

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

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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

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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

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

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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.

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2.) Levemir (insulin detemir) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; February 2015.

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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 ≥ 126 mg/dL on more than one occasion
 - random plasma glucose ≥ 200 mg/dL in patients with classic symptoms of hyperglycemia
 - plasma glucose ≥ 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 ≥ 92 mg/dL on one occasion
 - ii. plasma glucose ≥ 180 mg/dL measured 1 hour after an OGTT
 - iii. plasma glucose ≥ 153 mg/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 ≥ 95 mg/dL on one occasion (or ≥ 105 mg/dL)⁷
 - ii. plasma glucose ≥ 180 mg/dL measured 1 hour after an OGTT (or ≥ 190 mg/dL)⁷
 - iii. plasma glucose ≥ 155 mg/dL measured 2 hours after an OGTT (or ≥ 165 mg/dL)⁷
 - iv. plasma glucose ≥ 140 mg/dL measured 3 hours after an OGTT (or ≥ 145 mg/dL)⁷

6.) American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1): S13–S22

7.) National Diabetes Data Group. Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. Diabetes 1979;28:1039–1057

Background: Estimated Medicaid Population at Risk

Diagnosis	Estimated Prevalence (n) ⁸⁻¹⁰
Type 1 DM	~8,000
Type 2 DM	~150,000
Diagnosed (known) T2DM	~107,000
Undiagnosed T2DM	~43,000
Prediabetes	~486,000
Gestational DM	~500 to ~2,800 (2-10% of pregnancies ¹⁰)
Total	~160,000

8.) Hunt KJ, Schuller KL. The increasing prevalence of diabetes in pregnancy. *Obstet Gynecol Clin North Am.* 2007;34:173-199.

9.) Washington State Department of Health. Health of Washington State: Diabetes. Tumwater, WA. Jul 10 2014.

10.) Centers for Disease Control and Prevention. Diabetes Report Card³2012. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2012.

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Medicaid Medical Policy

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.

6.) American Diabetes Association. Classification and diagnosis of diabetes.¹⁵ Sec. 2. In Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1): S13–S22

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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).

6.) American Diabetes Association. Classification and diagnosis of diabetes.¹⁶ Sec. 2. In Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1): S13–S22

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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

6.) American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In: Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1): S13–S22
11.) Group Health Cooperative. Gestational Diabetes Screening and Treatment Guideline. Oct 2015.

Medicaid Medical Policy:

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

Name	Dosage Form	Strength	QLL
Lantus	Vial	100units/mL	30mL per 30 days (100 units per day)
	Solostar (autoinjector)	100units/mL (3 mL per pen)	30mL per 30 days (100 units per day)
Levemir	Vial	100units/mL	30mL per 30 days (100 units per day)
	Flexpen (autoinjector)	100units/mL (3 mL per pen)	30mL per 30 days (100 units per day)
	Flextouch (autoinjector)	100units/mL (3 mL per pen)	30mL per 30 days (100 units per day)
Toujeo	Solostar (autoinjector)	300units/mL	10mL per 30 days (100 units per day)
Tresiba	Flextouch (autoinjector)	100units/mL (3 mL per pen)	30mL per 30 days (100 units per day)
	Flextouch (autoinjector)	200units/mL (3 mL per pen)	15mL per 30 days (100 units per day)

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

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Questions?

Works Cited

1. Lantus (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; July 2015
2. Levemir (insulin detemir) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; February 2015.
3. Toujeo (insulin glargine) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2015.
4. Tresiba (insulin degludec) [prescribing information]. Princeton, NJ: Novo Nordisk; September 2015.
5. Basaglar (insulin glargine) [prescribing information]. Indianapolis, IN: Lilly USA; December 2015.
6. American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes – 2016. *Diabetes Care* 2016;39(Suppl. 1): S13–S22
7. National Diabetes Data Group. Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. *Diabetes* 1979;28:1039–1057
8. Hunt KJ, Schuller KL. The increasing prevalence of diabetes in pregnancy. *Obstet Gynecol Clin North Am.* 2007;34:173-199.
9. Washington State Department of Health. Health of Washington State: Diabetes. Tumwater, WA. Jul 10 2014.
10. Centers for Disease Control and Prevention. Diabetes Report Card 2012. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2012.
11. Group Health Cooperative. Gestational Diabetes Screening and Treatment Guideline. Oct 2015.