

Recommendations and Reasons

Committee to Evaluate Drugs (CED)

Epoetin alfa – additional dosage forms

Product:

EPOETIN ALFA (Eprex®)
20,000IU/0.5mL, 30,000IU/0.75mL
prefilled syringes (additional dosage
forms)

Class of drugs:

Erythropoiesis-stimulating agents

Indication:

Treatment of anemia

Manufacturer:

Janssen-Ortho Inc.

CED Recommendation

The CED recommended that epoetin alfa (Eprex) 20,000IU prefilled syringe be funded on the basis that this product will facilitate dosing in the treatment of anemia associated with cancer.

The CED recommended that epoetin alfa (Eprex) 30,000IU prefilled syringe not be funded on the basis that it is priced the same as the 40,000IU prefilled syringe.

Based on the CED's recommendation,

Executive Officer Decision

the Executive Officer decided to fund epoetin alfa (Eprex) 20,000IU prefilled syringe and not fund the 30,000IU prefilled syringe.

Status

Funding for epoetin alfa (Eprex) 20,000IU prefilled syringe is available as a General Benefit on the Ontario Drug Benefit Formulary for the treatment of chemotherapy-induced anemia. Funding for various other indications is also considered through the Exceptional Access Program.

Funding for epoetin alfa (Eprex) 30,000IU prefilled syringe is not available.

Highlights of Recommendation:

- ◆ Epoetin alfa (Eprex) is a synthetic protein used to increase red blood cell production and to decrease the need for red blood cell transfusions.
- ◆ Epoetin alfa (Eprex) 10,000IU prefilled syringe, 40,000IU prefilled syringe and 20,000IU vial are already listed on the Ontario Drug Benefit Formulary for the treatment of anemia caused by chemotherapy. Various dosage forms of this product are also available through the Special Drugs Program for patients with end-stage renal disease and through the Exceptional Access Program for a variety of indications. This review considered the funding of two additional dosage formats of epoetin alfa (Eprex): 20,000IU and 30,000IU prefilled syringes.
- ◆ The 20,000IU and 30,000IU prefilled syringes are identical in formulation to the existing 40,000IU/mL prefilled syringe, with the only difference being the fill volumes.
- ◆ In the treatment of anemia caused by chemotherapy, epoetin alfa (Eprex) is typically dosed at 40,000IU weekly, with an increase to 60,000IU weekly if the patient does not achieve an adequate response. The target hemoglobin is 120g/L. (A target hemoglobin level of greater than 120g/L has been associated with increased risk of death and serious cardiovascular adverse event.) Treatment is stopped if the target hemoglobin level is exceeded, and treatment may be restarted at a dose of 20,000IU weekly. As such, the Committee agreed that the 20,000IU prefilled syringe would facilitate dosing in this clinical setting. The Committee could not identify a therapeutic need for the 30,000IU prefilled syringe. Furthermore, if 30,000IU of epoetin alfa (Eprex) is required, the appropriate volume could be withdrawn from the vials.
- ◆ In the treatment of patients with end-stage renal disease, epoetin alfa (Eprex) is typically dosed according to body weight at a dosage of 150IU/kg three times weekly. Hospitals and clinics treating these patients typically use epoetin alfa (Eprex) multi-dose vials rather than prefilled syringes.
- ◆ The 20,000IU prefilled syringe costs \$267.90. This is the same price as the currently listed 20,000IU vial.

- ◆ The 30,000IU prefilled syringe costs \$401.85, which is the same as the currently listed 40,000IU prefilled syringe. This makes the 30,000IU prefilled syringe more expensive on a per unit basis.
- ◆ **Overall, the Committee noted that epoetin alfa (Eprex) 20,000IU prefilled syringe facilitates dosing in the cancer setting and funding this additional dosage form will likely be cost-neutral to the Ministry. On the other hand, the 30,000IU prefilled syringe is proportionately more expensive than the 40,000IU prefilled syringe and options are available for patients requiring the 30,000IU dose.**

Background:

Erythropoietin is produced naturally in the body, mostly by the kidneys. It signals the bone marrow to produce red blood cells, which carry oxygen in the blood. If the body does not produce enough erythropoietin, anemia can occur.

Epoetin alfa (Eprex) is synthetic erythropoietin and belong to a family of treatments called erythropoiesis-stimulating agents. It can be used in patients who do not make enough erythropoietin because their kidneys are not working properly, or to increase red blood cell production in certain patients scheduled for surgery. It has also been used to treat anemia caused by certain drug therapies, such as chemotherapy and drugs used to treat chronic viral hepatitis.

Erythropoiesis-stimulating agents have been associated with increased risks of death and cardiovascular complications (such as stroke and heart attack) in patients with cancer and kidney failure when treated with a target hemoglobin level that is greater than 120g/L. For this reason, it is advised that the dose of erythropoiesis-stimulating agents be titrated to gradually increase the hemoglobin concentration to the lowest level sufficient to avoid blood transfusions. (For details, see: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2007/aranesp_eprex_hpc-cps-eng.php)

continued...

Detailed Discussion:

No additional details. The full CED discussion is as outlined in the Highlights of Recommendation section.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review epoetin alfa (Eprex) 20,000IU/0.5mL and 30,000IU/0.75mL prefilled syringes.



Ministry of
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