Insulin Prior Authorization Program Summary

This prior authorization applies to Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Insulin prior authorization criteria is to encourage use of cost-effective preferred insulin agents over the non-preferred insulin agents. The program will accommodate for the use of non-preferred insulin in patients with a documented intolerance, FDA labeled contraindication, hypersensitivity, or insulin pump incompatibility to the preferred insulin that is not expected to occur with the requested agent. The program will accommodate for the use of non-preferred insulin agents in patients who have a physical or mental disability that would prevent the patient from using the preferred insulin agents. The program will also accommodate for the use of non-preferred insulin agents in patients who are pregnant. Requests for non-preferred insulin agents will be reviewed when patient-specific documentation is provided.

NON-PREFERRED PRIOR AUTHORIZATION TARGET AGENTS

Rapid, Regular

Admelog® (insulin lispro)
Apidra® (insulin glulisine)
Humalog® (insulin lispro)
Humalog® Junior Kwikpen (insulin lispro)
Humalog® Kwikpen U200 (insulin lispro)
Humulin® R U-100 (regular human insulin)

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)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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

1. The requested agent is a rapid insulin and the patient has a documented insulin pump incompatibility to the preferred rapid insulin agent 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 prescriber states that the patient has tried and failed a preferred insulin mix
   OR
3. The requested agent is a rapid, regular, mix, or NPH insulin and the patient has a documented adverse reaction, intolerance, or FDA labeled contraindication to the 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. The prescriber has documented that the patient has a physical or a mental disability that

would prevent him/her from using a preferred insulin agent
OR

5. The patient is pregnant

Length of Approval: 12 months

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA LABELED INDICATIONS[1-13,16-21]

Rapid-Acting Insulins	Indication	Onset	Peak	Duration
Admelog (insulin lispro)	Treatment of patients with T1DM[a] and T2DM for the control of hyperglycemia.	5-15 min	0.83 hr	< 5h
Fiasp (insulin aspart)		2.5 min	~63 min	~6h
Humalog (insulin lispro)		5-15 min	30-90 min	< 5h
NovoLog (insulin aspart)		5-15 min	30-90 min	< 5h
Apidra (insulin glulisine)		5-15 min	30-90 min	< 5h
Short-Acting Insulins				
Humulin R	• For the treatment of T1DM or T2DM inadequately managed by diet, exercise, and oral hypoglycemics. • For the treatment of gestational diabetes or for the treatment of patients with pre-existing diabetes mellitus (T1DM or T2DM) who are now pregnant: for pregnant patients with gestational-onset diabetes not controlled by diet-therapy alone. • For the treatment of diabetic ketoacidosis. • For the treatment of hyper-osmolar hyperglycemic state in patients with T2DM	30-60 min	2-3 h	5-8 h
Novolin R[b]		30-60 min	2-3 h	5-8 h
ReliOn		30-60 min	2-3 h	5-8 h

a - T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus
b – Manufacturer recommends Novolin R should not be used in external insulin pumps due to risk of precipitation

Intermediate-Acting Insulins	Indication	Onset	Peak	Duration
Humulin N	• For the treatment of T1DM or T2DM inadequately managed by diet, exercise, and oral hypoglycemics. • For the treatment of gestational diabetes or for the treatment of patients with preexisting T1DM or T2DM who are now pregnant.	2-4 h	4-10 h	10-16 h
Novolin N		2-4 h	4-10 h	10-16 h
ReliOn/Novolin N		2-4 h	4-10 h	10-16 h
Long-Acting Insulins				
Basaglar	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.	NA	NA	24 h
Lantus	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.	NA	NA	24 h
Toujeo	To improve glycemic control in adults with diabetes mellitus	6 h	12-16 h	24 h
Levemir	To improve glycemic control in adults and children with diabetes mellitus.	NA	NA	24 h
Tresiba	To improve glycemic control in adults with diabetes mellitus.	1 h	9 h	24 h
NPH-Regular Combinations				
Novolin 70/30	For the treatment of T1DM or for T2DM inadequately managed by diet, exercise, and oral hypoglycemics.	5-15 min	Dual	10-16 h
Humulin 70/30		5-15 min	Dual	10-16 h
ReliOn/Novolin 70/30		5-15 min	Dual	10-16 h
NPH-Lispro Combinations				
Humalog Mix 75/25	For the treatment of T1DM or for type 2DM inadequately managed by diet, exercise, and oral hypoglycemics.	5-15 min	Dual	10-16 h
Humalog Mix 50/50		5-15 min	Dual	10-16 h
NPH – NovoLog Combination				
NovoLog Mix 70/30	Improve glycemic control in patients with T1DM and T2DM.	5-15 min	Dual	10-16 h

a - T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus

DOSING AND ADMINISTRATION[1-13]
Novolin, Humulin, ReliOn - NPH, Regular, plus mixtures
NovoLog, Humalog, Admelog, Apidra, Fiasp - plus mixtures
Dosing must be individualized. The total daily insulin requirement may vary and is usually between 0.5 and 1.0 units/kg/day.

CLINICAL RATIONALE
The American Diabetes Association Standards in diabetes mellitus recommend the following therapy for type 1 diabetes mellitus:

- Use of multiple-dose insulin injections (3-4 injections per day of basal and prandial insulin) or continuous subcutaneous insulin infusion (CSII) therapy
- Matching prandial insulin to carbohydrate intake, pre-meal blood glucose, and anticipated activity
- Most patients should use insulin analogs to reduce hypoglycemic risk
- Individuals who have been successfully using continuous subcutaneous insulin infusion should have continued access after they turn 65 years of age.[14]

For type 2 diabetes mellitus, the American Diabetes Association recommends the following:

- Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacological agent for type 2 diabetes
- Consider initiating insulin therapy (with or without additional agents) in patients with newly diagnosed type 2 diabetes and markedly symptomatic and/or elevated blood glucose levels or A1C
- If noninsulin monotherapy at maximum tolerated dose does not achieve or maintain the A1C target over 3 months, then add a second oral agent, a glucagon-like peptide 1 receptor agonist, or basal insulin
- A patient-centered approach should be used to guide the choice of pharmacological agents. Considerations include efficacy, cost, potential side effects, weight, comorbidities, hypoglycemia risk, and patient preferences.
- For patients with type 2 diabetes who are not achieving glycemic goals, insulin therapy should not be delayed

The AACE/ACE algorithm recommends insulin for T2DM when noninsulin antihyperglycemic therapy fails to achieve target glycemic control or when a patient has symptomatic hyperglycemia. Therapy with long-acting basal insulin is preferred. If glycemic control is not achieved with basal insulin, prandial insulin can be added. Preference should be given to rapid-acting insulins (the analogs lispro, aspart, and glulisine or inhaled insulin) over regular human insulin because the former have a more rapid onset and offset of acting and are associated with less hypoglycemia. For the treatment of T1DM, regimens that provide both basal and prandial insulin should be used.[15]

References:

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