

Insulin Porcine

Product:

INSULIN ISOPHANE PORCINE (Hypurin® NPH) 100IU/mL injection vial; INSULIN PORCINE (Hypurin® Regular) 100IU/mL injection vial

Class of drugs:

Insulin

Indication:

Treatment of diabetes

Manufacturer:

Wockhardt UK Ltd.

CED Recommendation

The CED recommended that insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) not be listed on the Ontario Drug Benefit Formulary, on the basis that there is no clinical evidence these products offer improved efficacy or tolerability over recombinant human insulins.

Executive Officer Decision

Based on the CED's review and recommendation, the Executive Officer decided not to list insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) on the Ontario Drug Benefit Formulary. However, taking into consideration that there are no other treatment options for patients with a definite documented allergy to recombinant human insulin, funding would be considered on a compassionate basis through the Exceptional Access Program (EAP) for these patients.

Status

Funding available through the Ontario Public Drug Programs via the Exceptional Access Program.

Highlights of Recommendation:

- ◆ Insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) are animal sourced insulins, derived from pigs.
- ◆ There are no clinical trial data on insulin isophane porcine (Hypurin NPH) or insulin porcine (Hypurin Regular). However, these insulin products have been used in the United Kingdom for almost ten years without concerns of unexpected serious adverse effects.
- ◆ The use of animal derived insulin has been largely replaced by human recombinant insulins. Nevertheless, there may be a very small percentage of patients who cannot tolerate recombinant human insulin due to allergies or hypoglycemic reactions. Unfortunately, there are no data from clinical studies that insulin isophane porcine (Hypurin NPH) or insulin porcine (Hypurin Regular) improves tolerability or the glycemia profile in these patients.
- ◆ Insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) cost \$88 per vial. Human recombinant insulins cost less than \$20 per vial.
- ◆ **Overall, the Committee found no clinical evidence that insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) provide improved efficacy or tolerability over recombinant human insulins.**

Background:

Diabetes occurs when the body does not produce enough insulin, or does not use its own insulin properly to regulate levels of sugar in the blood. Normally, when the body digests food, a sugar called glucose enters the bloodstream as a fuel source. Insulin, which is produced by the pancreas, moves glucose from the bloodstream into cells thus maintaining blood glucose levels in a narrow range.

A lack of insulin or resistance to its effect leads to the development of diabetes mellitus, manifested as high blood glucose levels and weight loss due to an inability to drive glucose into cells where it is used as an energy source.

Long-term consequences of untreated or poorly treated diabetes are accelerated atherosclerosis causing heart attacks, strokes and peripheral vascular disease, kidney failure, blindness, neuropathy, limb loss from infections and early death.

Treatment for diabetes always begins with and includes a healthy diet and an exercise plan. Many people with diabetes need to take injections of insulin. Insulin products available in Canada are biologically engineered to be identical to human insulin (i.e. recombinant human insulin). Most patients now use recombinant human insulin products.

Iletin Pork Insulin was previously available in Canada, until the manufacturer discontinued production because of a lack of demand. Subsequent to the discontinuation of Iletin Pork Insulin, the manufacturer of Hypurin marketed its products in Canada.

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Detailed Discussion:

- ◆ There are no product specific clinical studies for insulin isophane porcine (Hypurin NPH) or insulin porcine (Hypurin Regular).
- ◆ Furthermore, there are no data from clinical trials to support the use of insulin isophane porcine (Hypurin NPH) or insulin porcine (Hypurin Regular) in patients who have allergic or hypoglycemic reactions to recombinant human insulin.
- ◆ Two small case studies reported that patients on animal sourced insulins were more aware of the occurrence of hypoglycemia. These findings have not been confirmed by clinical trials.
- ◆ Insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) cost \$88 per vial, about five times more expensive than the pork insulin that was previously available in Canada. Recombinant human insulins cost less than \$20 per vial.
- ◆ The Committee could not determine value-for-money of the product, as the manufacturer did not submit a formal pharmacoeconomic analysis for evaluation.
- ◆ Overall, the Committee found no clinical evidence that insulin isophane porcine (Hypurin NPH) and insulin porcine (Hypurin Regular) provide improved efficacy or tolerability over recombinant human insulins.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee (CEDAC) did not review insulin isophane porcine (Hypurin NPH) or insulin porcine (Hypurin Regular).



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