

6.09 EPOETIN LAMBDA

Injection 1,000 units in 0.5 mL pre-filled syringe

Injection 2,000 units in 1 mL pre-filled syringe

Injection 3,000 units in 0.3 mL pre-filled syringe

Injection 4,000 units in 0.4 mL pre-filled syringe

Injection 5,000 units in 0.5 mL pre-filled syringe

Injection 6,000 units in 0.6 mL pre-filled syringe

Injection 8,000 units in 0.8 mL pre-filled syringe

Injection 10,000 units in 1 mL pre-filled syringe,

Novicrit[®], Sandoz Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested an amendment of the existing restriction of epoetin lambda to remove the note 'Epoetin lambda should only be administered by the intravenous route' to allow for subcutaneous administration for the treatment of anaemia associated with intrinsic renal disease.

2 Requested listing

- 2.1 The submission requested the removal of the note section under the existing listing. No other changes to the current listing were requested.

3 Background

- 3.1 Epoetin lambda was TGA registered for subcutaneous administration for the treatment of patients with symptomatic or transfusion requiring anaemia associated with chronic renal failure during correction and maintenance therapy phases in March 2017. Prior to this, epoetin lambda was TGA registered for intravenous administration only.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

4.2 The PBAC noted that no consumer comments were received for this item.

Economic analysis

4.3 As a minor submission requesting a restriction change, an economic comparison was not relevant.

Estimated PBS usage & financial implications

4.4 The minor submission estimated there to be no financial implications to the PBS as all erythropoiesis stimulating agents have been listed on the PBS on a cost-minimisation basis compared to epoetin alpha, on a unit per unit basis, and no pricing change was requested.

4.5 The PBAC recalled that epoetin lambda was recommended for listing by the PBAC at a price that was 10% lower than the PBS prices of the other erythropoiesis stimulating agents at that time (i.e. epoetin alpha, and epoetin beta, darbepoetin and methoxypolyethylene glycol-epoetin beta). In recommending the listing the PBAC advised the Minister and the then Pricing Authority, that it was appropriate to apply the same price reduction offered in the submission to the other PBS-listed erythropoiesis stimulating agents, including epoetin-alfa, epoetin beta, darbepoetin and methoxypolyethylene glycol-epoetin beta, all of which were recommended for listing on a cost-minimisation basis with epoetin alfa. The Department advised that the restriction on the use of epoetin lambda to the intravenous route had meant that only 50% of the 10% price reduction was able to be flowed on to these other agents, reflecting the likely split between intravenous and subcutaneous use.

4.6 The PBAC advised that it considered that it would be appropriate for the Minister to seek to align the prices of epoetin-alfa, epoetin beta, darbepoetin and methoxypolyethylene glycol-epoetin beta with that of epoetin lambda, through reducing the prices of the first four drugs by 5% consistent with the price reduction that was not flowed on at the time epoetin lambda was listed.

5 PBAC Outcome

- 5.1 The PBAC recommended the amendment of the existing restriction of epoetin lambda to remove the note 'Epoetin lambda should only be administered by the intravenous route' to allow for subcutaneous administration for the treatment of anaemia associated with intrinsic renal disease.
- 5.2 The PBAC recalled that the note was previously based on information in the TGA approved Product Information, at the time of listing, which has since been updated to indicate that epoetin lambda can be administered subcutaneously where intravenous access is not readily available.
- 5.3 The PBAC previously advised that epoetin lambda should not be treated as interchangeable with other PBS-subsidised erythropoiesis stimulating agents (i.e. epoetin alpha, epoetin beta, darbepoetin and methoxypolyethylene glycol-epoetin beta) at the July 2010 PBAC meeting, because epoetin lambda could only be administered intravenously (Public Summary Document (PSD), July 2010). With the recommended amendment to the restriction, the PBAC advised that under s101 (3BA) of the *National Health Act, 1953* that epoetin lambda should be treated as interchangeable with all other PBS-subsidised erythropoiesis stimulating agents on an individual patient basis.
- 5.4 The PBAC noted that the amendment to the restriction wording would have flow on pricing implications for the other erythropoiesis stimulating medicines listed on the PBS.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

Delete NOTE:

Epoetin lambda should only be administered by the intravenous route

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.

8 Sponsor's Comment

The sponsor had no comment.