



Rapid to Intermediate Acting Insulin Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
3/1/2023

Date of Origin

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Admelog® (insulin lispro) Injection	To improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus	Rapid-Acting Insulins	1
Apidra® (insulin glulisine) Injection	To improve glycemic control in adults and pediatric patients with diabetes mellitus	Rapid-Acting Insulins	2
Fiasp® (insulin aspart) Injection	To improve glycemic control in adult and pediatric patients with diabetes mellitus	Rapid-Acting Insulins	3
Humalog®, Humalog Junior®, Insulin Lispro, Insulin Lispro Junior Injection	To improve glycemic control in adults and children with diabetes mellitus	Rapid-Acting Insulins	4
Humalog® Mi x 50/50 (50% insulin lispro protamine/50 % insulin lispro) Injection	To improve glycemic control in patients with diabetes mellitus	NPH-Lispro Combinations	14
Humalog® Mix 75/25, Insulin Lispro Protamine/Ins ulin Lispro (75/25) Injection	To improve glycemic control in patients with diabetes mellitus	NPH-Lispro Combinations	13
Humulin® 70/ 30	To improve glycemic control in adult patients with diabetes mellitus	NPH-Regular Combinations	11

Agent(s)	FDA Indication(s)	Notes	Ref#
(70% human insulin isophane/30% regular human insulin) Injection			
Humulin® N (human isophane insulin) Injection	To improve glycemic control in adult and pediatric patients with diabetes mellitus	Intermediate-Acting Insulins	9
Humulin® R (regular human insulin) Injection	To improve glycemic control in adult and pediatric patients with diabetes mellitus	Short-Acting Insulins	7
Novolin® 70/30, Insulin aspart protamine/insulin aspart Injection	To improve glycemic control in adults and pediatric patients with diabetes mellitus	NPH-Regular Combinations	12
Lyumjev® (insulin lispro-aabc) Injection	To improve glycemic control in adults with diabetes mellitus	Rapid-Acting Insulins	5
Novolin® N, ReliOn® N (human isophane insulin) Injection	To improve glycemic control in adult and pediatric patients with diabetes mellitus	Intermediate-Acting Insulins	10
Novolin® R, ReliOn® R (regular human insulin) Injection	To improve glycemic control in adult and pediatric patients with diabetes mellitus	Short-Acting Insulins	8
NovoLog®, Insulin Aspart Injection	To improve glycemic control in adults and pediatric patients with diabetes mellitus	Rapid-Acting Insulins	6
NovoLog® Mix 70/30, Insulin aspart protamine/insulin aspart	To improve glycemic control in patients with diabetes mellitus	NPH – NovoLog Combination	15

Agent(s)	FDA Indication(s)	Notes	Ref#
Injection			

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

CLINICAL RATIONALE

Overview	<p>The American Diabetes Association Standards of Medical Care in Diabetes recommend the following therapy for type 1 diabetes mellitus:</p> <ul style="list-style-type: none"> • Most individuals 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. • Individuals with type 1 diabetes should receive education on how to match mealtime insulin doses to carbohydrate intake, fat and protein content, and anticipated physical activity.(16) <p>For type 2 diabetes mellitus, the American Diabetes Association recommends the following:</p> <ul style="list-style-type: none"> • First-line therapy depends on comorbidities, patient-centered treatment factors, and management needs and generally includes metformin and comprehensive lifestyle modification. • 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. Consider the effects on cardiovascular and renal comorbidities, hypoglycemia risk, impact on weight, cost and access, risk of side effects, and patient preferences.(16) <p>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 greater than 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.(17)</p>
----------	--

REFERENCES

Number	Reference
1	Admelog prescribing information. Sanofi-Aventis US, LLC. December 2020.
2	Apidra (insulin glulisine [rDNA origin] injection) solution for injection. Sanofi-Aventis. December 2020.
3	Fiasp prescribing information. Novo Nordisk Inc. September 2022.

