Long Acting Insulin
Prior Authorization with Quantity Limit
Program Summary

For BCBS KS, this program targets the following non-preferred agents for prior authorization: Lantus, Insulin glargine, Insulin degludec, Rezvoglar

For BCBS KS, the following agents are not subject to prior authorization: Basaglar, Levemir, Semglee, Insulin glargine-yfgn, Toujeo, Tresiba

POLICY REVIEW CYCLE

Effective Date 4/3/2023 **Date of Origin**

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Basaglar® (insulin glargine) Injection	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus		1
Lantus® (insulin glargine) Injection	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus		2
Levemir® (insulin detemir) Injection	To improve glycemic control in adults and pediatric patients with diabetes mellitus		3
Rezvoglar™ (insulin glargine-aglr) Injection	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus Limitation of use: Not recommended for treating diabetic ketoacidosis		9
Semglee®, Insulin glargine-yfgn Injection	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus		4
Toujeo®, Toujeo® Max (insulin glargine) Injection	To improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus		5
Tresiba®, Insulin degludec Injection	To improve glycemic control in patients 1 year of age and older with diabetes mellitus		6

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Overview	The American Diabetes Association Standards of Medical Care in Diabetes recommend the following therapy for type 1 diabetes mellitus: • Most people with type 1 diabetes should be treated with multiple daily injections of prandial and basal insulin, or subcutaneous insulin infusion • Most individuals with type 1 diabetes should use rapid-acting insulin analogs to reduce hypoglycemia risk. • Patients with type 1 diabetes should receive education on how to match prandial insulin doses to carbohydrate intake, premeal blood glucose, and anticipated physical activity.(7) For type 2 diabetes mellitus, the American Diabetes Association recommends the following: • Metformin is the preferred initial pharmacological agent for type 2 diabetes • The early introduction of insulin should be considered if there is evidence of ongoing catabolism, if symptoms of hyperglycemia are present, or when A1C levels or blood glucose levels are very high • A patient-centered approach should be used to guide the choice of pharmacological agents. Considerations include comorbidities, hypoglycemia risk, impact on weight, cost, risk of side effects, and patient preferences.(7) The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) algorithm for type 2 diabetics recommends starting insulin therapy if the patient has an A1c > 9% and is having hyperglycemia symptoms. Patients with recent-onset type 2 diabetes or who have mild hyperglycemia (A1c less than 7.5%), lifestyle therapy plus antihyperglycemic monotherapy (preferably with metformin) is recommended. Patients who present with an A1c greater than 7.5% should be started initially on metformin plus another agent, one of which is insulin. Patients taking two oral antihyperglycemic agents who have an A1c greater than 8 and/or long-standing type 2 diabetes are less likely to reach their target with a third oral antihyperglycemic agent. Although adding a GLP-1 receptor agonist as the third agent may lower hyperglycemia, eventually many patients will still require insulin. When insulin becomes necessary, a single daily dose of basal insulin should be added to the regimen. Dosage should be adjusted at regular and at short intervals to achieve the glycemic goal. Patients whose glycemia remains uncontrolled while receiving basal insulin in combination with oral agents or GLP-1 receptor agonists may require mealtime insulin to cover postprandial hyperglycemia.(8)

REFERENCES

Number	Reference
1	Basaglar prescribing information. Eli Lilly and Company. July 2021.
2	Lantus prescribing information. Sanofi-Aventis US, LLC. January 2021.
3	Levemir prescribing information. Novo Nordisk, Inc. July 2022.
4	Semglee prescribing information. Mylan Specialty L.P. July 2021.
5	Toujeo, Toujeo Max prescribing information. Sanofi-Aventis U.S. LLC. December 2020.

