Texas Vendor Drug Program

Drug Use Criteria: Exogenous Insulin Products

Publication History

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Notes: Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage

1.1 Adults

Insulin is a hormone that is typically produced and secreted from pancreatic beta cells in response to elevated blood glucose by binding to receptors found on the liver, skeletal muscle, and adipose tissue cells. Carbohydrate, protein, and fat metabolism are regulated by insulin through suppression of glucose production by the liver, stimulation of tissue glucose uptake, and suppression of free fatty acid release from adipose tissue. Subsequently, blood glucose levels are reduced through insulin's mechanism.[1-4]

However, there is inadequate or no insulin secretion in type 1 diabetes mellitus (DM), and there is insulin deficiency and resistance in type 2 DM. Therefore, type 1 diabetics require insulin treatment to survive; type 2 DM patients may require insulin when other antidiabetic agents are not able to effectively control blood glucose levels. If either type 1 or 2 DM are left untreated and/or uncontrolled, chronic hyperglycemia may lead to micro- and macrovascular complications, such as retinopathy, nephropathy, neuropathy, hypertension, dyslipidemia, and cardiovascular disease.[1,5,6]

Exogenous insulin products are FDA-approved for use in type 1 and 2 DM. These products are used to mimic the physiologic pattern of insulin secretion. Phase 1 is basal insulin secretion, which suppresses hepatic glucose production in order to maintain blood glucose levels throughout the day. Phase 2 is increased insulin secretion in response to carbohydrate intake in order to lower postprandial blood glucose levels. Type 1 diabetics require both basal and preprandial insulin boluses, while type 2 diabetics may require basal and/or preprandial insulin boluses in addition to oral antidiabetic agents, diet, exercise, and weight reduction depending on the severity of their disease and glycemic control.[1-11]

Glycemic targets recommended by the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) 2017 guidelines are summarized in Table 1. However, these targets should be individualized based on patient factors, such as life expectancy, severity of disease, comorbidities, and hypoglycemic risk.[1,6,8-10,12,13]

Table 1. ADA and AACE/ACE 2017 General Glycemic Target Recommendations

Glycemic Targets	ADA – Type 1 and 2	AACE/ACE – Adult Type 2
Hemoglobin A1c	Adults: less than 7% Pediatrics: less than 7.5%	less than or equal to 6.5%
Preprandial blood glucose	Adults: 80–130 mg/dL Pediatrics: 90–130 mg/dL	less than 110 mg/dL
Postprandial blood glucose	Adults: less than 180 mg/dL	less than 140 mg/dL
Bedtime blood glucose	Everyone: 90–150 mg/dL	N/A

Dosage forms, usual dosage regimen, and maximum recommended dosage of exogenous insulin products for adult patients, categorized by time of onset, peak, and duration of action and are summarized in Tables 2-4.

Table 2. Adult Insulin Recommended Dosages for Single Insulin Products[2-4,14-27]

Type	Drug Name	Dosage Form	Usual Dosage Regimen	Max. Rcmd. Dosage
Rapid-acting	Insulin aspart	• Fiasp® vial (100 units/mL – 10 mL) • Fiasp® FlexTouch (100 units/mL – 5 x 3 mL) • Fiasp® PenFill® cartridges (100 units/mL – 5 x 3 mL) for FlexTouch® device • NovoLog® vial (100 units/mL – 10 mL) • NovoLog® FlexPen® (100 units/mL – 5 x 3 mL) • NovoLog® PenFill® cartridges (100 units/mL – 5 x 3 mL) for NovoPen Echo® device	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Rapid-acting	Insulin glulisine	Apidra® vial (100 units/mL – 10 mL) Apidra® SoloStar® pen (100 units/mL – 5 x 3 mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.

Type	Drug Name	Dosage Form	Usual Dosage Regimen	Max. Rcmd. Dosage
Rapid-acting	Insulin lispro	• Admelog® vial (100 units/mL – 3 or 10 mL) • Admelog® SoloStar® pen (100 units/mL – 3 mL) • HumaLog® cartridges (100 units/mL – 5 x 3 mL) for HumaPen® Luxura™ HD device • HumaLog® vial (100 units/mL – 3 or 10 mL) • HumaLog® KwikPen® (100 units/mL – 3 mL; 200 units/mL – 3 mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Rapid-acting	Inhaled insulin	Afrezza® (4 units, 8 units, 12 units – single-use cartridges)	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Short-acting	Regular insulin	Humulin® R vial (100 units/mL – 10 mL; 500 unit/mL – 20 mL) Humulin® R KwikPen® (500 units/mL – 2 x 3 mL) Novolin® R vial (100 units/mL – 10 units)	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Intermediate-acting	Isophane insulin (NPH)	Humulin® N vial (100 units/mL – 3 or 10 mL) Humulin® N KwikPen® (100 units/mL – 5 x 3 mL) Novolin® N vial (100 units/mL – 10 mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Long-acting	Insulin detemir	Levemir® vial (100 units/mL – 10 mL) Levemir® FlexTouch® pen (100 units/mL – 5 x 3 mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.