Number	Reference
4	Humalog, Humalog Kwikpen, Humalog Junior Kwikpen, Humalog Tempo Pen (insulin lispro injection [rDNA origin] solution for subcutaneous injection). Eli Lilly and Company. November 2019.
5	Lyumjev, Lyumjev Kwikpen, Lyumjev Junior Kwikpen, Lyumjev Kwikpen prescribing information. Eli Lilly and Company. August 2021.
6	NovoLog (insulin aspart [rDNA origin] injection) solution for subcutaneous use. Novo Nordisk, Inc. October 2021.
7	Humulin R (insulin human injection [rDNA origin]) solution for subcutaneous injection. Eli Lilly and Company. June 2022.
8	Novolin R (human insulin injection [rDNA origin]). Novo Nordisk, Inc. November 2019.
9	Humulin N (insulin [rDNA origin] isophane suspension). Eli Lilly and Company. June 2022.
10	Novolin N (human insulin isophane suspension injection) suspension. Novo Nordisk. November 2019.
11	Humulin 70/30 (70% human insulin isophane suspension and 30% human insulin injection (rDNA origin)). Eli Lilly and Company. June 2022.
12	Novolin 70/30 (70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection, [rDNA]). Novo Nordisk. April 2021.
13	Humalog Mix 75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection (rDNA origin)). Eli Lilly and Company. November 2019.
14	Humalog Mix 50/50 (50% insulin lispro protamine suspension and 50% insulin lispro injection [rDNA origin]). Eli Lilly and Company. November 2019.
15	NovoLog 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection. Novo Nordisk Inc. April 2021.
16	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
17	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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	50 UNIT/ML ; 75 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
HUMULIN 70/30 ; HUMULIN 70/30 KWIKPEN	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
HUMULIN N ; HUMULIN N KWIKPEN	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
HUMULIN R	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	M ; N ; O ; Y	N	2. Non-Preferred	
HUMULIN R U-500 (CONCENTR ; NOVOLIN R RELION	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	M ; N ; O ; Y	N	3. Standalone	
HUMULIN R U-500 KWIKPEN ; NOVOLIN R FLEXPEN RELION	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	M ; N ; O ; Y	N	3. Standalone	
NOVOLIN 70/30 ; NOVOLIN 70/30 FLEXPEN ; NOVOLIN 70/30 FLEXPEN REL ; NOVOLIN 70/30 RELION	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
NOVOLIN N ; NOVOLIN N FLEXPEN ; NOVOLIN N FLEXPEN RELION ; NOVOLIN N RELION	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
NOVOLIN R	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
NOVOLIN R FLEXPEN	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	
Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	70 UNIT/ML	M ; N ; O ; Y	N	1. Preferred	

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	50 UNIT/ML ; 75 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Humulin 70/30 ; Humulin 70/30 kwikpen ; Novolin 70/30 ; Novolin 70/30 flexpen ; Novolin 70/30 flexpen rel ; Novolin 70/30 relion	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Humulin n ; Humulin n kwikpen ; Novolin n ; Novolin n flexpen ; Novolin n flexpen relion ; Novolin n relion	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Humulin r ; Humulin r u-500 (concentr ; Novolin r ; Novolin r relion	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Humulin r u-500 kwikpen ; Novolin r flexpen ; Novolin r flexpen relion	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			
Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	70 UNIT/ML	100.0	MLS	30	Days	Quantity limit is cumulative			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	HIM
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	HIM
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	HIM
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	50 UNIT/ML ; 75 UNIT/ML	HIM
HUMULIN 70/30 ; HUMULIN 70/30 KWIKPEN	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	HIM
HUMULIN N ; HUMULIN N KWIKPEN	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	HIM
HUMULIN R	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	HIM
HUMULIN R U-500 (CONCENTR ; NOVOLIN R RELION	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	HIM
HUMULIN R U-500 KWIKPEN ; NOVOLIN R FLEXPEN RELION	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	HIM
Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	70 UNIT/ML	HIM
NOVOLIN 70/30 ; NOVOLIN 70/30 FLEXPEN ; NOVOLIN 70/30 FLEXPEN REL ; NOVOLIN 70/30 RELION	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	HIM
NOVOLIN N ; NOVOLIN N FLEXPEN ; NOVOLIN N FLEXPEN RELION ; NOVOLIN N RELION	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	HIM
NOVOLIN R	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	HIM
NOVOLIN R FLEXPEN	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	HIM

