Long-Acting Insulins
Medicaid Medical Policy

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Presentation Objectives

- To provide **background information** relevant to long-acting insulins
- To present the proposed **Medicaid medical policy** for **long-acting insulins**
Background Information

Lantus (insulin glargine)

FDA-approved Uses: (FDA Approval Date: April 20, 2000)

Lantus® is a long-acting human insulin analog indicated to improve glycemic control in adults and children with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.¹

Use in Specific Populations:¹

Pediatric: Has not been studied in children with type 2 diabetes. Has not been studied in children with type 1 diabetes <6 years of age.

Pregnancy: Category C. Use during pregnancy only if the potential benefit justifies the potential risk to fetus.
**Basaglar (insulin glargine)**

FDA-approved Uses: (FDA Approval Date: Dec 16, 2015)

Basaglar® is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.5

- Expected market entry on December 15, 2016
- Will not be AB rated with Lantus
- Hatch-Waxman exclusivity will be granted but duration of exclusivity is unknown

5.) Basaglar (insulin glargine) [prescribing information]. Indianapolis, IN: Lilly USA; December 2015.

**Levemir (insulin detemir)**

FDA-approved Uses: (FDA Approval Date: June 16, 2005)

Levemir® is a long-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.2

Use in Specific Populations:2

Pediatric: Has not been studied in children with type 2 diabetes. Has not been studied in children with type 1 diabetes <2 years of age.

Pregnancy: Category B.
**Toujeo (insulin glargine)**

FDA-approved Uses: (FDA Approval Date: Feb 25, 2015)

Toujeo® is a long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.³

Use in Specific Populations:³

**Pediatric:** The safety and effectiveness of Toujeo have not been established in pediatric patients.

**Pregnancy:** Use during pregnancy only if the potential benefit justifies the potential risk to fetus

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3.) Toujeo (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2015.

**Tresiba (insulin degludec)**

FDA-approved Uses: (FDA Approval Date: Sept 25, 2015)

Tresiba® is a long-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus.⁴

Use in Specific Populations:⁴

**Pediatric:** The safety and efficacy of Tresiba in children and adolescents under the age of 18 have not been established.

**Pregnancy:** Category C. Use during pregnancy only if the potential benefit justifies the potential risk to fetus

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4.) Tresiba (insulin degludec) [prescribing information]. Princeton, NJ: Novo Nordisk; September 2015.
Background: Disease States

- Type 1 Diabetes Mellitus (T1DM)
- Type 2 Diabetes Mellitus (T2DM)
- Gestational Diabetes Mellitus (GDM)

Background: Diabetes Mellitus

- ADA diagnostic criteria for diabetes mellitus is defined by at least 1 of the following:
  - fasting plasma glucose $\geq 126$mg/dL on more than one occasion
  - random plasma glucose $\geq 200$mg/dL in patients with classic symptoms of hyperglycemia
  - plasma glucose $\geq 200$mg/dL measured 2 hours after an oral glucose tolerance test (OGTT)
  - glycated hemoglobin A1C $\geq 6.5\%$; AND
- patient has no other characteristics that could potentially cause hyperglycemia or diabetes, such as acute or critical illness, medications, or neonatal hyperglycemia; AND
- patient has no other diseases of the exocrine system, endocrine system, or genetic conditions (monogenic diabetes or maturity onset diabetes of the young (MODY))
Differentiating Type 1 from Type 2 diabetes mellitus

**Type 1**
- typically occurs earlier in life
- usually underweight and have recent weight loss
- have low fasting insulin levels
- may have antibodies against glutamic acid decarboxylase (GAD65), the 40K fragment of tyrosine phosphatase (IA2), insulin, and/or zinc transporter 8 (ZnT8)

**Type 2**
- often occurs later in life
- Usually overweight/obese
- Often have other signs of insulin resistance such as acanthosis nigricans
- High fasting insulin and C-peptide levels

Medicaid Medical Policy: Gestational Diabetes Mellitus

ADA outlines the diagnostic criteria for gestational diabetes mellitus as:

1. Patient is pregnant and in the second or third trimester; **AND**

2. Patient has diagnosis of gestational diabetes mellitus (after ruling out Type 1 and Type 2) as defined by at least 1 of the following:
   a. the one-step strategy, using a 75g OGTT:
      i. fasting plasma glucose ≥92mg/dL on one occasion
      ii. plasma glucose ≥180mg/dL measured 1 hour after an OGTT
      iii. plasma glucose ≥153mg/dL measured 2 hours after an OGTT
   b. the two-step strategy (after failing a 50g GLT), using a 100g OGTT:
      i. fasting plasma glucose ≥95mg/dL on one occasion (or ≥105mg/dL)^7
      ii. plasma glucose ≥180mg/dL measured 1 hour after an OGTT (or ≥190mg/dL)^7
      iii. plasma glucose ≥155mg/dL measured 2 hours after an OGTT (or ≥165mg/dL)^7
      iv. plasma glucose ≥140mg/dL measured 3 hours after an OGTT (or ≥145mg/dL)^7