Type	Drug Name	Dosage Form	Usual Dosage Regimen	Max. Rcmd. Dosage
Long-acting	Insulin degludec	• Tresiba® vial (100 units/mL – 10 mL) • Tresiba® FlexTouch® pen (100 units/mL – 5 x 3 mL; 200 units/mL – 3 x 3 mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.
Long-acting	Insulin glargine	• Lantus® vial (100 units – 10 mL) • Lantus® SoloStar® pen (100 units/mL – 5 x 3 mL) • Toujeo® SoloStar® pen (300 units/mL – 3 x 1.5 mL) • Toujeo® Max SoloStar® pen (300 units/mL – 2 x 3 mL) • Basaglar® KwikPen® (100 units/mL)	See Table 2 Note #1, below.	See Table 2 Note #2, below.

Table 2 Note #1 for Usual Dosage Regimen

- Multiple or continuous insulin dosing may be required to maintain adequate glycemic control; should be individualized for each patient
- Total daily doses of ALL insulin formulations combined: 0.5 to 1 units/kg/day
- Insulin needs may be affected by body weight; non-obese patients may require less insulin than obese patients
  - Non-obese: 0.4 to 0.6 units/kg/day
  - Obese: 0.8 to 1.2 units/kg/day

Table 2 Note #1 for Maximum Recommended Dosage

- No maximum recommended dosage to exceed; insulin and other antidiabetic drugs should be adjusted to target glycemic goals and meet patients' needs

Table 3. Adult Insulin Recommended Dosages for Insulin Combination Products[2-4,28-35]

Combination Type	Drug Name	Dosage Form	Usual Dosage Regimen	Max. Rcmd. Dosage
Insulin Combinations	Insulin aspart protamine/ insulin aspart	• NovoLog® Mix 70/30 vial (100 units/mL – 10 mL) • NovoLog® Mix 70/30 FlexPen® (100 units/mL – 5 x 3 mL)	See Table 3 Note #1, below.	See Table 3 Note #2, below.
Insulin Combinations	Insulin degludec/ insulin aspart*	• Ryzodeg® 70/30 FlexTouch® (100 units/mL – 5 x 3 mL)*	See Table 3 Note #1, below.	See Table 3 Note #2, below.
Insulin Combinations	Isophane insulin (NPH)/ regular insulin	• Humulin® 70/30 vial (100 units/mL – 3 or 10 mL) • Humulin® 70/30 KwikPen® (100 units/mL – 5 x 3 mL) • Novolin® 70/30 vial (100 units/mL – 10 mL) • Novolin® 70/30 FlexPen (100 units/mL – 5 x 3 mL)	See Table 3 Note #1, below.	See Table 3 Note #2, below.
Insulin Combinations	Insulin lispro protamine/ insulin lispro	HumaLog® Mix 50/50 vial (100 units/mL – 10 units) HumaLog® Mix 50/50 KwikPen® (100 units/mL – 5 x 3 mL) HumaLog® Mix 75/25 vial (100 units/mL – 10 mL) HumaLog® Mix 75/25 KwikPen® (100 units/mL – 5 x 3 mL)	See Table 3 Note #1, below.	See Table 3 Note #2, below.

Combination Type	Drug Name	Dosage Form	Usual Dosage Regimen	Max. Rcmd. Dosage
Insulin/GLP-1 Receptor Agonist Combinations	Insulin glargine/ lixisenatide	Soliqua® 100/33 pen (insulin glargine 100 units/mL and lixisenatide 33 mcg/mL – 5 x 3 mL)@	15 – 60 units/day (15 – 60 units / 5 – 20 mcg)	60 units/day
Insulin/GLP-1 Receptor Agonist Combinations	Insulin degludec/ liraglutide	Xultophy® 100/3.6 pen (insulin degludec 100 units/mL and liraglutide 3.6 mg/mL – 5 x 3 mL)@	16 – 50 units/day (16 – 50 units / 0.58 – 1.8 mg)	50 units/day

- * Approved September 2015; anticipated availability not determined.
- @ Approved November 2016
- GLP-1 = glucagon-like peptide-1

Table 3 Note #1 for Usual Dosage Regimen

- Multiple or continuous insulin dosing may be required to maintain adequate glycemic control. This should be individualized for each patient.
- Total daily doses of ALL insulin formulations combined: 0.5 to 1 units/kg/day
- Insulin needs may be affected by body weight. Nonobese patients may require less insulin than obese patients.
- Nonobese: 0.4 to 0.6 units/kg/day
- Obese: 0.8 to 1.2 units/kg/day

