Insulin glargine – access widened from 1 August 2010

The Special Authority restriction for insulin glargine (Lantus brand only), a long-acting, once daily preparation, was removed on August 1 2010. Insulin glargine has been available in New Zealand under Special Authority since 2006 for use in people with Type 1 diabetes. Removal of the Special Authority restriction will widen access to this medicine for people with either Type 1 or Type 2 diabetes.

Access has initially been targeted to patients meeting at least one of the following criteria:

- Type 1 diabetes
- Other conditions related to diabetes e.g. cystic fibrosis, diabetes in pregnancy, pancreatectomy
- Type 2 diabetes after there has been unacceptable hypoglycaemic events with a three month trial of an insulin regimen
- Type 2 diabetes requiring insulin therapy with assistance from a carer or healthcare professional to administer injections

Full access for all people with Type 1 and 2 diabetes is planned in the future. If there are no changes to the datasheet over the next 18 months i.e. the indications are not limited and there are no additional warnings, precautions or contraindications, then the above criteria will be removed from February 1 2012.[1]

Glargine has a once daily basal action

Insulin glargine is a long-acting human insulin analogue which is given as a once daily, subcutaneous injection. It provides a smooth and peak-less profile of insulin release over 24 hours which aims to mimic the natural basal secretion of insulin from the pancreas. Insulin glargine given alone does not adequately cover the increase in glucose after meals.[2,3] People with Type 1 diabetes therefore usually require boluses of short-acting insulin at meals. People with Type 2 diabetes may also require oral hypoglycaemic agents or short-acting insulins.

The place of insulin glargine in treatment is to provide the basal component of an insulin regimen for people with type 1 diabetes and to supplement endogenous basal insulin in people with type 2 diabetes.[2]

Efficacy of insulin glargine

Two recent reviews have found no significant difference in HbA_{1c} levels in patients with type 2 diabetes using insulin glargine compared to patients using neutral protamine Hagedorn (NPH) insulin, the basal insulin used in many regimens.[4,5]

There is some evidence that patients with type 1 diabetes who use insulin glargine may have slightly lower fasting blood glucose levels, however, the majority of review articles conclude that HbA_{1c} levels tend to be similar to those found in patients using NPH insulins.[6,7]

Advantages of insulin glargine

Insulin glargine does not necessarily help patients achieve better glycaemic control than other insulins however there may be advantages for some patients. The two major advantages of insulin glargine are the:

- Convenience of once daily dosing which may provide a practical solution in certain patients e.g. those who require a caregiver for injections. Safety and efficacy do not differ with the timing of administration.[7]

- Lower rates of hypoglycaemia because of the smooth and peak-less release of insulin over 24 hours. Hypoglycaemia may still occur with insulin glargine but the evidence is that the overall rates of hypoglycaemia (including nocturnal hypoglycaemia) are lower.[2,4]

Safety issues with insulin glargine

Recent epidemiological studies have identified a potential association between the use of insulin glargine in people with type 2 diabetes and an increased risk of cancer. There is no evidence that there is a similar association in people with type 1 diabetes.[8] Medsafe and the Medicines Adverse Reactions Committee (MARC) reviewed the safety profile of insulin glargine and concluded that there is no conclusive evidence of an increased risk.[9] Further research is underway in an attempt to address this controversy.

Practice points[7]

- Insulin glargine is a clear solution. It should not be confused with clear, short-acting insulins and it should not be diluted or mixed with other insulins. This may mean patients require an additional injection compared to other regimens.
- For patients who have not previously used insulin, 10 IU is usually an appropriate starting dose although this dose should be adjusted individually.
- Patients who have previously been on a once daily insulin regimen may be switched to the same unit dose of insulin glargine. It is suggested that those on twice daily regimens have their initial dose reduced by approximately 20% and then the dose titrated to response.
- There is no difference in efficacy between the injection sites (abdomen, thigh or deltoid). Injection sites should be rotated as with all types of insulin.
- There may be an increased incidence of discomfort at injection sites with insulin glargine. This is presumed to be related to the acidic nature of the solution. The discomfort is usually reported as mild and not sufficient to result in the patient stopping treatment.

References:

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Changes to ezetimibe (Ezetrol) and ezetimibe/simvastatin (Vytorin) prescribing

From October 1 2010 access to ezetimibe (Ezetrol) and ezetimibe/simvastatin (Vytorin) has changed so that initial Special Authority applications and renewals will now be able to be received from any relevant practitioner (including general practitioners). Special Authority approvals will be valid for two years for initial applications meeting certain criteria as follows:

Ezetrol

Patients who have a calculated absolute risk of cardiovascular disease of at least 15% over five years, a LDL cholesterol ≥2.0 mmol/L and ANY one of the following:

- Rhabdomyolysis when treated with one statin
- Intolerance to both simvastatin and atorvastatin
- LDL cholesterol not reduced <2.0 mmol/L with the use of the maximal, tolerated dose of atorvastatin

Vytorin

Patients must have ALL of the following:

- A calculated absolute risk of cardiovascular disease of at least 15% over five years
- LDL cholesterol ≥2 mmol/L
- LDL cholesterol has not reduced <2.0 mmol/L with the use of maximal, tolerated dose of atorvastatin