Insulin glargine (Basaglar™) Abbreviated New Drug Update (ANDU)

January 2016

OVERVIEW¹

- Insulin glargine (Basaglar) is a long-acting insulin indicated to improve glycemic control in adults and pediatrics with T1DM and adults with T2DM. It should not be used to treat diabetic ketoacidosis.
- It is the first insulin product approved through an abbreviated approval pathway and is regarded by the FDA as a follow-on agent to Lantus.
- Dosage and Administration:
  - Administer subcutaneously (SC) once daily at any time of day, but at the same time every day, according to patient’s individualized need.
  - In patients with type 1 diabetes, use in combination with short-acting insulin.
  - If switching therapy from another insulin glargine 100 units/mL (Lantus®), continue with the same dose for Basaglar. If switching from once-daily insulin glargine 300 units/mL (Toujeo®) or twice-daily NPH insulin, the initial daily dose for Basaglar is 80% of the glargine 300 units/mL or NPH daily dose.
- Availability: 100 unit/mL in a 3 mL KwikPen®
- Contraindications: should not be used during episodes of hypoglycemia or in patients with hypersensitivity to insulin glargine or other components of the product
- Warnings:
  - May cause hypoglycemia, which can be life-threatening; monitor blood glucose when changes to insulin dose, physical activity, or meal pattern occur; hypokalemia may occur so monitor patients at risk; fluid retention and heart failure can occur with concomitant use of a thiazolidinedione (TZD); rotate injection site; do not mix insulin glargine with other insulins or solutions; do not share the KwikPen with other patients even if the needle is changed; as with any insulin, the potential for the development of anti-drug antibodies (ADA) exists; in clinical trials there was no evidence that ADAs affected efficacy or safety.
  - Pregnancy category C
- Adverse Reactions: hypoglycemia, allergic reactions, injection site reactions, lipodystrophy at injection site, edema, and weight gain.
- Drug Interactions:
  - Drugs that affect glucose metabolism
  - Anti-adrenergic drugs may mask the signs and symptoms of hypoglycemia, they include beta-blockers, clonidine, guanethidine, and reserpine.
CLINICAL CONSIDERATIONS

- Most long-acting insulins have an onset of action of about 60 minutes, except for insulin glargine 300 units/mL (Toujeo®), which develops over 6 hours.
- Duration of action of insulin glargine U-100 and insulin detemir is about 24 hours; duration of action for insulin glargine 300 units/mL (Toujeo) is up to 36 hours and that for degludec has been reported beyond 42 hours.
- According to the American Diabetes Association (ADA), most patients with T1DM should be treated with a multiple-dose insulin regimen or continuous SC insulin therapy. For patients with T2DM, insulin is recommended as add-on to an oral antidiabetic agent when an oral agent alone does not provide adequate glycemic control. Insulin therapy may be considered from the onset with or without other agents, in newly diagnosed T2DM patients with markedly symptomatic and/or elevated blood glucose levels or HbA1c. In addition, many patients with T2DM may ultimately require insulin therapy.
- Basaglar was approved through an abbreviated approval pathway under a 505(b)(2) application that relies mostly on Lantus data for safety and efficacy. It has an identical amino acid sequence to Lantus. Basaglar is not classified as a biosimilar; rather, it is a follow-on product offering another long-acting insulin. Lilly plans a December 2016 launch.

SUGGESTED UTILIZATION MANAGEMENT

<table>
<thead>
<tr>
<th>Anticipated Therapeutic Class Review (TCR) Placement</th>
<th>Hypoglycemics, Insulins</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Edit</strong></td>
<td>Prior authorization will be required if product is determined to be non-preferred</td>
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<tr>
<td></td>
<td>Approve for adult patients; approval for pediatric patients (type 1 diabetes mellitus only)</td>
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<tr>
<td><strong>Quantity Limit</strong></td>
<td>No</td>
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<tr>
<td><strong>Duration of Approval</strong></td>
<td>No</td>
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<tr>
<td><strong>Drug to Disease Hard Edit</strong></td>
<td>Hypoglycemia</td>
</tr>
</tbody>
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REFERENCES

1 Basaglar [package insert]. Indianapolis, IN: Lilly; December 2015.