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	ResultsRx
Admelog ; Admelog solostar ; Humalog ; Humalog junior kwikpen ; Humalog kwikpen ; Humalog tempo pen ; Lyumjev ; Lyumjev kwikpen ; Lyumjev tempo pen	insulin lispro inj soln ; insulin lispro soln cartridge ; insulin lispro soln pen-inj w/transmitter port ; insulin lispro soln pen-injector ; insulin lispro-aabc inj ; insulin lispro-aabc soln pen-inj ; insulin lispro-aabc soln pen-inj w/transmit port ; insulin lispro-aabc soln pen-injector	100 UNIT/ML ; 200 UNIT/ML	ResultsRx
Apidra ; Apidra solostar	insulin glulisine inj ; insulin glulisine soln pen-injector inj	100 UNIT/ML	ResultsRx
Fiasp ; Fiasp flextouch ; Fiasp penfill ; Novolog ; Novolog flexpen ; Novolog flexpen relion ; Novolog penfill ; Novolog relion	insulin aspart (with niacinamide) inj ; insulin aspart (with niacinamide) sol pen-inj ; insulin aspart (with niacinamide) soln cartridge ; insulin aspart inj soln ; insulin aspart soln cartridge ; insulin aspart soln pen-injector	100 UNIT/ML	ResultsRx
Humalog mix 50/50 ; Humalog mix 50/50 kwikpen ; Humalog mix 75/25 ; Humalog mix 75/25 kwikpen	insulin lispro prot & lispro inj ; insulin lispro prot & lispro sus pen-inj ; insulin lispro protamine & lispro inj	50 UNIT/ML ; 75 UNIT/ML	ResultsRx
Humulin 70/30 ; Humulin 70/30 kwikpen ; Novolin 70/30 ; Novolin 70/30 flexpen ; Novolin 70/30 flexpen rel ; Novolin 70/30 relion	insulin nph & regular susp pen-inj ; insulin nph isophane & regular human inj	70 UNIT/ML	ResultsRx
Humulin n ; Humulin n kwikpen ; Novolin n ; Novolin n flexpen ; Novolin n flexpen relion ; Novolin n relion	insulin nph (human) (isophane) inj ; insulin nph (human) (isophane) susp pen-injector	100 UNIT/ML	ResultsRx
Humulin r ; Humulin r u-500 (concentr ; Novolin r ; Novolin r relion	insulin regular (human) inj	100 UNIT/ML ; 500 UNIT/ML	ResultsRx
Humulin r u-500 kwikpen ; Novolin r flexpen ; Novolin r flexpen relion	insulin regular (human) soln pen-injector	100 UNIT/ML ; 500 UNIT/ML	ResultsRx
Novolog mix 70/30 ; Novolog mix 70/30 prefill ; Novolog mix 70/30 relion	insulin aspart prot & aspart (human) inj ; insulin aspart prot & aspart sus pen-inj	70 UNIT/ML	ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
PA	Preferred Agents	Non-Preferred Target Agents	Stand-Alone Agents
	Rapid, Regular	Rapid, Regular	Rapid, Regular
	Fiasp (insulin aspart) Insulin Aspart Novolin R (regular human insulin) NovoLog (insulin aspart)	Admelog (insulin lispro) Apidra (insulin glulisine) Humalog (insulin lispro) Humalog Junior Kwikpen (insulin lispro) Humalog Kwikpen U200 (insulin lispro) Humalog Tempo (insulin lispro) Humulin R U-100 (regular human	Humulin R U-500 (regular human insulin concentrated) Relion R (regular human insulin)

Module	Clinical Criteria for Approval		
		insulin) Insulin Lispro Insulin Lispro Junior Kwikpen Insulin Lispro Kwikpen Lyumjev (insulin lispro-aabc) Lyumjev Tempo (insulin lispro-aabc)	
	Mix, NPH Insulin aspart protamine/insulin aspart Novolin N (human insulin NPH) Novolin 70/30 (70% human insulin isophane suspension/30% human insulin) NovoLog 70/30 (70% insulin aspart protamine/30% insulin aspart)	Mix, NPH Humalog Mix 75/25 (75% insulin lispro protamine suspension/25% insulin lispro) Humalog Mix 50/50 (50% insulin lispro protamine suspension/50% insulin lispro) Humulin N (human insulin isophane suspension) Humulin 70/30 (70% human insulin isophane suspension/30% human insulin) Insulin Lispro Protamine/Insulin Lispro Kwikpen (75/25)	

Non-preferred insulin agents will be approved when ONE of the following is met:

1. BOTH of the following:
 - A. The requested agent is a rapid insulin **AND**
 - B. Information has been provided that the patient is currently using an insulin pump that has an incompatibility with all preferred rapid insulin agents that is not expected to occur with the requested agent **OR**
2. The request is for Humalog Mix 50/50 **AND** ONE of the following:
 - A. The patient is currently using Humalog Mix 50/50 **AND** the prescriber states the patient is at risk if switched to a different insulin **OR**
 - B. The patient has tried and had an inadequate response to a preferred insulin mix **OR**
3. BOTH of the following:
 - A. The requested agent is a rapid, regular, mix, or NPH insulin **AND**
 - B. ONE of the following:
 1. The patient has an intolerance or hypersensitivity to all preferred insulin agents of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent **OR**
 2. The patient has an FDA labeled contraindication to all preferred insulin agents of the same type (rapid or regular, mix or NPH) that is not expected to occur with the requested agent **OR**
4. Information has been provided that the patient has a physical or a mental disability that would prevent him/her from using all preferred insulin agents **OR**

Module	Clinical Criteria for Approval
	5. The patient is pregnant Length of Approval: 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 <p>Length of Approval: up to 12 months</p>