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Background: Estimated Medicaid Population at Risk

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Estimated Prevalence (n)⁸⁻¹⁰</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 DM</td>
<td>~8,000</td>
</tr>
<tr>
<td>Type 2 DM</td>
<td>~150,000</td>
</tr>
<tr>
<td>Diagnosed (known) T2DM</td>
<td>~107,000</td>
</tr>
<tr>
<td>Undiagnosed T2DM</td>
<td>~43,000</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>~486,000</td>
</tr>
<tr>
<td>Gestational DM</td>
<td>~500 to ~2,800 (2-10% of pregnancies¹⁰)</td>
</tr>
<tr>
<td>Total</td>
<td>~160,000</td>
</tr>
</tbody>
</table>

Medicaid Medical Policy:
Type 1 Diabetes Mellitus

Long-Acting Insulins (LAI) may be considered medically necessary for treatment of type 1 diabetes mellitus (T1DM) when the patient meets the diagnostic criteria for type 1 diabetes mellitus. Quantity and dispensing limits are listed on slide 22.

PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS

Patients with type 1 diabetes mellitus may receive long-acting insulin therapy and be approved for the duration of their eligibility.

Approved medications are listed in Table 1 on slide 22. Quantity level limits are listed along with each product.

Medicaid Medical Policy:
Type 2 Diabetes Mellitus

Long-Acting Insulins (LAI) may be considered medically necessary for treatment of type 2 diabetes mellitus (T2DM) when the patient meets criteria 1–2 of the INCLUSION CRITERIA and none of the EXCLUSION CRITERIA. Quantity and dispensing limits are listed on slide 22.

INCLUSION CRITERIA

1. Patient has diagnosis of type 2 diabetes mellitus.⁶

2. Blood glucose is uncontrolled when using other basal insulin regimens, such as combination of NPH insulin with meal-time boluses of fast-acting insulin for at least 3 months. Control is defined as achieving and maintaining stability at patient-specific goal (such as <8% A1C).

Medicaid Medical Policy:
Gestational Diabetes Mellitus

Long-Acting Insulins (LAI) may be considered medically necessary for treatment of gestational diabetes mellitus (GDM) when the patient meets criteria 1–3 of the INCLUSION CRITERIA and none of the EXCLUSION CRITERIA. Quantity and dispensing limits are listed on slide 22.

**INCLUSION CRITERIA**
1. Patient has diagnosis of gestational diabetes mellitus.⁶

2. Glucose is uncontrolled using combination of NPH insulin with meal-time boluses of fast-acting insulin for at least 1 month. Control is defined as maintaining average weekly postprandial reading <120mg/dL¹¹ or average weekly fasting blood glucose <90mg/dL¹¹

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**EXCLUSION CRITERIA**
1. Patient has ANY of the following contraindications:
   a. concurrent use of a product containing a exanatide, liraglutide, or rosiglitazone
   b. Any other contraindications or hypersensitivities to insulin products or one of their excipients¹⁻⁵

**PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS**
Patients meeting the criteria above may receive long-acting insulin therapy and be approved for the duration of their eligibility.

Must use all preferred product before a non-preferred product will be approved.
Medicaid Medical Policy:
Long-Acting Insulin QLLs

Table 1. Quantity Limits for Long-Acting Insulins

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage Form</th>
<th>Strength</th>
<th>QLL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vial</td>
<td>100 units/mL</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td>Lantus</td>
<td>Solostar (autoinjector)</td>
<td>100 units/mL (3 mL per pen)</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td></td>
<td>Vial</td>
<td>100 units/mL</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td>Levenir</td>
<td>Flexpen (autoinjector)</td>
<td>100 units/mL (3 mL per pen)</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td></td>
<td>Flextouch (autoinjector)</td>
<td>100 units/mL (3 mL per pen)</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td></td>
<td>Solostar (autoinjector)</td>
<td>300 units/mL</td>
<td>10 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td>Tresiba</td>
<td>Flextouch (autoinjector)</td>
<td>100 units/mL (3 mL per pen)</td>
<td>30 mL per 30 days (100 units per day)</td>
</tr>
<tr>
<td></td>
<td>Flextouch (autoinjector)</td>
<td>200 units/mL (3 mL per pen)</td>
<td>15 mL per 30 days (100 units per day)</td>
</tr>
</tbody>
</table>

Quantities of long-acting insulin exceeding 100 units per day will only be allowed when an enrollee demonstrates medical necessity.

Questions?
Works Cited

2. Levemir (insulin detemir) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; February 2015.
5. Basaglar (insulin glargine) [prescribing information]. Indianapolis, IN: Lilly USA; December 2015.