Table 3 Note #2 for Maximum Recommended Dosage

- No maximum recommended dosage to exceed; insulin and other antidiabetic drugs should be adjusted to target glycemic goals and meet patients' needs

Table 4. Adult Insulin Recommended Dosages for Insulin GLP-1 Receptor Agonist Combination Products[8-11,33, 34]

Drug Name	Dosage Form	Usual Dosage Regimen	Maximum Recommended Dosage
Insulin glargine/ lixisenatide	Soliqua® 100/33 pen (insulin glargine 100 units/mL and lixisenatide 33 mcg/mL – 5 x 3 mL)@	15 – 60 units/day (15 – 60 units / 5 – 20 mcg)	60 units/20 mcg/day
Insulin degludec/ liraglutide	Xultophy® 100/3.6 pen (insulin degludec 100 units/mL and liraglutide 3.6 mg/mL – 5 x 3 mL)	10 – 50 units/day (10 – 50 units / 0.36 – 1.8 mg)	50 units/1.8 mg/day

- GLP-1 = glucagon-like peptide-1

1.2 Pediatrics

Safety and efficacy for insulin aspart (Fiasp®), inhaled insulin (Afrezza®), insulin lispro/lispro protamine combinations (HumaLog® Mix 50/50 and 75/25), insulin aspart/insulin aspart protamine combinations (NovoLog® Mix 70/30), and insulin-GLP-1 combinations (Soliqua® 100/33 and Xultophy® 100/3.6) have not been studied or established in pediatric patients.[17,32-34] However, a clinical trial assessing inhaled insulin use in the pediatric population is currently in progress.[35]

Recommended age requirements for insulin products approved in pediatric patients are summarized in Tables 5 and 6. Usual dosage regimens and maximum recommended dosages are similar to adult patients.

Table 5. Pediatric Insulin Age Requirements for Single Insulin Products[2-4,14-16,18-27]

Type	Drug Name	Dosage Form	Approved Age Requirements	Max. Rcmd. Dosage
Rapid-acting	Insulin aspart	NovoLog® vial (100 units/mL – 10 mL) NovoLog® FlexPen® (100 units/mL – 5 x 3 mL) NovoLog® PenFill® cartridges (100 units/mL – 5 x 3 mL) for NovoPen Echo® device	Children ≥ 2 years and adolescents	See Table 4 Note #1, below.
Rapid-acting	Insulin glulisine	Apidra® vial (100 units/mL – 10 mL) Apidra® SoloStar® pen (100 units/mL – 5 x 3 mL)	Children ≥ 4 years and adolescents	See Table 4 Note #1, below.
Rapid-acting	Insulin lispro	Admelog® vial (100 units/m – 3 or 10 mL) Admelog® SoloStar® pen (100 units/mL – 3 mL) HumaLog® cartridges (100 units/mL – 5 x 3 mL) for HumaPen® Luxura™ HD device HumaLog® vial (100 units/mL – 3 mL) HumaLog® KwikPen® (100 units/mL – 3 mL; 200 units/mL – 3 mL)	Children ≥ 3 years and adolescents	See Table 4 Note #1, below.
Short-acting	Regular insulin	Humulin® R vial (100 units/mL – 10 mL; 500 unit/mL – 20 mL) Humulin® R KwikPen® (500 units/mL – 2 x 3 mL) Novolin® R vial (100 units/mL – 10 units)	No specific age requirement reported	See Table 4 Note #1, below.
Intermediate-acting	Isophane insulin (NPH)	Humulin® N vial (100 units/mL – 3 or 10 mL) Humulin® N KwikPen® (100 units/mL – 5 x 3 mL) Novolin® N vial (100 units/mL – 10 mL)	No specific age requirement reported	See Table 4 Note #1, below.

Type	Drug Name	Dosage Form	Approved Age Requirements	Max. Rcmd. Dosage
Long-acting	Insulin detemir	Levemir® vial (100 units/mL – 10 mL) Levemir® FlexTouch® pen (100 units/mL – 5 x 3 mL)	Children ≥ 2 years and adolescents	See Table 4 Note #1, below.
Long-acting	Insulin degludec	Tresiba® vial (100 units/mL – 10 mL) Tresiba® FlexTouch® pen (100 units/mL – 5 x 3 mL; 200 units/mL – 3 x 3 mL)	Children ≥ 1 year and adolescents Not recommended if require less than 5 units	See Table 4 Note #1, below.
Long-acting	Insulin glargine	Lantus® vial (100 units – 10 mL) Lantus® SoloStar® pen (100 units/mL – 5 x 3 mL) Toujeo® SoloStar® pen (300 units/mL – 3 x 1.5 mL) Basaglar® KwikPen® (100 units/mL)	Children ≥ 6 years and adolescents	See Table 4 Note #1, below.

