a transfusion requirement of at least 4 units of red cells per month over a period of 4 months.**

Continuation (myelodysplasia)
Re-assessment required after 12 months
All of the following:
1. The patient's transfusion requirement continues to be reduced with erythropoietin treatment;
2. Transformation to acute myeloid leukaemia has not occurred; and
3. The minimum necessary dose of erythropoietin would be used and will not exceed 80,000 iu per week.

Restricted (all other indications)
Haematologist

For use in patients where blood transfusion is not a viable treatment alternative.

- A Brand Switch Fee would apply to dispensings of Eprex from 1 March 2015 until 31 May 2015.

Proposed transition timelines

- If the proposal is accepted, the proposed implementation process and timelines would be as follows:

    - **1 September 2014** – Funded access to erythropoietin would be widened to include patients with myelodysplasia (in hospitals and in the community) and patients for whom blood transfusion is not a viable treatment alternative (in hospitals only).

    - **1 September 2014 to 28 February 2015** – Eprex (erythropoietin alfa) and NeoRecormon (erythropoietin beta) would remain listed in both Part II of Section H and Section B fully funded. During this 6-month period patients who had been receiving funded NeoRecormon would need to be transitioned to the Eprex brand of erythropoietin in order to remain on a fully funded brand from 1 March 2015.

      Whilst erythropoietin alfa and beta are considered therapeutically equivalent, the two medicines are not generically substitutable, so the transition to erythropoietin alfa would need to be managed by the prescribing clinician.

    - **1 March 2015** – NeoRecormon would be delisted from Section B, and Part II of Section H, of the Pharmaceutical Schedule.

    - **1 March 2015 to 28 February 2018** – Eprex would be the sole subsidised brand of erythropoietin in the community and the only available brand in DHB hospitals, subject to a 5% DV limit.

      A note would be added to the listing of Eprex (erythropoietin alfa) in Part II of Section H to make it clear that other types of erythropoietin could be used by hospitals as a DV pharmaceutical.

      Other types of erythropoietin would only be funded in the community from 1 March 2015 to 28 February 2018 if funding was approved in accordance with PHARMAC's Named Patient Pharmaceutical Assessment (NPPA) Policy.

Background

Erythropoietin is used to help increase the production of red blood cells in the body. In New ealand, there are currently two types of erythropoietin funded, erythropoietin alfa (Eprex) and erythropoietin beta (NeoRecormon). There are minor differences in the chemical structure of erythropoietin alfa and beta but they have the same physiological effect on the body. PHARMAC has received clinical advice from nephrologists and haematologists that erythropoietin alfa and beta can be considered therapeutically equivalent and that it would be reasonable to enter into a sole supply arrangement for one type of erythropoietin. The advice received also indicates that the two types of erythropoietin can be considered dose equivalent.

PHARMAC ran a Request for Proposals (RFP) process for the sole supply of erythropoietin in hospitals and community in February 2014. Janssen-Cilag's proposal for its brand of

erythropoietin (Eprex) is the preferred bid received in the RFP. Eprex has been used and funded in New ealand for more than 20 years.

Following reviews at its meetings in August 2012, November 2012 and February 2013, PHARMAC's clinical advisory committee, the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended that funded access to erythropoietin should be widened to include patients with myelodysplasia with a low priority. The minutes for those reviews can be found on our website:

- http://www.pharmac.health.nz/assets/ptac-minutes-2012-08.pdf
- http://www.pharmac.health.nz/assets/ptac-minutes-2012-11.pdf
- http://www.pharmac.health.nz/assets/ptac-minutes-2013-05-01.pdf

This proposal would result in sufficient savings to District Health Boards to enable PHARMAC to widen access to the treatment to include patients with myelodysplasia (in hospitals and in the community) and patients for whom blood transfusion is not a viable treatment alternative (in hospitals only). As with all medicines, PHARMAC is able to consider funding an alternative type of erythropoietin for patients in the community for whom Eprex is not appropriate for clinical reasons and this would be done in accordance with PHARMAC's NPPA Policy.

If this proposal is approved, PHARMAC will work with clinicians to manage the change in types of funded erythropoietin, including producing general guidelines and information for clinicians, pharmacists and patients.