Number	Reference
6	Tresiba prescribing information. Novo Nordisk Inc. July 2022.
7	American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022. Available at https://diabetesjournals.org/care/issue/45/Supplement_1
8	AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm (2020) Executive Summary. Available at: https://pro.aace.com/pdfs/diabetes/AACE_2019_Diabetes_Algorithm_03.2021.pdf
9	Rezvoglar prescribing information. December 2021.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
	insulin glargine-yfgn inj	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
Semglee	Insulin Glargine-yfgn Soln Pen-Injector	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
	insulin glargine-yfgn soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
Semglee	insulin glargine-yfgn inj	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
	insulin degludec inj	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	03-01-2023
	insulin degludec soln pen-injector	200 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	03-01-2023
	insulin degludec soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	03-01-2023
Lantus ; Semglee	insulin glargine inj	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
	insulin glargine soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
Lantus	Insulin Glargine Inj ; insulin glargine inj	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
Lantus solostar	insulin glargine soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
Rezvoglar kwikpen	insulin glargine-aglr soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	04-03-2023

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Basaglar kwikpen ; Basaglar tempo pen ; Lantus ; Lantus solostar ; Rezvoglar kwikpen ; Semglee ; Toujeo max solostar ; Toujeo solostar	insulin glargine inj ; insulin glargine pen-inj with transmitter port ; insulin glargine soln pen-injector ; insulin glargine-aglr soln pen-injector ; insulin glargine-yfgn inj ; insulin glargine-yfgn soln pen-injector	100 UNIT/ML ; 300 UNIT/ML	100	MLS	30	DAYS	Quantity limit is cumulative			
Levemir ; Levemir flexpen ; Levemir flextouch	insulin detemir inj ; insulin detemir soln pen-injector	100 UNIT/ML	100	MLS	30	DAYS	Quantity limit is cumulative			
Tresiba ; Tresiba flextouch	insulin degludec inj ; insulin degludec soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	100	MLS	30	DAYS	Quantity limit is cumulative			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	insulin glargine-yfgn inj	100 UNIT/ML	Commercial ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	insulin glargine-yfgn soln pen-injector	100 UNIT/ML	Commercial ; HIM
Semglee	insulin glargine-yfgn inj	100 UNIT/ML	Commercial ; HIM
Semglee	Insulin Glargine-yfgn Soln Pen-Injector	100 UNIT/ML	Commercial ; HIM
	insulin degludec inj	100 UNIT/ML	Commercial ; HIM
	insulin degludec soln pen-injector	200 UNIT/ML	Commercial ; HIM
	insulin degludec soln pen-injector	100 UNIT/ML	Commercial ; HIM
	insulin glargine soln pen-injector	100 UNIT/ML	Commercial ; HIM
Lantus	Insulin Glargine Inj ; insulin glargine inj	100 UNIT/ML	Commercial ; HIM
Lantus ; Semglee	insulin glargine inj	100 UNIT/ML	Commercial ; HIM
Lantus solostar	insulin glargine soln pen-injector	100 UNIT/ML	Commercial ; HIM
Rezvoglar kwikpen	insulin glargine-aglr soln pen-injector	100 UNIT/ML	Commercial ; HIM

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Basaglar kwikpen ; Basaglar tempo pen ; Lantus ; Lantus solostar ; Rezvoglar kwikpen ; Semglee ; Toujeo max solostar ; Toujeo solostar	insulin glargine inj ; insulin glargine pen-inj with transmitter port ; insulin glargine soln pen-injector ; insulin glargine-aglr soln pen-injector ; insulin glargine-yfgn inj ; insulin glargine-yfgn soln pen-injector	100 UNIT/ML ; 300 UNIT/ML	ResultsRx
Levemir ; Levemir flexpen ; Levemir flextouch	insulin detemir inj ; insulin detemir soln pen-injector	100 UNIT/ML	ResultsRx
Tresiba ; Tresiba flextouch	insulin degludec inj ; insulin degludec soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Agents	Non-Preferred Target Agents
Semglee Insulin glargine-yfgn	Lantus Insulin glargine Rezvoglar
Tresiba	Insulin degludec

EVALUATION

Non-preferred Target Agent(s) will be approved when ONE of the following is met:

1. The patient has an intolerance, or hypersensitivity to ALL preferred long acting insulin agents that is not expected to occur with the requested agent (medical records required) **OR**
2. The patient has an FDA labeled contraindication to ALL preferred long acting insulin agents that is not expected to occur with the requested agent (medical records required)

Length of Approval: 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

Module	Clinical Criteria for Approval
	2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does not have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months