Table 4 Note #1 for Maximum Recommended Dosage

- No maximum recommended dosage to exceed; insulin and other antidiabetic drugs should be adjusted to target glycemic goals and meet patients' needs.

Table 6. Pediatric Insulin Age Requirements for Insulin Combination Products[2-4,28,30,31]

Drug Name	Dosage Form	Approved Age Requirements	Max. Rcmd. Dosage
Isophane insulin (NPH) and regular insulin	• Humulin® 70/30 vial (100 units/mL – 3 or 10 mL) • Humulin® 70/30 KwikPen® (100 units/mL – 5 x 3 mL) • Novolin® 70/30 vial (100 units/mL – 10 mL) • Novolin® 70/30 FlexPen (100 units/mL – 5 x 3 mL)	Children and adolescents	No maximum recommended dosage to exceed; insulin and other antidiabetic drugs should be adjusted to target glycemic goals and meet patients' needs

2 Duration of Therapy [1-5]

Exogenous insulin products are indicated for the management of type 1 and 2 DM and may be continued indefinitely, as blood glucose control in DM is a chronic, lifelong process.[1,6-11]

3 Duplicative Therapy

Adjunctive administration of multiple exogenous insulin products may be required or recommended to maintain adequate glycemic control. If multiple exogenous insulin products are required or recommended, the patients generally have one long-acting or intermediate-acting basal insulin product and one short- or rapid-acting preprandial insulin product.1,6-11 Patient profiles containing prescriptions for multiple short-acting or multiple long-acting exogenous insulin products will be reviewed.

4 Drug-Drug Interactions

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. Drug-drug interactions considered clinically relevant for exogenous insulin products are summarized in Table 6. Only those drug-drug interactions identified as clinical significance level 1 or those considered life-threatening which have not yet been classified will be reviewed:

Table 6. Select Insulin Drug-Drug Interactions[2,37,38]

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
All insulin products	Angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs)	Adjunctive use may increase hypoglycemia risk as ACE inhibitors, ARBS improve insulin sensitivity	Monitor blood glucose levels and observe for signs/symptoms of hypoglycemia	Moderate (DrugReax) 3-moderate (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
All insulin products	Beta blockers	Combined use may increase or decrease blood glucose levels as beta blockers can alter glucose metabolism; beta blockade may also mask hypoglycemia signs/ symptoms	Monitor patients for signs/ symptoms of hypo- or hyperglycemia with combined therapy; measure blood glucose levels	Moderate (DrugReax) 3-moderate (CP)
All insulin products	Glucagon-like peptide-1 (GLP-1) receptor agonists	Concurrent use may increase hypoglycemia risk	Monitor blood glucose levels and consider insulin dose reductions or therapy modification; avoid combination of liraglutide and insulin if liraglutide is used primarily for weight loss	liraglutide – major; others – moderate (DrugReax) 2-major (CP)
All insulin products	Lithium	Combined use may increase risk of hypo- or hyperglycemia due to lithium varying effects on glucose metabolism	Monitor blood glucose levels, especially when adding, discontinuing, modifying therapy	Moderate (DrugReax) 3-moderate (CP)
All insulin products	Metreleptin (Myalept®)	Concurrent use may increase risk of hypoglycemia	Use with caution and monitor blood glucose levels closely; potential large decreases in insulin dosage adjustments may be required, or consider therapy modification	Major (DrugReax) 3-moderate (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
All insulin products	Peroxisome proliferator-activated receptor (PPAR)-gamma agonists	Insulin may enhance rosiglitazone, pioglitazone adverse effects (e.g., edema, heart failure); combined use may increase hypoglycemia risk	Avoid combination with rosiglitazone; if insulin is combined with pioglitazone, consider dose reductions or therapy modification; monitor patients for signs/symptoms of heart failure and hypoglycemia	Major (DrugReax) 2-major (CP)
All insulin products	Pramlintide	Concurrent use may increase hypoglycemia risk	Decrease preprandial insulin dose by 50% or consider therapy modification; monitor blood glucose frequently and adjust insulin dose based on glycemic control	Major (DrugReax) 2-major (CP)
All insulin products	Fluoroquinolone antibiotics	Concomitant use may increase risk of hypo- or hyperglycemia	Monitor blood glucose levels closely and adjust insulin dose as needed; further insulin dosage adjustments may be required upon fluoroquinolone discontinuation	Major (DrugReax) 3-moderate (CP)
All insulin products	Somatostatin analogs	Concurrent use may diminish insulin therapeutic effects as somatostatin analogs associated with hyperglycemia	Monitor blood glucose levels frequently and adjust insulin dose as needed	major (DrugReax) 3-moderate (CP)

5 References

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